International Center for Law & Economics

ROI Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

National Institute for Standards & Technology, Docket 230831–0207

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I. Introduction

This comment is submitted in response to the National Institute of Standards and Technology's (NIST) request for information (RFI) on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.[1]

The U.S. patent system has been a major driver of innovation, and provides an important foundation for the nation's technological leadership around the world. Undoubtedly, there are cases at the margins where one could find some invention has not been optimally commercialized. But the measure of the system's success is not in isolated anecdotes, but rather, in data demonstrating it has been a major driver of economic growth and consumer welfare—both in general and particularly in the consistent development of lifesaving and life-enhancing medicines and medical devices.

This suggests that the integrity of the current patent rights framework under the Bayh-Dole Act is crucial for sustaining innovation, promoting commercialization, and ultimately enhancing consumer welfare. As such, any proposal to expand "march-in rights" must be treated with caution.

Further, while the administration's focus in this draft guidance appears to be centered primarily on the pharmaceutical sector,[2] the proposed modifications have the potential to trigger extensive spillover effects across various other patent-reliant industries. For instance, industries such as biotechnology, software development, and advanced manufacturing—which rely fundamentally on strong patent protections to secure investments for research and development—could face unforeseen challenges. These sectors are driven by innovation underpinned by intellectual property. Increased uncertainty regarding the longevity and security of patent rights could lead them to experience a slowdown in the pace of that innovation, as venture capitalists may become more reluctant to fund new ventures. Of particular concern is that march-in petitions brought under a more liberal standard may become a useful tool for firms looking to stymie their competition.

The proposed changes are clearly unnecessary, given the history of success that characterizes the post-Bayh-Dole era. Indeed, these suggested modifications threaten to undermine a substantial portion of the U.S. economy and to harm both consumer health and general welfare. Apart from being ill-advised from an economic perspective, the proposed changes also appear to be at odds with the Bayh-Dole Act's very legal and policy basis. As Adam Mossoff has observed, "the text of the Bayh-Dole Act and its consistent interpretation by federal officials militates against" the view that it authorizes imposing price controls on patented inventions produced with support from federal funding.[3]

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[1] Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 FR 85593 (Dec. 8, 2023), https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the [hereinafter "RFI"]

[2] For example, five of the eight "scenarios" presented in the RFI focus on biotechnology.

[3] Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, 97 ST. JOHN'S L. REV. (forthcoming 2023) (manuscript at 18), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348499.

In summary, the ongoing debate about modifying march-in rights under the Bayh-Dole Act touches on fundamental aspects of innovation, economic growth, and public welfare. This is not merely about adjusting a legislative framework; it is about preserving the delicate balance that has propelled the United States to the forefront of global innovation, particularly in life-saving pharmaceuticals and technologies. Any alterations to the Act's implementation risk distorting this balance, potentially stifling innovation and undermining the economic and health benefits that have been realized. As such, it is imperative to carefully consider any proposed modifications to ensure that they support, rather than hinder, the Act's foundational goal of fostering innovation and delivering tangible benefits to society.

II. Success of the Bayh-Dole Act and the Importance of Patent Rights

The Bayh-Dole Act, formally known as the University and Small Business Patent Procedures Act of 1980 (Act),[4] is a landmark piece of intellectual-property legislation. The Act allows universities, small businesses, and nonprofit organizations to retain and exercise patent rights to inventions developed under federally funded research programs. This legislative framework was designed to:

- Facilitate the transfer of federally funded research from academic and research institutions to the private sector for further development and commercialization;
- Encourage the practical application of these inventions for public benefit;
- Stimulate collaboration between public research entities and the private sector; and
- Enhance the contribution of federally funded inventions to the market, thereby boosting economic growth and public welfare.[5]

The Act has been a pivotal catalyst in advancing U.S. technological innovation, primarily by establishing a property-rights framework that creates incentives for the commercialization of scientific developments that received some degree of government funding. These property rights empower entities to license their inventions for more extensive applied research and development, thereby enhancing their accessibility and application for the broader public good.

The Act has been paying dividends since its inception in 1980. One important effect has been that, by enabling private companies to benefit from R&D that they (co-)fund at publicly supported universities, it has led to a dramatic increase in private-sector sponsorship of R&D at such universities. A report from the General Accounting Office (now known as the U.S. Government Accountability Office) found that, between 1980 and 1985 alone:

> total business sponsorship of university research grew 74 percent, from $277 million in fiscal year 1980 to $482 million in fiscal year 1985 (in constant 1982 dollars). For 23 of

[4] 35 U.S.C. § 200, et seq. (2011).

[5] *Id.* at § 202.

> the 25 universities we surveyed… industrial sponsorship of research more than doubled from $70 million in fiscal year 1980 to $160 million in fiscal year 1985 (in constant 1982 dollars).[6]

The Association of University Technology Managers (AUTM) estimates that, between 1996 and 2010, academic licensors contributed between $86 billion and $338 billion to U.S. gross domestic product (in 2005 dollars), in addition to supporting between 900,000 and 3 million person-years of employment over that that period.[7] In a survey of the 2019-2020 period, AUTM found that innovations of the sort that are at the core of the Bayh-Dole Act's focus led to a 7% increase in startups; a 7% increase in invention disclosures; an 11% increase in net patent applications; a 3% increase in licenses executed; and a 31% increase in new products introduced to market based on academic research.[8]

Along with many other pro-innovation policies enacted over the last several decades, one of the Act's enduring legacies is the fundamental shift it initiated in relocating innovative activity from Europe and Asia to the United States, with the latter now firmly established as the most important locale for producing new medicines:

> In the last decade, while the U.S. had 111 [new chemical entities] discovered, Switzerland-headquartered companies were second with 26. This means that actual [new chemical entities] discovered that had a significant U.S. nexus for research and development is much higher than the 57 percent of total [new chemical entities] discovered, perhaps closer to 65 percent. One other point worth noting… is the reduction in overall [new chemical entities] discovered from the decade of the 1980s to now. The U.S. has the vast majority of clinical trials. A similar trend has taken place for medical devices.[9]

The United States has continued to develop a large number of new chemical entities in absolute terms, and in relative terms, has come to completely dominate the field.[10] This boom of patented innovations has also given rise to numerous transformative products we now consider

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[6] U.S. General Accounting Office, *Patent Policy Recent Changes in Federal Law Considered Beneficial*, GAO Report No. RCED-87-44 (1987), *available at* https://www.gao.gov/products/rced-87-44.

[7] Lori Pressman *et al.*, *The Economic Contribution of University/Nonprofit Inventions in the United States: 1996–2010*, BIOTECHNOLOGY INDUSTRY ORGANIZATION (Jun. 20, 2012) at 13, *available at* https://archive.bio.org/sites/default/files/Pressman%2520BIO%25202012%2520Final%2520r1%2520w%2520cover%2520sheet_0.pdf.

