THE ROLE OF THE **BAYH-DOLE ACT** IN FOSTERING **TECHNOLOGY TRANSFER** AND IMPLICATIONS FOR **INNOVATION**

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EXECUTIVE SUMMARY

The Bayh-Dole Act (commonly referred to simply as "Bayh-Dole" and codified at 35 U.S.C. §§ 200-211) created the uniform framework that facilitates orderly and efficient technology transfer from universities and other institutions receiving government research funding to the private sector.[1] Bayh-Dole allows universities and other institutions to own title to the patents arising directly from their research activities. With these clear patent rights, universities are then free to license the right to use the most promising technologies to private sector partners in order to commercialize them. As such, Bayh-Dole – which passed with strong bipartisan support – created a viable route by which new insights and valuable research results from universities and other institutions could make their way efficiently to start-up and established firms, which then assume the full risk of development and cost for commercializing the few technologies that eventually prove to lead to technically and economically viable products.

This paper focuses specifically on the contributions of Bayh-Dole in fostering technology transfer in the life sciences and current threats to this robust framework. Ill-informed proposals to eliminate fundamental aspects of the cooperative academia-industry relationship which developed as a result of Bayh-Dole and has been operating successfully for nearly 40 years, or to use this framework to regulate drug prices, reflect a fundamental lack of understanding of the research and development (R&D) process and the benefits that accrue to patients, society, and the economy through the development of innovative treatments.

In the specific case of biopharmaceuticals, together with other factors such as the development of advanced scientific tools and techniques and the emergence of the modern risk-based venture capital market, Bayh-Dole helped lay the foundation for today's robust biomedical R&D ecosystem and its spirit of entrepreneurship, which has helped propel U.S. global leadership in the life sciences. The clear and consistent approach to U.S. licensing policy and intellectual property (IP) rights established by Bayh-Dole creates a predictable mechanism by which early-stage research that is supported in whole or in part by the federal government can attract the subsequent private sector investment necessary to successfully develop and commercialize products for the benefit of patients, society, and the economy.

Assessments of Bayh-Dole have found it to be a vast improvement over the previous state of affairs:

- Prior to Bayh-Dole, commercialization rates of federally funded research were estimated

to be less than 5%. Since the passage of the law, however, commercialization of federally funded research has increased dramatically – comparing 1980 and 2009, U.S. universities increased their level of patenting tenfold.[2]

- Collaborations between universities and government-funded researchers and the private sector have proven to be a successful model to leverage complementary roles in basic research and applied development of medical innovations, and to address unmet patient needs. Without clear patent rights and protections and the economic incentive of exclusive licensing established under Bayh-Dole, private firms might not devote scarce resources to the highly-uncertain development efforts needed to advance research from laboratories receiving public sector funding to the market or the bedside, in the case of medical therapies.

- Such collaborations and licensing models have been a critical building block of the U.S. biomedical R&D ecosystem and to the significant contributions it has made to the U.S. economy – and have contributed to U.S. global leadership in biomedical innovation.

- While collaborations and licensing between academia and the private sector are particularly important to the biomedical R&D ecosystem, they are vital to driving innovation in other industries as well, particularly high-technology industries such as semiconductors. As a result, technology transfer activity has a significant impact on the U.S. economy, with one study finding that between 1996 and 2017, academia-private sector patent licensing across all industries bolstered U.S. GDP by up to $865 billion (in 2012 U.S. dollars) and supported up to 5.9 million person-years of U.S. employment.[3]

- A National Academy of Sciences study found “no reason to believe that either governmental retention of title or routine retention of title by individual inventors would yield more commercial applications or achieve a better balance of the public’s stakes” than Bayh-Dole.[4]

To ensure timely and effective commercialization of federally funded research, Congress built in safeguards through a provision of Bayh-Dole that grants the federal agency funding the research a limited right to “march-in” and require the owner of a patent developed through federal funding to grant additional licenses to the technology. This provision is applicable only under certain very limited and specified circumstances, such as if the current licensee fails to make efforts to achieve practical application of the product or fails to reasonably satisfy public health and safety needs (with the latter having been considered and rejected in the case of manufacturing shortage).

There have been several recent petitions to the National Institutes of Health (NIH) to use march-in rights in an effort to directly reduce the prices of innovative medicines. These misguided efforts threaten to upset the success achieved under Bayh-Dole over the past 39 years in fostering early basic research and ensuring the use and translation of those early findings into new medical innovations. The limited march-in right established by the authors of Bayh-Dole reflected an understanding of the inherently uncertain nature of scientific development and the need to provide clear, consistent, and predictable ground rules

for government licensing that encourage public and private sector collaborations to harness promising scientific research into advances for patients and consumers. The intent of march-in authority was to ensure that grantees were in fact making efforts to commercialize the licensed technology and bring applications to market, to the benefit of patients and society.

To date, NIH has considered and denied six march-in petitions.[5] The NIH has never concluded that licensors failed to take adequate steps to commercialize the subject inventions. The history and NIH's responses to the six petitions suggest that march-in was never intended to address concerns about drug pricing and could potentially have a chilling effect on industry willingness to partner with academia and the public sector.

