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**UNDERSTANDING THE BAYH-DOLE ACT  
AND MARCH-IN RIGHTS THROUGH  
A HISTORICAL LENS**

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The opinions expressed in this article are those of the authors and do not necessarily reflect the views of Covington & Burling LLP or its clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

# UNDERSTANDING THE BAYH-DOLE ACT AND MARCH-IN RIGHTS THROUGH A HISTORICAL LENS

## INTRODUCTION

The Bayh-Dole Act's ("Bayh-Dole" or the "Act") impact on U.S. innovation has been so meaningful as to lead some to opine that the Act is "[p]ossibly the most inspired piece of legislation to be enacted in America" since the 1950s.<sup>1</sup> Bayh-Dole fundamentally changed the nature of technology transfer in the United States by shifting the paradigm of ownership of Bayh-Dole inventions to the university or small business that did the actual inventing,<sup>2</sup> rather than providing for funding agencies to obtain ownership. This immensely effective change on technology transfer programs at research institutions has significantly increased the licensing of early stage research to commercial entities that have the knowledge and resources required to transform research into market-ready products that span across many sectors.

Bayh-Dole has been both praised and criticized. The expansion and success of the biopharmaceutical industry and increasing concerns over the cost of U.S. healthcare and drug spending has heightened these contrasting views. Innovators

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<sup>1</sup> *Innovation's golden goose*, THE ECONOMIST, Dec. 14, 2002.

<sup>2</sup> 35 U.S.C. § 201. Since enactment, Bayh-Dole has been extended to any party to a funding agreement regardless of size. See 37 C.F.R. § 401.1(b); Exec. Order 12591, 52 Fed. Reg. 13414 (Apr. 10, 1987); see also Exec. Order 12618, 52 Fed. Reg. 48661 (Dec. 22, 1987).

and economists argue that the Act works exactly as intended by encouraging private industry to partner with public or publicly funded institutions to ensure that inventions make it to the American marketplace, increasing both technological innovation and economic development. Some researchers and policy commenters argue that the insertion of commercial interests into academic research and development creates inevitable conflicts that threaten to insert bias into the research process. Other policy makers focused on the cost of healthcare and prescription medicines argue that the taxpayers who fund research grants to academic institutions should not have to pay for inventions resulting from such early investment, and state that the government should retain, and use, greater “march-in” rights in resulting inventions for the benefit of the public.

There are differing views among academics, scientists, and policy makers on the legislative purpose of the Bayh-Dole Act and the scope to which it applies. Lawmakers and drug-pricing activists concerned over the cost of prescription drugs have argued that Section 203 of the Bayh-Dole Act can be exercised when an invention subject to the Bayh-Dole Act needs to be practiced in connection with a product that is considered too expensive.<sup>3</sup> Section 203 provides the government the right to “march-in” on the inventor’s exclusive right to her invention and issue a non-

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<sup>3</sup> Christopher Rowland, [\*A rare deterrent to limitless drug price increases may die under Trump\*](#), WASH. POST. (Apr. 18, 2019).

exclusive, partially exclusive, or exclusive license in exceptional circumstances.<sup>4</sup>

However, the Act does not mention price in its bases for march-in, leaving those with knowledge of the legislative history to explain that the Act's requirement for benefits of the Bayh-Dole invention to be "available to the public on reasonable terms"<sup>5</sup> was never intended to cover the price of the invention.<sup>6</sup>

The purpose of this CONTEMPORARY LEGAL NOTE is to examine the Bayh-Dole Act and the "march-in rights" it grants to the government in limited situations. To do so, we will examine the goals and purposes of the Act as stated within the legislative history, and the language of the Act itself as it lays out the rights and obligations of stakeholders.

## **I. GOALS AND PURPOSE OF THE BAYH-DOLE ACT AND MARCH-IN RIGHTS: CREATING (AND PROTECTING) A PUBLIC INTEREST IN INNOVATION**

### **A. Legislative History Generally**

The Bayh-Dole Act was first introduced to the Senate as Senate Bill 414 (S. 414) by Senators Robert Dole and Birch Bayh in 1979. Following overwhelming approval by the Senate, the bill was introduced into the House of Representatives where it did

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<sup>4</sup> We note that although the Bayh-Dole Act allows a contractor to retain title to a subject invention, the contractor would need to pursue and obtain a patent to obtain an exclusive right to the subject invention. Failure to elect title or pursue patent protection within specified times can lead to the government obtaining title to the subject invention. *See* 35 U.S.C. § 202(c)(2).