[8] Joseph Allen, *A Pandemic Can't Stop Bayh-Dole–But Politicians Might*, IPWATCHDOG (Aug. 31, 2021), https://ipwatchdog.com/2021/08/31/pandemic-cant-stop-bayh-dole-politicians-might/id=137235.

[9] Shanker Singham, *Improving U.S. Competitiveness; Eliminating Anti-Competitive Market Distortions*, at 12 (Int'l Roundtable Trade & Competition Pol'y., Nov. 15, 2011), *available at* https://shankersingham.com/2019/10/05/on-improving-us-competitiveness.

[10] *Id.*

commonplace, such as various cancer treatments,[11] prosthetics and medical devices,[12] a variety of web technologies, and improved foods.[13]

Nevertheless, the Act and the patent system are not without critics. Some have challenged the idea that the patent system does not sufficiently stimulate the production of inventions at universities,[14] or that, when such inventions occur, "large portion of those royalties… are derived from a few sizeable inventions at a handful of academic institutions."[15] Thus, according to these critics, the Act does not promote widespread welfare gains, so much as enable large gains to a small number of parties.

Proposed changes to federal policy have also threatened to pare back the gains the Act has helped to facilitate. In addition to this draft guidance, which would introduce *de facto* price controls on any industry substantially reliant on patented invention, the U.S. Energy Department has been imposing more stringent domestic-manufacturing requirements on licensees—an obligation that makes little sense in our globalized economy and that is more likely to impose red tape without substantially improving domestic production.[16] In a 2021 letter to the Pentagon, Sen. Elizabeth Warren (D-Mass.) and Rep. Lloyd Doggett (D-Texas) noted that "[r]ecognizing the high prices of medical products developed, in part, with DOD funding, the Senate Armed Services Committee directed DOD to utilize march-in rights to lower prices."[17] That is to say, at least some members of Congress have called explicitly for diminution of property rights and imposition of price controls.

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[11] *See, e.g., Molecular Biomarkers Improve Treatment of Colorectal Cancers*, AUTM (2008), https://autm.net/about-tech-transfer/better-world-project/bwp-stories/medical-diagnostic-predictors-of-therapy-response (*last visited* Feb. 1, 2024); *3-D Virtual Colonoscopies: Changing Attitudes, Reducing Cancer*, AUTM, https://autm.net/about-tech-transfer/better-world-project/bwp-stories/3-d-virtual-colonoscopy (*last visited* Feb. 1, 2024).

[12] *See, e.g., Increasing Mobility for Amputees*, AUTM (2016), https://autm.net/about-tech-transfer/better-world-project/bwp-stories/all-terrain-knee-(1) (*last visited* Feb. 1, 2024); *Innovative Bandage Saves Lives*, AUTM (2008), https://autm.net/about-tech-transfer/better-world-project/bwp-stories/alphabandage (*last visited* Feb. 1, 2024); *Cochlear Implant Brings Sound and Language to Thousands*, AUTM (2006), https://autm.net/about-tech-transfer/better-world-project/bwp-stories/cochlear-implant (*last visited* Feb. 1, 2024).

[13] *Honeycrisp: The Apple of Minnesota's Eye*, AUTM (2018), https://autm.net/about-tech-transfer/better-world-project/bwp-stories/honeycrisp-apple (*last visited* Feb. 1, 2024).

[14] *See, e.g.*, Lisa Larrimore Oullette & Andrew Tutt, *How Do Patent Incentives Affect University Researchers?*, 61 INT'L REV. L. & ECON. 1 (2020), https://doi.org/10.1016/j.irle.2019.105883.

[15] David Orozco, *Assessing the Efficacy of the Bayh-Dole Act Through the Lens of University Technology Transfer Offices (ITOS)*, 21 N.C. J.L. & TECH. 115, 142 (2019)

[16] *See Frequently Asked Questions (FAQs) for Applicants and Awardees of DOE Financial Assistance and R&D Contracts Regarding the Department's Determination of Exceptional Circumstances (DEC) for DOE Science and Energy Technologies Issued in June of 2021*, U.S. Department of Energy (2021), *available at* https://www.energy.gov/sites/default/files/2022-03/FAQs_03092022.pdf; *see also* Joseph Allen, *DOE's Misuse of Bayh-Dole's 'Exceptional Circumstances' Provision: How Uniform Patent Policies Slip Away*, IPWATCHDOG (May 26, 2022), https://ipwatchdog.com/2022/05/26/misuse-bayh-doles-exceptional-circumstances-provision-uniform-patent-policies-slip-away/id=149275.

[17] *See* Elizabeth Warren & Lloyd Doggett, *Letter to the Secretary of Defense Regarding Reducing Drug Prices* (Jul. 22, 2021), *available at* https://www.warren.senate.gov/imo/media/doc/Letter%20to%20DOD%20about%20Reducing%20Drug%20Prices%20Final%207.22.21.pdf.

But critics of the current patent system take far too dim a view of the Bayh-Dole Act's legacy. Both the patent system and the Act provide important incentives not just to spur invention, but also to encourage commercialization. As noted above, the Act has performed remarkably well at opening opportunities for the commercialization of inventions, and it is this commercialization function that helps to ensure that crucial discoveries are not left to gather dust. Indeed, one of the main drivers of the Act's success is its harmony with the economic theory of patent rights.

A. The Centrality of Strong Patent Protections

The biotechnology sector historically has depended on patents as a means to organize collaboration among universities, startups, and larger corporations. The costly and complex process of moving a discovery from the laboratory to the marketplace depends heavily on the temporary exclusivity granted by patent rights, as well as the data-protection rights of biologics subject to regulatory approval.[18] Such property rights are fundamental for attracting investors to commit resources to these ventures, which are fraught with high risks and significant costs.

Nobel laureate Kenneth Arrow observed that the product of inventive activity is *knowledge*.[19] This distinguishes knowledge from other goods or services, in that knowledge is costly to produce, but nearly costless to distribute.[20] In addition, information is often indivisible.[21] Indivisibility means that the information cannot be divided or allocated across producers, products, or outputs—*e.g.*, once a drug's chemical structure is known, this knowledge does not vary with how many doses are produced, or who produces them.[22] In addition, unlike most products and services, once knowledge is obtained, it is known forever. Those in possession of it can often utilize it with relatively little or no further expenditure. While a bicyclist may need to buy a new bicycle, his knowledge of how to ride will, once acquired, remain with him throughout his life. Likewise, once one knows how to produce a new drug, copies can often be reproduced at relatively low cost.

Another feature of knowledge is that consumers may not know its value until considerable resources have been expended to uncover it.[23] Consumers of a new drug do not know its safety and efficacy of until investigations have established how it performs biologically, which requires extensive modeling, as well as animal and human trials—the latter of which is especially costly.[24]

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[18] Dana P. Goldman, Darius N. Lakdawalla, & Tomas Philipson, *The Benefits From Giving Makers Of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data*, 30 HEALTH AFFAIRS 1, 84-90 (2011), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334.