Bayh-Dole is one of the most successful and far-reaching legislative initiatives in contemporary history. Commercial development of federally supported research has gone from being a major concern in terms of national competitiveness in the 1970s to being a fundamental element of the current, highly successful U.S. biomedical ecosystem. The innovative therapies in cancer and many other disease areas that have resulted since have revolutionized medicine and patients' lives, and the economic impacts from technology transfer activities have included thousands of new companies founded and millions of jobs supported across the U.S. The use, or even threat, of march-in as an approach to regulate drug prices would create substantial uncertainty for private sector technology development partners and dramatically alter the framework that contributed to the growth and sustainability of the modern R&D ecosystem. At a time when the science has never been more challenging and the potential for fundamentally altering disease processes more promising, public policies should support critically needed public-private collaborations, rather than undermine the future of the technology transfer and U.S. biomedical R&D enterprise that is the envy of the world.

INTRODUCTION: ORIGINS OF BAYH-DOLE SPURRED BY CONCERNS ABOUT LOSS OF U.S. GLOBAL COMPETITIVENESS

Before the passage of the University and Small Business Patent Procedures Act (commonly referred to as "Bayh-Dole") in 1980, there was no clear and coordinated patent ownership or exclusive licensing policy across federal agencies. In order to obtain title rights to an invention resulting from federally funded research and development (R&D), grantees such as universities could request a waiver, either in advance during contract negotiations or on a case-by-case basis, after disclosure of the invention to the federal agency sponsoring the research, but the process was inconsistent and unpredictable.

As later Government Accountability Office (GAO) reports summarized, *"Those seeking to use government-owned technology found a maze of rules and regulations set out by the agencies in question because there was no uniform federal policy on patents for government-sponsored inventions or on the transfer of technology from the government to the private sector,"*[6] and *"at the time the bill was considered, 26 different federal agency policies existed regarding the use of results from federally funded research."*[7]

Not only did federal agency policies vary in whether they permitted university ownership, but the licenses granted were non-exclusive licenses. As a result, there were disincentives for researchers, particularly in the life sciences, to participate in federally sponsored research. Recalls Joseph Allen (then a staffer to

> "Possibly the ***most inspired piece of legislation to be enacted in America over the past half-century*** was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."
>
> – *The Economist*, December 2002

Senator Birch Bayh, one of the two primary sponsors of Bayh-Dole), a biopharmaceutical company *"had several promising government-funded inventions taken away under existing federal patent policies. They explained that taking early stage inventions from their creators, making them widely available through non-exclusive licenses doomed the technology's development."*[8] Indeed, as co-sponsor of the bill, Senator Robert Dole stated in July 2005, the Government's *"track record of promoting the adoption of new university-born technologies by industry during the 1960's and 1970's was dismal. The failure to capitalize on the knowledge that resulted from Federal funding of basic research delayed innovations and denied the benefits of further development, disclosure, exploitation, and commercialization to the American people."*[9]

Moreover, federal agencies had limited incentives and expertise with which to pursue commercialization on their own. A National Research Council report identified the gap: *"In the pre-1980 system of government ownership of inventions arising from federally funded research—whether in government laboratories, universities, or companies—the incentives to pursue further development and commercialization were severely attenuated and the capacity to do so severely limited. Government agencies, in particular, had no incentive and negligible capacity."*[10]

This created, in turn, a lack of incentives for university grantees to invest in commercialization infrastructure: *"Where research performers had the possibility of persuading federal agencies to transfer rights to them, the uncertainty of success and the complexities of obtaining waivers of government ownership under different agency rules were often high. Most institutions had no reason to hire specialized personnel and create administrative units to handle these matters."*[11]

As a result of the lack of title to inventions for federal grantees (and the associated patent protection critical to commercial value), companies had little incentive to invest the significant time and money required to translate the basic research into a successful marketable product.[12] As one government report noted, *"at the present time, the Government frequently takes title to inventions produced from research supported by Federal funds…the Federal Government currently has title to some 28,000 patents. Many of these patents are on inventions of great potential economic impact. However, only about five percent of federally owned patents are utilized in the private sector."*[13, 14]

Bayh-Dole was conceived as an effort to ensure that promising technologies funded by the federal government would not sit on the shelf, but could be developed into useful, sometimes life-saving, products for Americans. In 2004, Senator Birch Bayh recalled the intent of Congress in enacting the Bayh-Dole Act, highlighting a perceived loss of national competitiveness, a need to provide additional incentives for investments in innovation, and a means by which to reap the benefits of federal investments in R&D already made. As he noted, *"by the late 70s, America had lost its technological advantage… Since the*

government refused to permit ownership of the patents, private industry and business refused to invest the resources necessary to bring the products to consumers. As Thomas Edison said: 'Invention is 1% inspiration and 99% perspiration.' With regard to publicly funded research, government typically funds the inspiration and industry the perspiration."[15]

THE BAYH-DOLE ACT: KEY POLICY OBJECTIVES AND PROVISIONS RELATED TO MARCH-IN

The Bayh-Dole Act provided the first-ever comprehensive framework regarding technology transfer from government-funded research at universities and other institutions to the private sector in an effort to encourage the development of promising inventions. The House Committee on the Judiciary described the intent of the proposed legislation as creating a *"single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application."*[16]