<sup>5</sup> 35 U.S.C. §§ 201(f) and 203(a)(1).

<sup>6</sup> Birch Bayh, *Statement of Senator Birch Bayh to the National Institutes of Health* at 3 (May 15, 2004).

not pass. Eventually, much of the Act's language in S. 414 was added to H.R. 6933 as a late amendment to broader legislation. As such, H.R. 6933 contains significantly less discussion of the Bayh-Dole Act, with Senator Bayh stating, "The amendment that I am offering represents in essence the patent policy incorporated in S. 414, which was overwhelmingly passed by the Senate after being unanimously reported out of the Senate Judiciary Committee . . . The full legislative history of this provision is found in the Senate Judiciary Committee report on S. 414 (96-480) which fully spells out the intent of the Congress and specifies how this patent policy is to be implemented."<sup>7</sup>

The House report offers little insight into the reasoning underlying the amendment and subsequent passage of the Bayh-Dole Act. However, the broader House bill was passed to address "the failure of American industry to keep pace with the increased productivity of foreign competitors"<sup>8</sup> and identified an "economic malaise" that was attributed to declining research and development investment resulting from "bureaucratic roadblocks" as evidenced by 26 different government patent policies.<sup>9</sup> In a brief reference to the Bayh-Dole amendment, the House report stated that a uniform approach to intellectual property rights would facilitate the "effective commercialization of government financed research."<sup>10</sup>

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<sup>7</sup> 126 Cong. Rec. 30,364 (1980); H.R. Rep. No. 96-1307 (Part I) (1980). For this reason, the authors of this Contemporary Legal Note primarily rely upon the legislative history contained within Senate Judiciary Committee Report on S. 414 (96-480).

<sup>8</sup> H.R. Rep. No. 96-1307, at 2.

<sup>9</sup> *Id.* at 1–2.

<sup>10</sup> *Id.* at 2, 5.

The Senate Judiciary Committee report offers more insight into the balance of priorities the Bayh-Dole Act was drafted to address. By and large, the Senate report reflects the focus on the necessity of reforming government patent policies in order to promote utilization and commercialization of government-sponsored research.<sup>11</sup> More specifically, the Senate Judiciary Committee Report stated the Committee believed the Act would lead “to greater productivity in the United States, provide new jobs for our citizens, create economic growth, foster increased competition, make Government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs.”<sup>12</sup> The Senate recognized that a key issue in the “inability of the Federal agencies to deliver new inventions and processes from their research and development programs to the marketplace where they can benefit the public” was “ineffective patent policies regarding ownership of potentially important discoveries.”<sup>13</sup> As the Senate report noted, “The private sector simply needs more protection for the time and effort needed to develop and commercialize new products than is afforded by a nonexclusive license,”<sup>14</sup> the then default inventor interest.

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<sup>11</sup> See generally S. Rep. No. 96-480, at 1–3 (1979).

<sup>12</sup> *Id.* at 3.

<sup>13</sup> *Id.* at 2.

<sup>14</sup> *Id.*

The Senate report also identified a clear public interest in defaulting to inventor or contractor retention of title, noting that the Act

will increase the likelihood that useful inventions held in agency portfolios will be developed and commercialized rather than lying unused because of lack of necessary patent protection for interested developers. These unused patents now represent a partial waste of our vast research and development programs and their development will insure that the public is receiving the full benefits of this taxpayer-supported effort.<sup>15</sup>

Although the legislative history of the Act identifies the public interest as ensuring that taxpayer investment in basic research is not wasted on patented inventions that are never commercialized, it should be noted that one senator disagreed with this premise. Senator Russell Long was the only senator who spoke against the bill.<sup>16</sup> Senator Long fundamentally disagreed with the inventors or contractors receiving any rights at all in the invention, advocating for a system of public domain.<sup>17</sup> Of course, ultimately Senator Long's position did not carry the day and the Act passed the Senate with overwhelming bipartisan support, as reflected by

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<sup>15</sup> *Id.* at 30.

<sup>16</sup>126 Cong. Rec. 8746 (1980).