[19] Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, at 609, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY (R. R. Nelson, ed., 1962).

[20] *See id.* at 614 ("The cost of transmitting a given body of information is frequently very low.").

[21] *See id.*. at 615.

[22] *See id.* ("[T]he use of information about production possibilities, for example, need not depend on the rate of production.")

[23] *Id.*

[24] Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016), https://pubmed.ncbi.nlm.nih.gov/26928437.

All these factors place drugs in the category of goods that are expensive to research, develop, and bring to market, but relatively cheap to imitate, as explained by Kip Viscusi and his co-authors:

> Suppose the inventor discovers an important drug, Panacea. The inventor could keep the chemical structure secret and try selling the drug as a cure for certain diseases. But a rival could easily buy a few pills, hire a chemist to figure out the structure, and begin selling exact copies at a lower price.[25]

These rivals would benefit from the inventor's investment in researching the new discovery at little expense of their own. In what is likely the most-cited empirical research on imitation costs, Edwin Mansfield *et al.* find that 60% of the patented innovations in their sample were imitated much more quickly and at much lower cost than the initial innovation:

> In the ethical drug industry [*i.e.*, the part of the industry involved in researching, developing and bringing drugs to market with regulatory approvals], patents had a bigger impact on imitation costs than in the other industries, which helps to account for survey results indicating that patents are regarded as more important in ethical drugs than elsewhere. … ***Without patent protection, it frequently would have been relatively cheap (and quick) for an imitator to determine the composition of a new drug and to begin producing it***. However, for many of these electronics and machinery innovations, it would have been quite difficult for imitators to determine from the new product how it is produced, and patents would not add a great deal to imitation cost (or time).[26]

If the benefits of the costly investment can be easily appropriated by rivals, then the incentives for invention evaporate. This leads to reduced investment, as explained in a section titled "Imitation Discourages Research" in Dennis Carlton and Jeffrey Perloff's textbook:

> Without a patent, anyone could use new information and *imitations* of new inventions could be sold legally. Suppose you discovered a cure for AIDS. You could sell your new drug for large sums of money if a patent gave you exclusive rights. Without a patent, other companies could duplicate your drug, and competition would drive the price to the competitive level. You would incur all the research costs, but not all the private benefit.[27]

Commenting on a 1990s-era proposal to regulate the pricing of "breakthrough" drugs, Viscusi *et al.* conclude that the proposal would ripple through companies' R&D portfolios:

> If one regards R&D investment as somewhat like a lottery—with low probabilities of achieving huge returns—top decile regulation changes completely the nature of the game.

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[25] W. KIP VISCUSI, JOHN M. VERNON & JOSEPH E. HARRINGTON, JR., ECONOMICS OF REGULATION AND ANTITRUST (2d ed., 1995) at 832.

[26] Edwin Mansfield, Mark Schwartz, & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J. 907, 913 (1981). [emphasis added]

[27] DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION (4th ed., 2005) at 532. For a numerical example, *see*, RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW (4th ed., 1992) at 38.

> Winning the lottery now provides only a reasonable or breakeven return, with other outcomes worse![28]

Not only would such regulations affect companies' expected returns, but they would also increase the *variation* in those returns. The added regulatory uncertainty would reduce firms' confidence in the reliability of their return-on-investment projections. Because of the well-known and widely accepted risk-return tradeoff, firms that face increased uncertainty in investment returns will demand higher expected returns from the investments they pursue.[29] In other words, policies such as the proposed "march-in" rights simultaneously reduce *expected* investment returns and increase the *required* rate of return to invest in R&D, thereby reducing investment.

The history of patent commercialization supports the economic theory above. Prior to enactment of the Bayh-Dole Act, the federal government had a patchwork of often-stringent requirements on patenting and licensing agreements for projects it had funded.[30] The result was that many firms were hesitant to make large investments in the basic discoveries that were necessary to create commercial products.[31] Indeed, this makes sense, as a key feature of the patent system is that it can ensure the stability needed to attract investment and the large-scale diffusion of innovations across the market.

The evidence abundantly demonstrates that robust property-rights systems have been crucial to economic growth and prosperity.[32] These rights facilitate specialization and trade, which lead to innovation and growth. Intellectual property plays a crucial role in this dynamic. While there may be debates over the exact parameters of any patent-protection regime, strong evidence supports the

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[28] VISCUSI, VERNON & HARRINGTON, JR., *supra* n. 25, at 863.

[29] *See* EDWIN J. ELTON & MARTIN J. GRUBER, MODERN PORTFOLIO THEORY AND INVESTMENT ANALYSIS (4th ed, 1991).

[30] *See, e.g.*, Jonathan Barnett, *The Great Patent Grab*, in THE BATTLE OVER PATENTS: HISTORY AND POLITICS OF INNOVATION (Stephen H. Haber & Naomi R. Lamoreaux eds., Oxford University Press 2021), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3909528; Mossoff, supra n. 3, at 18-20 ("Government ownership of patents proved to stifle, rather than to promote distribution of new innovations.")

[31] *Id.*

[32] Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811, 811 (2016) ("There is abundant evidence from economics and history that the world's wealthy countries grew rich because they had well-developed systems of private property"); *see also*, Zorina Khan & Kenneth L. Sokoloff, *Institutions and Democratic Invention in 19th-Century America: Evidence from "Great Inventors" 1790-1930*, 94 AM. ECON. REV. 400 (2004); Josh Lerner, *The Economics of Technology and Innovation: 150 Years of Patent Protection*, 92 AM. ECON. REV. 221 (2002); Albert G.Z. Hu & Ivan P.L. Png, *Patent Rights and Economic Growth: Evidence from Cross-Country Panels of Manufacturing Industries*, 65 OXFORD ECON. PAPERS 675 (2013) (finding faster growth and higher value in patent-intensive industries in countries that improve the strength of patents); Bronwyn H. Hall & Rosemarie Ham Ziedonis, The *Patent Paradox Revisited: An Empirical Study of Patenting in the US Semiconductor Industry, 1979-1995,* 32 RAND J. ECON. 101, 125 (2001) (identifying "two ways in which the pro-patent shift in the U.S. legal environment appears to be causally related to the otherwise perplexing surge in U.S. patenting rates, at least in the semiconductor industry"); Nikos C. Varsakelis, *The Impact of Patent Protection, Economy Openness and National Culture on R&D Investment: A Cross-country Empirical Investigation*, 30 RES. POL'Y 1059, 1067 (2001) ("Patent protection is a strong determinant of the R&D intensity, and countries with a strong patent protection framework invest more in R&D."); David M. Gould & William C. Gruben, *The Role of Intellectual Property Rights in Economic Growth*, in DYNAMICS OF GLOBALIZATION & DEVELOPMENT 209 (Satya Dev Gupta & Nanda K. Choudhry eds., 1997) ("The evidence suggests that intellectual property protection is a significant determinant of economic growth. These effects appear to be slightly stronger in relatively open economies and are robust to both the measure of openness used and to other alternative model specifications.")