The stated policy objectives in the Bayh-Dole Act are to:

> (U)se the patent system to promote the utilization of inventions arising from federally supported research or development;
>
> to encourage maximum participation of small business firms in federally supported research and development efforts;
>
> to promote collaboration between commercial concerns and nonprofit organizations, including universities;
>
> to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;
>
> to promote the commercialization and public availability of inventions made in the United States by United States industry and labor;
>
> to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[17]

Bayh-Dole does not automatically grant universities and other recipients of federal research funding the title to the inventions they discover. They may assert as a matter of right (except in "exceptional

circumstances") title to patents on inventions they create using that funding, but they also must meet certain obligations, including filing for patent protection (for patentable inventions), sharing a portion of license revenue with the inventor(s), and meeting certain reporting and disclosure requirements. As a result, universities and other institutions often invest a significant amount of staff time and other resources to pursue patenting and later, technology transfer, of federally funded inventions. Universities and other institutions are incentivized to make these investments on the basis that they will be able retain full title to those patents (aside from certain narrow reserved rights by the government) and can seek licensing opportunities with industry, to help recoup those costs, fund research and education needs, and support universities' missions of advancing discovery and the social benefits of new knowledge. In fact, as a 2012 Congressional Research Service report notes, *"one of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."*[18]

The government does, however, retain certain limited rights. Under Section 203 of the Act, the government has a limited right to "march in" and *"require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself."*[19]

The objective of march-in authority was to ensure that the federal investments in innovation in fact made their way into commercialization activities.

Consequently, to exercise "march-in" authority, the relevant federal agency must determine that:

- The contractor has not made, and is not expected to make, efforts to commercialize the invention within an agreed upon time frame;
- Public health or safety needs are not reasonably satisfied by the contractor or licensee;
- The use of the invention is required by the federal government and the contractor or licensee cannot meet the government's requirements; or
- The owner of an exclusive license has not obtained certain necessary waivers, or met related requirements.

Since the passage of Bayh-Dole, there have been six instances of petitions requesting the exercise of march-in rights in connection with NIH-funded research relating to a biopharmaceutical product.

These petitions have claimed that either licensing activity did not address public health or safety needs or that manufacturer pricing was excessive, for various reasons:

- One claimed, as a result of a private patent dispute, that the licensor had failed to take steps to achieve practical application (CellPro, 1997);
- Four claimed that manufacturer pricing was excessive and/or allowed excessive pricing

differentials between the U.S. and other countries (Norvir®, 2004; Norvir®, 2012; Xalatan®, 2004; Xtandi®, 2016); and

- One was intended to address product shortages due to manufacturing difficulties (Fabrazyme®, 2010).

All of these march-in petitions have been denied, with the NIH consistently concluding that producers were addressing shortages, that the products had reached practical application and met health or safety needs and/or *"that the extraordinary remedy of march-in is not an appropriate means of controlling prices."*[20] In denying the 1997 CellPro petition, NIH noted that to approve it would *"have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies."*[21] In denying the 2012 petition, NIH found that, *"We do not think that the AbbVie pricing policies and pricing disparities between the United States and other countries trigger any of the four Bayh-Dole march-in criteria,"* and more generally, *"NIH continues to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients."*[22] In denying the 2016 Xtandi® march-in petition, NIH noted that the medicine had reached "practical application" in that it was "broadly available as a prescription drug."[23]

A summary of NIH responses to march-in petitions is available in the Appendix.

THE ECONOMIC AND SOCIETAL IMPACT OF BAYH-DOLE: FUELING INNOVATION AND LOCAL ECONOMIES

By any measure, the Bayh-Dole Act has had a tremendous impact on the national economy over the nearly four decades since its passage. Its economic contributions can be measured by an increase in the rate of commercialization of university-based technologies through patenting, licensing, research joint ventures, and the creation of startups in all industries. According to one study, university patenting across all technology areas has increased ten-fold since the passage of Bayh-Dole – in 1980, universities were awarded 390 patents; for 2009, the corresponding figure was 3,088.[24] The Association of University Technology Managers (AUTM) undertakes an annual survey of licensing professionals and reports several measures of technology transfer. According to the AUTM data, between 2005 and 2017, all measures of technology transfer activity had increased significantly, and hundreds of new start-up companies had been formed as a direct result of Bayh-Dole.[25]

Bayh-Dole Technology Transfer Activity Among Universities and Institutions Across All Technology Areas:

Selected Technology Transfer Metrics	FY2005	FY2017
U.S. patents issued	3,278	7,459
Licenses executed	4,178	6,232
Total license income to universities from tech transfer	$2.1 billion	$3.1 billion
Startup companies formed	451	1,080

Source: AUTM 2017 U.S. Licensing Activity Survey.