<sup>17</sup> *See generally* 126 Cong. Rec. 1995–2008 (1980). Specific examples abound, frequently with colorful language. *See, e.g., id.* at 1999 (“In my opinion [granting exclusive patent rights] is stealing. Stealing. [The invention] belongs to the Government. It belongs to the 200 million people that paid for it.”); *id.* at 2000 (describing the hearing testimony of Admiral H.G. Rickover and apparently endorsing the Admiral’s view that “this [bill] is a giveaway, it is a rape of the public interest, in so many ways.”); *id.* at 2002 (“[T]he idea of public taxation for private gain is contrary to every concept of democracy.”).

the 91-4 vote.<sup>18</sup>

## B. Legislative History of March-In Rights

As noted, current assertions that the Bayh-Dole Act may be used to address drug-pricing concerns relate to the Act’s “march-in” provisions. Specifically, Section 203(a) of the Act enumerates four bases for a funding agency’s right to march-in on the title holder’s exclusive right to grant a non-exclusive, partially exclusive, or exclusive license to a third party. One such basis is that such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.<sup>19</sup> This march-in provision is referred to as the practical application requirement. The Act defines practical application as “to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions *as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on*

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<sup>18</sup> Senator Long was joined in the defeated minority by Senators Byrd, Johnston, and Randolph. 126 Cong. Rec. 8746 (1980). Five senators were absent, though several were noted supporters, including Senator Nelson, who submitted extensive remarks in support of the bill and indicated he would have voted for it. *Id.* at 8741–43; *see also* 126 Cong. Rec. 1799 (1980) (submitted statement of Sen. Kennedy). Notably, Senators Kennedy and Nelson had been considered standout “licensing opponents” just a year earlier. *See* Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST (Apr. 8, 1979), *reprinted in The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 29, 31 (1979) [hereinafter *Senate Judiciary Bayh-Dole Hearings*] (opining that “[t]rouble [for the Bayh-Dole bill] still may come” from these senators and other consumer advocates).

<sup>19</sup> 35 U.S.C. § 203(a)(1).

*reasonable terms.*” (emphasis added).<sup>20</sup>

Congressional discussion of a funding agency’s right to “march-in” on the exclusive right of the title holder is limited. The House report contained almost no discussion of march-in rights at all, other than to note that that portion of the bill was “intended to continue existing practice[,] and [that] the Committee intend[ed] that agencies continue to use the march-in provisions in as a restrained and judicious manner as in the past.”<sup>21</sup>

The Senate Report ties the presence of march-in rights directly to the public policy goal of ensuring that taxpayer dollars are not wasted on inventions that will not be commercialized. The report observes:

It is essentially a waste of public money to have good inventions gathering dust on agencies’ shelves because of unattractiveness of non-exclusive licenses. The presence of ‘march-in-rights’ in the licensing program (where the agency could issue additional licenses to competitors if such licensing were required to meet a public need) should be a sufficient safeguard to protect public welfare requirements and prevent any undesirable economic concentration.<sup>22</sup>

Although reference to “public welfare requirements” and prevention of “undesirable economic concentration” may appear to some as a reference to pricing, a complete review of the Senate Judiciary Report shows that the primary concern was the use of government research for anti-competitive purposes. The Senate Report

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<sup>20</sup> 35 U.S.C. § 201(f).

<sup>21</sup> H.R. Rep. No. 96-1307 (Part I), at 15 (1980).

<sup>22</sup> S. Rep. No. 96-480, at 28.

similarly refers to “undue concentration” when detailing the conditions under which the government may license Bayh-Dole inventions it obtains title to, prohibits a federal agency from granting an exclusive license where “such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws.”<sup>23</sup> There is no other discussion of “concentration,” but there is further discussion of the importance of patent rights to small companies, the report noting a statement from Deputy Attorney General, Antitrust Divisions, Ky P. Ewing who stated, “It is often small competitors and potential entrants who benefit most from the patent grant...Patent rights for these firms provide a competitive edge that can counter the larger, existing competitor’s popular trade name, access to investment capital, or reliable marketing organization.”<sup>24</sup>

These statements and concerns regarding access to markets and fair competition are consistent with a statute whose purpose was to be an “important first step in turning around the undesirable productivity and innovation slumps that the United States is now experiencing.”<sup>25</sup> Under the Bayh-Dole Act, the public interest is served by creating strong intellectual property rights for innovators in order to

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<sup>23</sup> *Id.* at 11.