idea that robust patent protection is vital for economic growth. Stephen Haber highlights that enforceable patent rights correlate with significant GDP increases.[33] Patricia Schneider's research indicates that intellectual property substantially fosters innovation in developed countries.[34] Similarly, Yee Kyoung Kim and colleagues conclude that intellectual property boosts innovation.[35] Theoretical work by Daron Acemoglu and Ufuk Akcigit underscores the importance of patents, especially where inventors are significantly advanced technologically.[36] Yum Kwan and Edwin Lai suggest that inadequate intellectual-property protection causes greater welfare losses than does overprotection.[37]

Relatedly, Nobel laureate economist William Nordhaus has found that, even with patented discoveries, only a tiny fraction of the social returns from technological advancements is captured by producers, while the majority of benefits accrue to consumers.[38]

Patents are particularly important for startups, whose ability to exercise enforceable patent rights is key to market entry. There are three primary reasons for this: 1) injunctions protect startups from being copied by established firms, who might otherwise copy startups' discoveries and pay court-set

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[33] Haber, *supra* note 32, at 816. ("Figure 1 therefore presents a graph of the strength of enforceable patent rights and levels of economic development for all non-petro states in 2010. There is nothing ambiguous about the resulting pattern: there are no wealthy countries with weak patent rights, and there are no poor countries with strong patent rights. Indeed… as patent rights increase, GDP per capita increases with it. Roughly speaking, for every one-unit increase in patent rights (measured from zero to fifty) per capita income increases by $780. A simple regression of patent rights and patent rights squared on GDP indicates that roughly three-quarters of the cross-sectional variance in per capita GDP around the world is explained by the strength of patent rights.") (emphasis added); *see also* Ronald A. Cass & Keith N. Hylton, *Laws Of Creation: Property Rights* In THE WORLD OF IDEAS 45-46 (2013) (discussing results of regression analysis providing evidence that "countries with stronger intellectual property rights tend to grow economically more than those with weak intellectual property rights.")

[34] Patricia Higino Schneider, *International Trade, Economic Growth and Intellectual Property Rights: A Panel Data Study of Developed and Developing Countries*, 78 J. DEV. ECON. 529, 539 (2005) ("The results suggest that IPRs have a stronger impact on domestic innovation for developed countries. This variable is positive and statistically significant in all OLS regressions in Table 4 (developed countries).")

[35] Yee Kyoung Kim, Keun Lee, Walter G. Park, & Kineung Choo, *Appropriate Intellectual Property Protection and Economic Growth in Countries at Different Levels of Development*, 41 RES. POL'Y 358, 367 (2012) ("[T]he impact of patenting intensity on growth is much larger in high income countries, as can be seen from the positive coefficient of the interaction term between the high income country dummy and patenting intensity – this coefficient being statistically significant at the 1% level of statistical significance. From column 6, the measured net effect of patent intensity on growth in high income countries is 0.0683 (=−0.027 + 0.953, where the former is the coefficient of the patenting intensity of middle-to-low-income countries and the latter the coefficient of the interaction term between the high income country dummy and patenting intensity).")

[36] Daron Acemoglu & Ufuk Akcigit, *Intellectual Property Rights Policy, Competition and Innovation*, 10 J. EUR. ECON. ASS'N. 1, 1 (2012) ("[O]ptimal policy involves state-dependent IPR protection, providing greater protection to technology leaders that are further ahead than those that are close to their followers.")

[37] Yum K. Kwan & Edwin L-C Lai, *Intellectual Property Rights Protection and Endogenous Economic Growth*, 27 J. ECON. DYNAMICS & CONTROL 853, 854 (2003) ("The calibration results indicate that there is under-protection of IPR (relative to the optimal level) within plausible range of parameter values, and that under-protection of IPR is much more likely than over-protection. More complete computation indicates that in the case of over-protection, the welfare losses are trivial; whereas in the case of under-protection, the welfare losses can be substantial. One interpretation of this result is that the US should protect IPR much more than it currently does.")

[38] William D. Nordhaus, *Schumpeterian Profits in the American Economy: Theory and Measurement* at 1 (Nat'l Bureau of Econ. Res. Working Paper No. 10433 Apr. 2004), http://www.nber.org/papers/w10433.

royalties; 2) patents serve as collateral to secure startup funding; and 3) patents attract venture-capital investment.

Diminishing patent rights by removing exclusion rights would allow larger firms to imitate startup innovations, reinforcing their market dominance. Without the threat of copying, established companies are forced to either innovate independently or acquire innovative startups. This aspect is particularly crucial for startups, as it protects their inventions from being misappropriated by larger rivals. The literature on firms' strategies to prevent rivals from copying their inventions suggests that, while patents are not the only method, they are crucial in certain industries, most notably in pharmaceuticals and chemicals. [39]

Another key aspect of strong intellectual property rights is that they can allow firms to raise funds through the process of collateralization. This is particularly relevant for startups that lack tangible assets, as they can offer patents as security for funding.[40] As Gaétan de Rassenfosse puts it:

> SMEs can leverage their IP to facilitate R&D financing.... [P]atents materialize the value of knowledge stock: they codify the knowledge and make it tradable, such that they can be used as collaterals. Recent theoretical evidence by Amable *et al.* (2010) suggests that a

[39] *See, e.g.*, Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175-176 (1986) (Mansfield shows through surveys that patent protection only had a limited impact on innovation in industries other than the pharmaceutical industry and, to a lesser extent, the chemical industry. Mansfield argues that this is because the effectiveness of patents depends on the extent to which they increase imitation costs; and that this increase is more substantial in the chemical and pharmaceutical industries). Note that this study largely predates standard-reliant industries, such as mobile-communications technology, where patents likely play a very important role in creating appropriability. *See also* Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, Sidney G. Winter, Richard Gilbert, & Zvi Griliches, *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 797 (1987). Levin *et al.*'s findings are broadly in line with Mansfield's. More recently, these findings were supported by Cohen *et al. See* Wesley M. Cohen, Richard R. Nelson, & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)* (Nat'l Bureau of Econ. Res. Working Paper 7552, Feb. 2000), https://www.nber.org/papers/w7552.