University research and startups, which rely on Bayh-Dole's incentives and a partnership model between academia and the private sector, have become an engine for regional economic performance and growth. The importance of start-up firms to regional and national job creation is substantial – it has been estimated elsewhere that start-up businesses are a primary driver of job growth, accounting for 70% of gross job creation.[26] As AUTM's President David Winwood has noted, *"when academic research yields a new idea, that idea often leads to a new startup company and then to new products in the marketplace. These ideas have the capacity to save lives, improve the way we work and play, and boost local economies--from seed varietals for our farmers to improved treatments for obesity and diabetes. Time and again these companies blossom, grow and stay in our local communities enhancing economic development."*[27]

Bayh-Dole's impact on start-up activity across all industries is substantial:

- In 2017, 1,080 startup companies were formed as a result of Bayh-Dole and technology transfer activities, 782 of them having their primary place of business in the licensing institution's home state.[28]
- 11,210 startup companies were reported as having been formed between 1980 and 2014 as a result of technology transfer activities – in 2014, these firms introduced over 960 products.[29]
- Universities create an average of more than two start-up companies each day, and these university-based start-ups have longer life spans and raise more capital than non-university-affiliated start-ups, meaning they support job creation and sustained economic benefits to local economies.[30]

More specific to the life sciences industry, Bayh-Dole has become a critical element in the rise of "biotech clusters" (geographic concentrations of biotech firms actively exchanging expertise, human capital and infrastructure, often located near or including universities) and other mechanisms that help pave the way for technology transfer from academia to industry. Summarized one researcher, *"In recent years, there has been a substantial rise in the rate of commercialization of university-based technologies – through patenting, licensing, research joint ventures, and the formation of startup companies. We have also witnessed an increase in investment in science parks and other property-based institutions that facilitate the transfer of technology from universities to firms…most commentators attribute a substantial portion of this activity to the Bayh-Dole Act of 1980, which dramatically changed the incentives of U.S. universities to commercialize their intellectual property. Bayh-Dole instituted a uniform patent policy across federal agencies, removed many restrictions on licensing, and most importantly, allowed universities, rather than the federal government, to own patents arising from federal research grants."*[31]

While collaborations and licensing between academia and the private sector are particularly important to the biomedical R&D ecosystem, they are vital to driving innovation in other industries as well, particularly high-technology industries such as semiconductors.[32] Overall, the licensing activity spurred by Bayh-Dole has been estimated to have contributed up to $865 billion (in 2012 U.S. dollars) to GDP and supported up to 5.9 million person-years of U.S. employment between 1996 and 2017 across all industries.[33]

The enormous economic impact of Bayh-Dole rests on its contributions to society through the commercialization of technologies. By allowing for both retention of patent title by entities receiving government funding and exclusive licensing, Bayh-Dole enables the private sector to effectively apply early insights from universities and other research institutions to develop the next generation of treatments and cures for patients. Indeed, studies have characterized the roles of industry and academia in the innovation process as complementary. University research, supported by grants and contracts from the public, non-profit, and private sectors is typically focused on the basic research stage (e.g., identification of biochemical mechanism(s) in disease etiology, potential targets). Private sector investment is more heavily concentrated in subsequent stages of pre-clinical development and clinical testing to obtain FDA approval (e.g., medicinal chemistry, process and formulation science, pharmacokinetics and metabolism modeling, safety science, and clinical trials to demonstrate safety and efficacy).

Researchers have estimated that as a result, 67% to 97% of drug development research is conducted by the private sector.[34] Another study found that *"biotechnology companies invest $100 in development for every $1 the government invests in research that leads to an innovation."*[35] Basic research represents only a small portion of the total investment required to bring an idea from "the bench to the bedside"; without clear rules and incentives for industry to partner in undertaking risky drug development, many promising insights would be left "stranded in the lab." According to the Congressional Research Service, *"While basic research is often important to innovation, studies have shown that, on average, it constitutes only 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace."*[36]

Without the potential for both retention of patent title by entities receiving government funding and exclusive licensing, private firms would be unlikely to make substantial investments in uncertain and lengthy drug development programs. Thus, Bayh-Dole provided the incentives and framework needed to facilitate academia-industry partnerships and drive initial insights from university labs to clinical development by industry, and ultimately into FDA-approved medicines that can help patients live longer, healthier lives. In fact, by the mid to late 1990s, over 90% of life science companies in the U.S. had a cooperative relationship with universities.[37] Together with other mechanisms, university patenting and licensing is needed for effective knowledge transfers between academia and the private sector.

Concrete examples of the societal benefits from Bayh-Dole licensing of university-based research, when combined with further development by the private sector, include a number of important biopharmaceutical therapies including new vaccines, treatments for costly and burdensome chronic diseases, and innovative new approaches to treating complex diseases such as cancers and HIV.[38] While the basic underpinnings of these therapies were discovered in universities, biopharmaceutical companies could not have invested the significant resources needed to further develop them into actual FDA-approved medicines without Bayh-Dole. A review of the development histories and relative R&D contributions by the public and private sector for 35 important drugs found that the scientific contributions of the private sector were crucial to all of them. The central scientific contribution by the private sector was evident in all categories of development (basic science, applied science, and clinical, delivery and manufacturing improvements), being most significant in applied science, followed by contributions to enhancing clinical performance and improving commercial production.[39] These findings were confirmed in a subsequent analysis by some of the same researchers of 26 individual drugs, drug classes and a combination therapy identified by a previous analysis as "most transformative drugs of the past 25 years."[40]