[40] *See, e.g.*, Mario Calderini & Maria Cristina Odasso, *Intellectual Property Portfolio Securitization: An Evidence Based Analysis*, INNOVATION STUDIES WORKING PAPER (ISWOP), NO. 1/08, at 33 (2008) ("[I]t seems that patent securitization should be more suitable for small and medium companies with a consistent IP portfolio but that have not easy access to capital market or have a higher financial risk and few possibility to raise unsecured financing."); *see also* Dov Solomon & Miriam Bitton, *Intellectual Property Securitization*, 33 CARDOZO ARTS & ENT. L.J. 125, 171-73 (2015) ("Among the famous securitization transactions in the field of IP rights are the securitizations of the copyrights of the singer David Bowie, the trademark of the Domino's Pizza chain, and the patent on the HIV drug developed by Yale University."); Nishad Deshpande & Asha Nagendra, *Patents as Collateral for Securitization*, 35 NATURE BIOTECHNOLOGY 514, 514 (2017) ("Patents are important assets for biotech organizations, not only for protecting inventions but also as assets to raise monies."); Tahir M. Nisar, *Intellectual Property Securitization and Growth Capital in Retail Franchising*, 87 J. RETAILING 393, 393 (2011) ("A method of raising finance particularly suited to retail franchisors is intellectual property (IP) securitization that allows companies to account for intangible assets such as intellectual property, royalty and brands and realize their full value. In recent years, a number of large restaurant franchisors have securitized their brands to raise funds, including Dunkin Brands and Domino's Pizza (Domino's). We use property rights approach to show that IP securitization provides mechanisms that explicitly define ownership of intangible assets within the securitization structure and thus enables a company to raise funds against these assets.")

> systematic use of patents as collateral would allow a high growth rate of innovations despite financial constraints.[41]

But the complexity in valuing patents,[42] particularly in the face of infringement risks, underscores why reliable IP rights are so important to maintaining patents' value as collateral. As Jayan Kumar observes (in the parallel context of copyright):

> Infringement action (most obviously music piracy) can seriously erode revenue streams and plans for combating infringement through litigation must be in place in order to protect the value of IP. Given the above risks and complexities, due diligence on IP before securitization is more expensive than with traditionally securitized assets.[43]

This last point becomes crucial to consider for the draft guidance, given that liberalizing march-in rights will almost certainly lead to increased litigation exposure across all industries that rely on patented technologies.

Lastly, as suggested above, intellectual-property protection influences venture-capital activity significantly. Patents impede imitation, can be used as collateral, and can help facilitate specialization, thereby fostering the entry of new specialized firms. Additionally, patents often signal to investors a company's potential success and value. Empirical studies show that patent filings have significant positive effects on investor valuations, especially for early-stage companies, and play an important role as a "commitment device," protecting entrepreneurs from investor expropriation. For example, David Hsu and Rosemarie Ziedonis find:

> a statistically significant and economically large effect of patent filings on investor estimates of start-up value.... A doubling in the patent application stock of a new venture [in] this sector is associated with a 28 percent increase in valuation, representing an upward funding-round adjustment of approximately $16.8 million for the average start-up in our sample.[44]

They also note that the effect is more pronounced in earlier financing rounds, when uncertainty surrounding the value of the underlying company is greater.[45] Along similar lines, Carolin Häussler, Dietmar Harhoff, and Elisabeth Mueller show that "companies' patenting activities have consistent and cogent effects on the timing of VC financing. Having at least one patent application reduces the

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[41] Gaétan De Rassenfosse, *How SMEs Exploit Their Intellectual Property Assets: Evidence from Survey Data*, 39 SMALL BUS. ECON. 437, 439 (2012).

[42] *See* Solomon & Bitton, *supra* note 40 (discussing the difficulties in evaluating patents as a barrier to securitization); *see also* Aleksandar Nikolic, *Securitization of Patents and Its Continued Viability in Light of the Current Economic Conditions*, 19 ALBANY L.J. SCI. & TECH. 393, 491 (2009) ("Anyone attempting to accurately assess the value of a patent portfolio faces numerous challenges including potential invalidity proceedings, potential infringement and infringement proceedings, obsolescence, or lack of demand for a license or the invention itself.")

[43] Jayant Kumar, *Intellectual Property Securitization: How Far Possible and Effective*, 11 J. INTELLECTUAL PROP. RIGHTS 98, 98 (2006).

[44] David H. Hsu & Rosemarie H. Ziedonis, *Patents as Quality Signals for Entrepreneurial Ventures*, ACAD. MGMT. PROCEEDINGS, Vol. 1, at 6 (2008), *available at* https://faculty.wharton.upenn.edu/wp-content/uploads/2015/07/11.pdf.

[45] *Id.*

time to the first VC investment by 76%."[46] Other authors argue that patents may serve as a commitment device to protect entrepreneurs from the risk of expropriation by their early investors.[47]

The conclusion is clear: intellectual property is a significant contributor to innovation and should be a central element of growth strategies. This view is widely accepted among economists, particularly in industries with very large upfront costs and steeply declining marginal costs of production—of which, pharmaceuticals is perhaps the most extreme example.

Having said that, it would be naïve to think that U.S. intellectual-property law has reached a state of perfection. Intellectual-property protection must strike a delicate balance between guarding knowledge that could otherwise be replicated at minimal cost—thereby encouraging the creation of such knowledge—and ensuring that the knowledge is disseminated to the public. Even a minor shift in that balance toward dissemination and away from protection could have disproportionate effects, making copying (*i.e.*, free-riding on the innovations of others) a more attractive strategy. This could lead to underinvestment and economic stagnation. Thus, when thinking about making changes to the status quo, policymakers should proceed with utmost care. The world preeminence that the current U.S. patent system has helped bring to fruition could easily be destroyed.

III. March-In Rights and the Danger to Innovation

The proposed changes to the Bayh-Dole Act's march-in rights[48] pose serious threats to the successful innovation regime that has propelled the United States to the forefront of global innovation. In particular, the proposed revisions would expand the criteria for federal agencies to exercise march-in rights, potentially allowing for broader interpretation and application. Most concerning is that the proposed framework would allow agencies to consider such factors as the pricing of commercial

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[46] Carolin Häussler, Dietmar Harhoff & Elisabeth Müller, *To Be Financed or Not… – The Role of Patents for Venture Capital-Financing*, at 3 (ZEW-Centre for European Economic Research Discussion Paper 09-003, Mar. 28, 2013), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1393725; *see also* De Rassenfosse, *supra* note 41, at 441.

[47] See Ronald J. Mann & Thomas W. Sager, *Patents, Venture Capital, and Software Start-Ups*, 36 RESEARCH POL'Y 193, 207 (2007). ("We note one additional possibility suggested by the data, that portfolio firms obtain the patents not because they increase the value of the firm to its investors, but because they protect the contributions of the firm from expropriation by the investors. The idea here is that by giving the portfolio firm a cognizable property right in its technology, the patents increase the value of the firm by decreasing the costs of moral hazard and hold-up in the relations between the entrepreneurs and their investors. Shane (2002) proposes a similar mechanism to explain patterns in licensing of patents assigned to MIT.")

[48] 35 U.S.C. 203 allows for a limited number of conditions under which federal agencies can grant licenses to inventions at least partially funded by federal money. These conditions include when a contractor or assignee is not expected to commercialize an invention in a reasonable amount of time, or when health or safety concerns are not expected to be reasonably satisfied by a contractor or assignee. *Id.* at (a)(1)-(2). To date, march-in rights have never been exercised. It should also be noted that "price" is not mentioned anywhere in § 203 as a basis for "march in," which could lead to the possibility of a valid Supreme Court challenge to such a change under the "major questions doctrine." *See, e.g., The Major Questions Doctrine*, CRS Report No. IF12077 (Nov. 2, 2022), https://crsreports.congress.gov/product/pdf/IF/IF12077. ("Under the major questions doctrine, the Supreme Court has rejected agency claims of regulatory authority when (1) the underlying claim of authority concerns an issue of "vast 'economic and political significance,'" and (2) Congress has not clearly empowered the agency with authority over the issue.") Moreover, the claim that the act was intended to be used to impose price controls is, at best, a stretch of statutory interpretation and, more realistically, a completely ill-fated enterprise that depends on taking statutory terms out of context. *See* Mossoff, *supra* n. 3, at 22-33.

goods and services arising from federally funded inventions.[49] Tellingly, the proposed framework would grant agency regulators authority to determine when a price is "extreme and unjustified given the totality of circumstances" and to decide, on that basis, whether to exercise march-in rights.[50]

These proposed changes raise concerns about their potential impact on the incentives for private-sector investment in the commercialization of federally funded research. Such changes threaten to disrupt the delicate balance of incentives that the Bayh-Dole Act has successfully established for more than four decades, potentially hindering innovation and diminishing consumer welfare in the long run.

But more importantly, one fundamental flaw in the draft framework would return us to a pre-1980 *status quo ante*. One of the primary questions that needs to be brought into focus in this proceeding is: what method of price discovery leads to the optimal commercialization of new patented inventions? Since much of this proceeding is focused on pharmaceutical products, we will restrict our discussion to the pricing of these products. Much of the economics of pricing patented medicines, however, transfers well to other contexts involving patent protections. As we discuss below, regulators are fundamentally incapable of matching, on average, the market's efficiency in setting prices.

To understand the pricing of new pharmaceuticals, it's helpful to begin with standard neoclassical price theory. The most basic model assumes that patented pharmaceuticals establish a monopoly, and that the monopolist sets different prices for different consumers based on their willingness to pay. In principle, such a "price-discriminating monopolist" will charge each consumer a different price and the lowest price paid will be equal to the drug's marginal cost of production. In other words, those consumers least willing to pay will pay the same price as in a "perfectly competitive" market. Moreover, the amount of the drug produced will be the same as under perfect competition. The big difference is that the producer receives all the consumer surplus. In practice, pharmaceutical companies are not perfectly discriminating monopolists, but they do typically set different prices in different countries and for different patient groups.[51]

In reality, very few—if any—new pharmaceuticals actually enjoy a monopoly. At best, they represent a new class of drug for treating a condition. Even in such cases, they typically compete with older products that are either less effective or have more side effects for some proportion of patients.[52]

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[49] RFI at 85599.

[50] *Id.*

[51] *See* PAUL KRUGMAN & ROBIN WELLS, ECONOMICS (4th ed., 2015) at 391 (Regarding pricing of patent-protected drugs, "A monopolist will maximize profits by charging a higher price in the country with a lower price elasticity (the rich country) and a lower price in the country with a higher price elasticity (the poor country). Interestingly, however, drug prices can differ substantially even among countries with comparable income levels.")

[52] For example, the H2 antagonist Tagamet (cimetidine) was developed by Smith, Kline & French to prevent and treat gastroesophageal reflux disease (GERD) and gastric ulcers. In response, Glaxo developed a similar but more effective H2 antagonist, Zantac (ranitidine) (*See* Viscusi *et al.*, *supra* note 25 at 851-852). This within-class competition was followed by the

This competition introduces a dynamic interplay between the new and old products, influencing the innovator's pricing strategy.

The neoclassical model shows that even a profit-maximizing monopolist has incentives to offer products at a range of prices to different consumers. But when the "monopolist" assumption is relaxed—reflecting the reality of competitive dynamics both within and between classes of drugs for any particular condition–it becomes even more difficult, if not impossible, to determine whether a particular drug price is "extreme and unjustified." There is thus a high likelihood that any such intervention would be arbitrary and capricious.

Unfortunately, if given such a mandate, regulators are likely to have incentives to intervene for political reasons. In essence, regulators gain little by declining to intervene in the presence of an alleged "extreme and unjustified" drug price.[53] Meanwhile, the consequences of (practically ubiquitous) improper intervention would not be borne by the regulator, but by the innovators and patients.

When a private firm misjudges demand and sets its prices incorrectly, it faces punishment by the market. This, in turn, leads the firm to correct its pricing strategy. Liberalized march-in rights, by contrast, create incentives for a one-way ratchet, whereby regulators—themselves insulated from market discipline—are driven by political pressures to demand price reductions, regardless of the effect on firms' incentives to develop new medicines.

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development of a new, more-effective, and longer-lasting class of anti-GERD drugs known as proton-pump inhibitors (PPI), starting with omeprazole and soon followed by a slew of others, including lansoprazole and pantoprazole. *See* Daniel S. Strand, Daejin Kim, & David A. Peura1, *25 Years of Proton Pump Inhibitors: A Comprehensive Review*, 15 GUT LIVER. 11(1), 27-37 (2017), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5221858. The development of treatments for Alzheimer's has followed a similar trajectory. Biogen's Aduhelm (aducanumab), was recently retired, but the drug, which works by clearing the amyloid plaques that block neurotransmission in people with Alzheimer's, has been hailed as a "groundbreaking discovery that paved the way for a new class of drugs and reinvigorated investments in the field." *See* Editorial Board, *Requiem for an Alzheimer's Drug*, WALL ST. J. (Jan. 31, 2024), https://www.wsj.com/articles/aduhelm-biogen-alzheimers-treatment-drug-development-pharma-fda-1d866bd7. The development of Aduhelm thus served as both a foundation for other drugs in the same class of anti-amyloid monoclonal antibody treatments, such as Leqembi (lecanemab) (*see* Christopher H. Van Dyck *et al.*, *Lecanemab in Early Alzheimer's Disease*, 388 N. ENGL. J. MED. 9-21 (2023), https://www.nejm.org/doi/full/10.1056/NEJMoa2212948) as well as continued within-class competition for those later drugs, until its retirement. Similarly, Cognex (tacrine)—the first in an earlier class of ameliorative drugs for Alzheimer's (acetylcholineesterase inhibitors, AChEIs), which work by preventing the breakdown of the neurotransmitter acetylcholine—was, like Aduhelm, ultimately deemed relatively ineffective and withdrawn (*See* Nawab Qizilbash *et al.*, *WITHDRAWN: Tacrine for Alzheimer's Disease*, 18 COCHRANE DATABASE SYS. REV. 3 (2007), https://pubmed.ncbi.nlm.nih.gov/17636619) because it had been superseded by other AChEIs, such as Aricept (donepezil). *See* Sharon L. Rogers *et al.*, *Donepezil Improves Cognition and Global Function in Alzheimer Disease*, 158(9) ARCH INTERN MED. 1021-1031 (1998), *available at* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/205223.