As several independent government assessments of Bayh-Dole have found, the legislation has achieved its core objective of increasing technology transfer from academia to the private sector:

- National Academy of Science (NAS): *"The Bayh-Dole Act is a sound and flexible framework for promoting the commercialization of university-developed inventions resulting from federally sponsored research...The committee has no reason to believe that either governmental retention of title or routine retention of title by individual inventors would yield more commercial applications or achieve a better balance of the public's stakes."*[41]

- Congressional Research Service (CRS): *"Observers generally agree that the Bayh-Dole Act has successfully met its objectives… The government receives a significant payback through taxes on profits and society benefits from new jobs created and expanded productivity."*[42]

- General Accounting Office (GAO): *"University administrators and small business representatives whom we interviewed stated that federal patent policy changes since 1980 have had a significant positive impact on their research and innovation efforts… Officials within the agencies and universities we visited said the act was having a positive impact and was working as the Congress intended. They believed that the universities and researchers were receiving greater benefits from their inventions and were transferring technology better than the government did when it retained title to inventions."*[43]

POTENTIAL NEGATIVE IMPACT OF THE USE OF MARCH-IN TO ADDRESS DRUG PRICING

Expanding the use of march-in rights for purposes other than those intended by the legislation would negate current exclusive licenses and in essence constitute government pricing controls. Ultimately this would undermine the careful balance and successful synergy between early public-funded basic research by universities and other institutions and subsequent risk-based R&D by the private sector. This synergistic relationship relies on clear, consistent and predictable "ground rules" for licensing of government-funded technologies.

These recent proposals harken back to objections to the Bayh-Dole framework at the time of passage. Senator Bayh summarized the arguments of "well-intentioned voices," who argued, *"If the taxpayer funds the research, the taxpayer should own the ideas produced"* and his response – *"However, the result of this policy was billions of taxpayer dollars spent on thousands of ideas and patents which were collecting dust at the PTO. The taxpayers were getting no benefit whatsoever."* Instead, after vigorous debate, Bayh-Dole reflected the conclusion that *"market forces would do a better job of commercializing government-funded technology than federal agencies could."*[44]

The intent of march-in authority was to ensure that grantees were in fact making good faith efforts to commercialize the licensed technology and bring inventions to market to the benefit of patients and society, in an era when there were few university technology transfer offices to facilitate these efforts. All six "march-in" petitions decided by NIH to-date have been denied, with findings that licensors in fact have taken steps to commercialize the technologies, that *"any licensing plan that might result from such a proceeding would not, in our judgment, address the problem"* (i.e., product shortage relating to manufacturing technology challenges), or that *"because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by the NIH, the NIH believes that the extraordinary remedy of march-in is not an appropriate means of controlling prices."*[45]

In addition to practical considerations whether march-in authority would prove to be effective in the case of a public health emergency, based on interviews with agency personnel and other expert stakeholders, the GAO previously identified a fundamental concern relating to the potential impact of march-in authority exercise: *"the potential 'chilling effect' that such an action might have could deter investors from investing in the commercialization of the research results and [deter] some researchers from participating in federal research efforts."*[46]

Indeed, experience with the NIH's previous failed effort to influence drug pricing by placing conditions on patent licensing agreements suggests that expanding the use of march-in to address drug pricing could chill academia-industry collaboration and the innovation generated from those collaborations. In 1989, the NIH adopted a policy of requiring a "reasonable pricing" clause in its Cooperative Research and Development Agreements (CRADAs) between NIH intramural laboratories and private sector partners involving exclusive licenses. Under the policy, exclusive licenses to the private sector for discoveries

funded in part by the NIH required that there be *"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."*[47] While well-intentioned, as summarized in a Congressional Research Service report to Congress, after extensive review and public hearings the NIH concluded the policy resulted in unintended negative consequences harmful to scientific collaboration and the public: *"the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public."*[48] Given NIH's mission to provide scientific leadership to the nation by *"seek(ing) fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability,"*[49] diverting its scarce resources into setting, monitoring, and evaluating the effects of what were, in effect, pricing controls in a complex biopharmaceutical discovery and development ecosystem was counterproductive.

Creating unsustainable uncertainty for the private sector, the process involved NIH making a "fair" pricing determination for a medicine only after a company had spent years of effort and millions in financial investment to complete development and begin commercializing the medicine. Industry was deterred from collaborating with NIH, and following the change, CRADAs flat-lined between 1990 and 1994 at approximately 30 per year.[50] Following public hearings with various stakeholders from both the public and private sectors, the NIH removed the reasonable pricing requirement for CRADAs in 1995, and *"(t)he effect of abandoning the clause was immediate. Subsequent to rescission of the clause in April 1995, the number of CRADAs executed by NIH increased substantially,"* reaching five times the 1990-94 level, or more than 150 in 1997.[51] Given the chilling effect on public-private collaborations as a result of NIH's failed attempt to influence pricing of biopharmaceutical products under the Act through constraining licensing agreements, NIH has not pursued similar approaches since. Indeed, NIH Director Francis Collins has stated that when the reasonable pricing clause came into effect *"basically industry completely lost interest in [engaging in CRADAs] at all. It was a deal breaker, and I don't think that would be any different now."*[52] There is no reason to believe that expanding the use of march-in rights under Bayh-Dole to control drug pricing would have any different effect. As Director Collins goes on to say, *"As much as we are concerned about the drug pricing issue, I don't think we have levers to pull to help with this that wouldn't have other really negative consequences. The march-in approach does not appeal to us at all."*[53]

The GAO also identified another concern with the exercise of march-in authority: *"commercial products or processes based on federal inventions sometimes employ multiple patents, some of which are not federally funded. Such circumstances often pose difficult, if not intractable, issues that could make marching in unattractive for federal officials seeking to commercialize an invention...federal agencies may only have the authority to march in on one aspect of a product or process, yet marching in may negatively affect the value of all the other patented inventions associated with the product or process."*[54] This is particularly true in the case of biopharmaceutical products, where there may be multiple patents on various aspects of a medicine, including the composition of the active ingredient, the method of use of the medicine, the technology or methods used to produce it, and its dosage form. In cases where a government-funded patent is only one of a set of patents related to a product, the use of march-in may not result in any earlier access to the medicine, yet would nevertheless create significant uncertainty for licensees who, having spent the time and resources needed to develop the government-funded patented technology into FDA-approved medicines, may likely be unwilling to do so again.

The uncertainty created by expanding the use of march-in to address pricing concerns undermines the fundamental intent of Bayh-Dole. When universities make investments to secure patent protection for their government-funded inventions and license them to industry, it is with the assumption they will be able to recoup these costs and fund future technology transfer, research, and educational activities that result in new innovations, new companies, and new jobs. When private sector companies agree to license promising, yet early, technologies from academia or other entities who have received federal funding and invest significant financial and other resources into developing and testing those technologies, it is under the assumption that they will have the opportunity to recoup these investments without the added risk of arbitrary and unanticipated government action and unpredictable price-setting after years of investment. This is particularly a concern for start-up and small firms, whose most important assets are intellectual property and licensing expectations. Indeed, as a 2012 Congressional Research Service report found, *"one of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."*[55] Undermining this certainty by marching into a company's exclusive license to a federally funded patent years after it has made significant investments to develop and commercialize the product is likely to drive the private sector away from technology transfer agreements under Bayh-Dole, to the detriment of patients, consumers and the economy.

CONCLUSION

Reviewing others' assessments of the far-ranging impact of the law, Senator Bayh noted in his remarks to NIH opposing march-in, *"Changes to Bayh-Dole should be made only after giving careful consideration to what has been accomplished by those who have utilized the provisions of the law. The London 'Technology Economist Quarterly' called Bayh-Dole 'Possibly the most inspired piece of legislation to be enacted in America over the past half century.' ... The Economist estimated that Bayh-Dole created 2,000 new companies, 260,000 new jobs, and now contributes $40 billion annually to the U.S. economy [across all industries]. This assessment was made almost six years ago and more progress has been made since then."*[56]

Senator Bayh's perspective is no less true today — Bayh-Dole is one of the most far-reaching and successful legislative initiatives in contemporary history. Commercial development of federally supported R&D investments has gone from being a major concern about U.S. national competitiveness in the 1970s to being a fundamental element of the growth and sustainability of the nation's biopharmaceutical research ecosystem—which leads the world today. During the 1970s, firms headquartered in the four largest European countries accounted for over half (55%) of the new chemical entities brought to market, with the U.S. accounting for less than one-third; by contrast, by the 2000s, the positions had almost exactly reversed (57% for the U.S. to the European countries' 33%).[57] Whether measured in employment, risk capital, patents, or other metrics, the U.S. leads the world in life sciences innovation.[58] The innovations that have resulted have furthered medicine and extended patients' lives in cancer and many other costly and challenging disease areas.

Bayh-Dole has been so effective that in 2006, the U.S. House of Representatives unanimously passed a resolution (H. Con. Res. 319) recognizing the contributions of the Act to the U.S. economy and reaffirming its commitment to the Bayh-Dole approach to technology transfer:

"Resolved by the House of Representatives (the Senate concurring), That it is the sense of the Congress that—

> *(1) the Bayh-Dole Act (Public Law 96–517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States; and*
>
> *(2) it is appropriate that the Congress reaffirm its commitment to the policies and objectives of the Bayh-Dole Act by acknowledging its contributions and commemorating the silver anniversary of its enactment."*[59]

Without Bayh-Dole's clear, consistent, and predictable framework for retention of patent title by entities receiving government funding and the right to enforce and exclusively license these patent rights, private companies would not invest in the extensive, risky process of commercializing government-funded technologies into medicines and other therapies for use by patients. The federal government's "march-in" rights under Bayh-Dole were intended to ensure that private firms made adequate efforts to in fact develop the technologies they licensed. March-in was never intended to address concerns about drug pricing, which are more appropriately addressed by other initiatives and approaches (for instance, that eliminate barriers to opportunities for payers and innovators to jointly develop approaches that reward and incent therapy value). Expanding the use of march-in to address drug pricing would have a chilling effect on essential public-private sector collaborations, to the detriment of the U.S. economy and national competitiveness, and most importantly, to the detriment of patients who are counting on the collective efforts of the public and private sector to make progress against our most costly and challenging diseases.