[53] *See, e.g.*, Eric Fruits, *The Oregon Health Plan: A "Bold Experiment" That Failed* (Cascade Policy Institute, Sep. 2010), https://ssrn.com/abstract=1680047 (describing how covered treatments under Oregon's Medicaid program was originally based on objective "cost-effectiveness" criteria, but quickly transitioned to subjective criteria based on public pressure).

A. Intrinsic Complexities

The economics of drug development and pricing in the pharmaceutical industry present unique challenges that set it apart from many other sectors. While the fundamental principles of the price system apply to patented inventions in this field, the intricacies of pharmaceutical development necessitate more complex pricing strategies.

One of the defining characteristics of pharmaceutical R&D is the very long time it takes to bring a drug to market. From initial discovery to market launch, the process of developing a new drug typically takes between 12 and 15 years.[54] This extended timeframe is due largely to the rigorous clinical trials and associated regulatory approvals that each new drug must undergo to ensure safety and efficacy. This prolonged development period represents a significant commitment of time and resources, often with no guarantee of success.[55]

Many potential drugs that enter the development pipeline do not make it to market, either due to inefficacy, safety concerns, or other factors discovered during the development process.[56] This high attrition rate means that successful drugs must not only cover their own development costs but also compensate for the expenses incurred by those that failed.[57] A 2016 study found that the likelihood of a molecule selected for clinical trials successfully concluding all three phases of trials and going to market is around 12%.[58] Taking into account this low success rate, the authors estimate the average cost of developing a new approved drug to be $2.8 billion.[59]

Given these unique challenges—long development times, substantial upfront investments, and a high rate of failure—pharmaceutical pricing must be carefully calibrated. Pricing strategies must account for recouping large investments while also considering the competitive market landscape, regulatory environment, and patient access.

B. Regulatory Complexities

The challenge is magnified when one considers the complex regulatory environment that exerts significant distortionary pressures on drug pricing. For example, there are several federal programs—

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[54] *AI's Potential to Accelerate Drug Discovery Needs a Reality Check*, NATURE (Oct. 10, 2023), https://www.nature.com/articles/d41586-023-03172-6.

[55] Duxin Sun, Wei Gao, Hongxiang Hu, & Simon Zhou, *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARM. SIN. B 3049 (Jul. 2022); *see also*, Krugman & Wells, *supra* note 51 at 264 ("there is a huge failure rate along the way, as only one in five drugs tested on humans ever makes it to market.")

[56] Sun *et al.*, *supra* note 55.

[57] *Research and Development in the Pharmaceutical Industry*, CONGRESSIONAL BUDGET OFFICE (Apr. 2021), https://www.cbo.gov/publication/57126 ("For established drug companies, current revenue streams from existing products also provide an important source of financing for their R&D projects.")

[58] DiMasi, Grabowski, & Hansen, *supra* n. 24.

[59] *Id.*; *see also*, CBO, *supra* note 57 ("average R&D expenditures per new drug range from less than $1 billion to more than $2 billion").

including Medicaid,[60] the 340B Drug Pricing Program,[61] and the regulations for the coverage gap for Medicare Part D[62]—that impose price controls on pharmaceuticals. While these controls aim to make medications more affordable for certain groups, the challenges they inadvertently create for pharmaceutical companies include potential distortions of downstream pricing for drugs outside of these programs.

For example, among these policies' unintended consequences is to penalize companies that offer drugs at lower prices. The mandated discounts and rebates for government programs often mean that pharmaceutical companies receive less revenue for the same product, relative to the open market.[63] To compensate for revenue losses incurred in these programs, pharmaceutical companies are often compelled to raise prices for patients not covered by these federal programs.[64] This situation creates a disparity in drug pricing, where the burden of subsidizing the cost for government programs falls indirectly on other consumers, often resulting in higher overall healthcare costs.

Furthermore, this regulatory thicket complicates drugmakers' pricing strategies. Instead of pricing based strictly on market demand or research and development costs (which is complicated enough on its own), companies must navigate a maze of regulations and mandatory discounts. This distorts natural market dynamics, often leading to higher prices for some consumers to balance the reduced revenue from government-mandated pricing. This approach can also stifle innovation, as pharmaceutical companies may redirect resources from research and development to regulatory compliance and strategic-pricing management.

C. The Fraught Nature of Intervening in Market-Based Drug Pricing

It's worth noting that march-in rights have not, to date, been exercised. This fact serves as an implicit acknowledgment of the pharmaceutical industry's effective functioning within the constraints noted

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[60] *See* The Medicaid Prescription Drug Rebate Program, established by the Omnibus Budget Reconciliation Act (OBRA) of 1990, 42 U.S.C. 1396r-8 (c)(1)(C). This program requires drug manufacturers to provide rebates for medications dispensed to Medicaid patients. The amount of rebate is determined by a formula that takes into account the average manufacturer price (AMP) and the best price (or lowest price) offered to any other buyer; *see also* Ramsey Baghdadi, *Medicaid Best Price*, HEALTH AFFAIRS (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000173 ("Program participation by drug manufacturers is essentially mandatory; companies declining to participate are excluded from all federal programs, including Medicare.").

[61] The 340B Drug Pricing Program, established by the Veterans Health Care Act of 1992, requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices. 42 U.S.C. § 256b (1993).

[62] Under the Affordable Care Act, a significant provision was introduced that directly affects the Medicare Part D coverage gap, commonly known as the "donut hole." *See* 42 U.S.C. § 1395w-114a (2018). This provision mandates pharmaceutical manufacturers to offer a 50% discount on drugs for beneficiaries during this coverage gap. *Id.*

[63] *See, e.g.*, Mark Duggan & Fiona M. Scott Morton, T*he Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing* (Nat'l Bureau of Econ. Res. Working Paper w10930, Feb. 2000), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=622874 (demonstrating that Medicaid pricing pressure on pharmaceuticals leads to downstream distortions in the price of pharmaceuticals purchased outside of the Medicaid program).

[64] *Id.*

above. Moreover, it reflects regulators' prudent reluctance to intervene in a complex and delicately balanced ecosystem. Indeed, any intervention in such a nuanced sector runs the risk of arbitrariness, given the intricacies involved in drug development and pricing. The restraint regulators have shown underlines their understanding of the unique economic dynamics of the pharmaceutical industry and the potential unintended consequences of intervention.

Further, the economics of the pharmaceutical industry also reveal the role that successful, high-revenue drugs have played in cross-subsidizing those discoveries that generate lower revenues.[65] This interplay between different segments of a pharmaceutical company's portfolio is another crucial factor that militates against pricing interventions. The inherent support that successful patented medicines offer to the research and development of less profitable drugs (and total failures) is a vital component of the industry's ecosystem.