APPENDIX

Summary of NIH responses to march-in petitions:

- In a patent dispute with The Johns Hopkins University and Baxter Healthcare Corporation, CellPro, Inc. petitioned NIH to exercise its march-in rights in connection with certain patents relating to stem cell separation methods owned by The Johns Hopkins University and licensed first to Becton-Dickinson and then to Baxter Healthcare Corporation (filed March 3, 1997; denied August 1, 1997). CellPro claimed Baxter had failed to take effective steps to achieve practical application of the subject inventions: *"Baxter has threatened to require CellPro to remove the Ceprate products from the market on the basis of patents issued to Johns Hopkins that are governed by the Bayh-Dole Act."*[60]

  NIH denied the petition, determining that Baxter "met the statutory and regulatory standard for practical application" as evidenced by its "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public", further finding that *"Hopkins and Baxter have taken, or are expected to take within a reasonable time, effective steps to achieve practical application of the applicable patents ...and that the available information fails to demonstrate an unmet health need that is not reasonably satisfied by Hopkins and Baxter."*[61] Anticipating the disincentives that would be created if NIH initiated march-in proceedings, many universities opposed the petition, and NIH noted that to approve it would *"have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies."*

- Two petitions by Essential Inventions, Inc. (filed January 29, 2004; denied July 29, 2004) and by Knowledge Ecology International (KEI), the American Medical Students Association, the U.S. Public Interest Research Group, and the Universities Allied for Essential Medicines (filed October 25, 2012; denied November 1, 2013) calling for march-in in connection with certain patents owned and used by Abbott Laboratories (and subsequently, AbbVie) in the manufacture of the AIDS "booster" drug ritonavir (Norvir®), on the basis of excessive pricing.

  The 2004 petition requested march-in to *"grant an open license to use six patents related to the manufacture of ritonavir. The grounds for the request are that the patent owner charges unreasonable prices for Norvir/ritonavir, harming the public,"*[62] highlighting a December 2003 price increase, and differential pricing between publicly funded and private sector health care plans *("As a consequence of the discriminatory price increase, US employers/insurers/consumers who buy ritonavir with private sector insurance will pay five to ten times more than employers/insurers/consumers in other high-income countries.").*

  In denying the 2004 petition, NIH found that *"No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied"* and with regard to pricing, *"because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such*

products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices."[63]

NIH found that the 2012 petition made similar claims as previously, namely that *"AbbVie failed to achieve practical application of Norvir because of its high, differential pricing structure between publicly funded and private sector health care plans."*[64] The 2012 petition further requested NIH to adopt *"two general policy rules regarding the commercialization of federally funded inventions"*[65] relating to allowable pricing disparities between the United States and other developed countries.

In denying the 2012 petition, NIH found that, *"We do not think that the AbbVie pricing policies and pricing disparities between the United States and other countries trigger any of the four Bayh-Dole march-in criteria,"* and more generally, *"NIH continues to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients."*[66]

- Petition by Essential Inventions, Inc. requesting march-in for patents on Pfizer's glaucoma therapy latanoprost (Xalatan®), on the basis of pricing differentials between the U.S. and Canada and Europe (filed January 29, 2004; denied September 17, 2004)

Petitioner stated, *"(t)o remedy Pfizer's unreasonable pricing of Xalatan, we request that you issue an "open license" for all latanoprost patents that are subject to federal rights,"*[67] and *"expressing concern that the price of Xalatan is higher in the United States than in Canada or Europe."*[68]

NIH denied the petition, determining that, *"Xalatan has been available for use by glaucoma patients since 1996 and is being actively marketed by Pfizer and prescribed by physicians as both a first-line and second-line treatment. Accordingly, this drug has reached practical application and met health or safety needs as required by the Bayh-Dole Act."*

As in its Norvir denial, NIH noted that, *"because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by the NIH, the NIH believes that the extraordinary remedy of march-in is not an appropriate means of controlling prices."*[69]

- Petition by three individuals for march-in to relevant agalsidase beta (Fabrazyme®) patents in order to address shortages relating to manufacturing-related difficulties being monitored under a Genzyme Consent Decree with the FDA (filed August 2, 2010; denied December 1, 2010)

Three individual patients with Fabry's disease petitioned HHS to grant *"an open license under the Bayh-Dole Act that would allow supply of agalsidase beta in the U.S. and abroad to treat Fabry patients. Specifically, this petition requests that NIH authorize*

responsible entities and individuals to use U.S. Patent No. 5,356,804 and U.S. Patent No. 5,580,757 in order to manufacture, import, export or sell agalsidase beta,"[70] with the relevant patents being owned by Mount Sinai School of Medicine and exclusively licensed to Genzyme.

NIH denied the petition, determining that a march-in proceeding was not warranted because *"any licensing plan that might result from such a proceeding would not, in our judgment, address the problem identified by the Requestors."*[71]

- Petition filed by Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) to march-in to relevant patents on enzalutamide (Xtandi®) on the basis of high and/or differential pricing between the U.S. and other markets (filed January 4, 2016; denied June 20, 2016)

  Petitioners request the Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and/or the Department of Defense (DoD) exercise a royalty-free right in the relevant patents awarded to the Regents of the University of California and licensed to Astellas Pharma, or to grant a request for marchin rights for the prostate cancer drug enzalutamide (Xtandi®), on the basis that the prices in the U.S. are higher than in other countries, despite U.S. taxpayer-funded grants from the NIH and DoD. More generally, petitioners request that the U.S. federal government *"adopt the policy that the federal government will use its royalty free rights, or grant licenses under federal march-in rights, when prices in the United States are excessive, and/or higher than they are in high income foreign countries, and to apply that policy in this case for patents on enzalutamide."*[72]

  NIH denied the petition determining that a march-in proceeding was not warranted because the product had reached "practical application" in that it was *"broadly available as a prescription drug."*[73]

[1] § 6(a) of Pub. L. 96-517, Dec. 12, 1980, 94 Stat. 3018. Also known as the University and Small Business Patent Procedures Act of 1980.

[2] Ezell, S. (2019). The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System. Information Technology and Innovation Foundation (ITIF). Available at: https://itif.org/sites/default/files/2019-bayh-dole-act.pdf.

[3] Pressman, L. et al. (2019). The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2017. Biotechnology Innovation Organization (BIO) and Association of University Technology Managers (AUTM). Available at: https://autm.net/AUTM/media/About-Tech-Transfer/Documents/Economic_Contribution_Report_BIO_AUTM_JUN2019_web.pdf.

[4] Merrill, S. A. and Mazza, A.M., eds. (2011). Managing University Intellectual Property in the Public Interest. National Academies of Science, Engineering, and Medicine. At p. 80. Available at: http://nap.edu/13001.

[5] One was the result of a private patent dispute, four claimed that manufacturer pricing was excessive and/or allowed excessive pricing differentials between the U.S. and other countries, and one was intended to address product shortages due to manufacturing difficulties.

[6] U.S. Government Accountability Office (GAO). (1998). Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities." Available at: http://www.gao.gov/archive/1998/rc98126.pdf

[7] GAO. (2009) Report to Congressional Committees entitled "Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions." GAO-09-742. Available at: http://www.gao.gov/assets/300/293020.pdf.

[8] Allen, J. (2010) The Enactment of Bayh-Dole, An Inside Perspective. Available at: http://www.ipwatchdog.com/2010/11/28/the-enactment-of-bayh-dole-an-inside-perspective/id=13442/

[9] House Committee Report 109-409, 109th Cong., 2d Sess (2006).

[10] Merrill, S. A. and Mazza, A.M., eds. (2011). Managing University Intellectual Property in the Public Interest. National Academies of Science, Engineering, and Medicine. At p. 61. Available at: http://nap.edu/13001.

[11] Merrill, S. A. and Mazza, A.M., eds. (2011). Managing University Intellectual Property in the Public Interest. National Academies of Science, Engineering, and Medicine. At p. 61. Available at: http://nap.edu/13001.

[12] House Committee on Science and Technology Report 97-379. (1981). Uniform Federal Research and Development Utilization Act of 1981.

[13] House Committee on Science and Technology Report 97-379. (1981). Uniform Federal Research and Development Utilization Act of 1981.

[14] Some (See Mowery, D. et al. (2001). The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980. Research Policy 30, 99. Also Mowery, D. et al. (2004). Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act. Stanford University Press.) have criticized this figure as being artificially low

and misleading, noting that it includes defense contracts, which would not be licensed (due to national security considerations). However, others have noted that removing DoD-related patents from this calculation reportedly does not undermine this finding: "(O)nce DOD-related patents are removed, the essential point remains — fewer than 10% of the roughly 12,000 unexpired government patents were licensed. This contrasts to a contemporary figure of about 30%." (See The Bayh-Dole Act at 25. Available at: https://ipmall.law.unh.edu/sites/default/files/BAYHDOLE/BayhDole25_WhitePaper.pdf. In addition, a 1987 GAO report, reviewing implementation of the law and an Executive Order extending coverage from small businesses to all grantees, reported that some waivers were granted (implying that not all DoD-related patents should be removed from the calculation) GAO, 1987 at p. 17.

[15] Statement of Senator Birch Bayh to the National Institutes of Health. May 25, 2004. Available at: https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf

[16] Report to Accompany H.R. 6933, 96th Cong., 2d Sess., H.Rept. 96-1307, Part 1, 3.

[17] 35 USC §§ 200–212.

[18] Schacht, W. (2012). The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service Report 7-5700. Available at: https://www.fas.org/sgp/crs/misc/RL32076.pdf. (Schacht (2012))

[19] 35 USC § 203(a).

[20] 35 USC § 203(a).

[21] Determination in the Case of Petition of CellPro, Inc. Washington, DC: NIH; 1997 August Available at: http://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf.

[22] National Institutes of Health Office of the Director Determination in the case of Norvir® Manufactured by AbbVie. Available at: https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

[23] National Institutes of Health, Determination in the case of Xtandi® Manufactured by Astellas. Available at: http://www.ott.nih.gov/sites/default/ffles/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf.

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