So-called "blockbuster" drugs are a boon not just for the pharmaceutical companies, but also for the broader healthcare system. Some of the profits from these successful drugs are reinvested into further research and development, fueling the discovery and production of new medications.[66] This cycle of profit and reinvestment is critical to sustain the development of drugs that may have a smaller absolute market but are vital for treating rarer conditions. In this way, the big winners in a pharmaceutical company's portfolio underpin the development and continued availability of lower revenue drugs and experiments with seemingly promising, but ultimately unfruitful, lines of research.

Therefore, any intervention in pharmaceutical pricing must be approached with caution. The cross-subsidization model represents a delicate balance essential not just for pharmaceutical firms' financial health, but also to ensure the availability of a wide range of medications that meet diverse health-care needs. Unfortunately, this balance has already been weakened by price controls both in the United States and internationally, and could be substantially harmed by new price controls or other regulatory interventions.

Intervening in the pharmaceutical industry's complex, carefully balanced, intricate, and multifaceted domain of drug development and commercialization risks creating an environment in which

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[65] *See, e.g.*, Sun *et al.*, *supra* note 55. (discussing the fact that 90% of clinical trials fail, which means that the 10% of successful candidates effectively fund the experiments with the other 90%). As the authors note:

> Drug discovery and development is a long, costly, and high-risk process that takes over 10–15 years with an average cost of over $1–2 billion for each new drug to be approved for clinical use. For any pharmaceutical company or academic institution, it is a big achievement to advance a drug candidate to phase I clinical trial after drug candidates are rigorously optimized at preclinical stage. However, nine out of ten drug candidates after they have entered clinical studies would fail during phase I, II, III clinical trials and drug approval. It is also worth noting that the 90% failure rate is for the drug candidates that are already advanced to phase I clinical trial, which does not include the drug candidates in the preclinical stages. If drug candidates in the preclinical stage are also counted, the failure rate of drug discovery/development is even higher than 90%.

[66] John LaMattina, *Pharma R&D Investments Moderating, But Still High*, FORBES (Jun. 12, 2018), https://www.forbes.com/sites/johnlamattina/2018/06/12/pharma-rd-investments-moderating-but-still-high (Noting that R&D investment has typically been at 15% for the pharmaceutical industry).

outcomes are dictated by centralized agencies, rather than by decentralized, bottom-up processes. In such a system, regulators' necessarily limited knowledge will inevitably result in inferior outcomes. Moreover, it will lead to picking winners and losers in an arbitrary and capricious manner.

The issue's complexity is compounded by the fact that the vast majority of drugs that are developed receive some federal funding.[67] While it is impossible to know whether the same drugs would be developed without such funding, the fact is that such funding crowds out private investment in basic R&D. Moreover, it means that the proposed expansion of march-in rights would apply to nearly every patented drug currently on the market and in development. Therefore, such interventions would not only be arbitrary and capricious, in ways that raise constitutional questions, but also ominous and all-encompassing.

Moreover, the error costs associated with such interventions cannot be overlooked. In the pharmaceutical industry, the journey from lab to market is fraught with uncertainties and high failure rates. For instance, only a quarter of drugs that complete Phase 3 clinical trials proceed to Phase 4.[68] Reasons for this can include a lack of efficacy in larger populations or commercial non-viability.[69] A regulatory body attempting to override these decisions would need to possess better knowledge than the compound's own developers and commercializers regarding what will ultimately prove viable in the market. This prospect is clearly absurd and would lead to misallocation of resources, with companies being perversely encouraged to chase a higher number of unsuccessful endeavors.

Thus, any regulatory intervention in this space must be undertaken with a deep understanding of the inherent complexities and uncertainties of drug development. A regulator's decision to intervene in the commercialization process could result in significant wasted resources and could potentially impede the development of truly effective and needed medicines. The challenge lies in striking the right balance between encouraging innovation and ensuring access to effective and affordable medications, without falling into the trap of overregulation that could stifle progress in this vital field.

IV. Conclusion

In short, the narrative that drives the conversation around altering march-in rights is deeply flawed. The Bayh-Dole Act does not unjustly deprive taxpayers of the innovations they partially funded through their contributions to the federal government. In fact, the Act has fostered an explosion of

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[67] *See* Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou, & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4(4) JAMA HEALTH FORUM (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10148199. ("Funding from the NIH was contributed to 354 of 356 drugs (99.4%) approved from 2010 to 2019 totaling $187 billion, with a mean (SD) $1344.6 ($1433.1) million per target for basic research on drug targets and $51.8 ($96.8) million per drug for applied research on products.")

[68] FDA, *Step 3: Clinical Research* (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research.

[69] *Id.*

innovative activity that yields enormous benefits, both seen and unseen, to American consumers. The observable benefits are evident in the ever-expanding access to new medicines and devices that improve health outcomes for consumers.[70] The unseen—or rather, the easy to miss—benefits include the economic growth that has resulted from the United States serving as a major hub for innovative research and development.[71] The status quo is wildly successful and any perceived failures should be addressed with targeted solutions, not with a wholesale alteration to the framework that has been responsible for driving these changes.

Further, it's crucial to understand the effects that expanding march-in rights to address instances of "extreme" pricing could have on the nature of the Act itself. Originally designed as a pro-innovation policy, the Bayh-Dole Act could inadvertently transform into a regulatory tool for market manipulation.

Regulations are often complex and challenging to navigate. This complexity creates opportunities for incumbent firms to leverage regulations to their advantage, and to the detriment of competition and consumer welfare. In the context of the Bayh-Dole Act, expanding march-in rights to tackle "extreme" pricing could lead to just such a perverse outcome. Such a scenario would mark a significant shift from the Bayh-Dole Act original intent of fostering innovation toward a landscape where regulatory manipulation becomes a key competitive strategy. This potential transformation underscores the need for careful consideration and a balanced approach in any amendments to the Act. Addressing the issue of pricing should not compromise the Act's ability to stimulate innovation and healthy market competition.

Finally, expanding march-in rights under the Bayh-Dole Act, although primarily targeted at pharmaceutical producers, sets a precedent with far-reaching implications for all patent-reliant industries, including computers, biotech, and manufacturing. Industries that thrive on intellectual property to develop and safeguard their innovations will be watching this development closely. This potential for regulatory and legal manipulation could alter the competitive landscape, where gaining an upper hand might no longer depend solely on innovation and market strategies, but increasingly on the ability to navigate and exploit expanded march-in rights.

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[70] *See, e.g., What's Driving the Improvement in U.S. Cancer Survival Rates?,* CITY OF HOPE (Jan. 26, 2023), https://www.cancercenter.com/community/blog/2023/01/cancer-survival-rates-are-improving Cancer death rates are down 33% since 1991. This is, in large part, due to the development of increasingly effective means of treating cancer and improving survivability odds.

[71] *See supra* notes 6-9 and accompanying text.