<sup>24</sup> *Id.* at 24.

<sup>25</sup> *Id.* at 29.

increase innovation and commercialization of federally-supported research across all agency research and development sectors. That is, Bayh-Dole applies equally to the Department of Defense, the Department of Energy, and the National Institutes of Health. And although Bayh-Dole was intended to improve the commercialization of all federally-supported technologies, the Committee, for example, noted the particular importance of removing barriers between early stage research on “new drugs and medical processes” and the marketplace.<sup>26</sup> As the Committee noted, the federal government was expected to be the “most important source of basic research money for the development of new drugs and medical processes which are essential to the well-being of the public.”<sup>27</sup> The Bayh-Dole Act was enacted to ensure that innovations, including “new drugs and medical processes,” that receive federal support in the early stages of research are made available to the marketplace.<sup>28</sup> It is within the context of ensuring that federally-supported inventions are “delivered to the marketplace as efficiently as possible”<sup>29</sup> that Bayh-Dole march-in rights and obligations, including the requirement for practical application, must be understood.

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<sup>26</sup> *Id.* (stating that if the “benefits of this research are being held up or denied because of artificial barriers...it can be detrimental to the public well-being.”).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* (stating that if the “benefits of this research are being held up or denied because of artificial barriers...it can be detrimental to the public well-being.”).

<sup>29</sup> *Id.* As late as 1976 the government had licensed less than 4 percent of the as many as 28,000 patents it owned. *Id.* Bayh-Dole was enacted to address this problem across all sectors. See *id.* at 3.

## II. OVERVIEW OF THE BAYH-DOLE RIGHTS AND OBLIGATIONS

Viewing the Bayh-Dole Act through the historical lens of trying to spur U.S. innovation and job creation provides additional understanding on Bayh-Dole rights and obligations, including understanding when the Bayh-Dole Act applies and the division of rights and obligations between the inventor or contractor and the government.

### A. When the Bayh-Dole Act Applies

The Act applies to “Subject Inventions,” which are inventions “conceived or first actually reduced to practice in the performance of work under a funding agreement.”<sup>30</sup> The temporal element of a funding agreement triggers attachment of Bayh-Dole rights and obligations—*i.e.*, the key is whether the invention was conceived or first actually reduced to practice under a government agreement. Working under a funding agreement before or after the invention was conceived or first actually reduced to practice has no effect on whether the Act applies. The rights and obligations under the Act apply not just upon conception, but also upon the first actual reduction to practice in the performance of work under a funding agreement. Notably, constructive reduction to practice through filing a patent application is insufficient to establish actual reduction to practice. But an invention that is conceived and constructively reduced to practice through filing a patent application

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<sup>30</sup> 35 U.S.C. § 201(e).

may still qualify as a subject invention if it is first actually reduced to practice during the performance of work under a funding agreement supported by a federal agency.

The definition of a Bayh-Dole subject invention as involving this overlap between performance under a funding agreement, conception, and first actual reduction to practice creates a narrow window of applicability that is consistent with the Act's goals. The Act facilitates the commercialization of inventions that the government would have otherwise patented itself. Although the Act only addresses background inventions in the context of limiting the government's ability to require licensing of background inventions,<sup>31</sup> the Senate Report stated that "[b]ecause of the concerns so often expressed by witnesses about Government treatment of background inventions of small business contractors, the Committee has broadened S. 414 to address this issue." The Act, therefore, was not intended to be expansively applied to any technology that interacted with federal support at any point in its development cycle, but only to those technologies that met the "subject invention" definition.

## **B. Contractor Rights and Obligations**

As seen in the Senate Report, Bayh-Dole was drafted to address and balance the interests of the federal government providing funding, the contractor who may be conducting the early research, and the licensees that may be doing the commercializing. As the Act shifted the default of invention ownership from the

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<sup>31</sup> 35 U.S.C. § 202(f).

funding agency to the contractor, the balance of obligations equally shifted to the contractor. These obligations must be completed in a timely fashion, in keeping with the Act's emphasis on removing administrative obstacles from bringing products to market. For example, under Section 202, a contractor must:

- **Disclose the Subject Invention:** A contractor must disclose a subject invention to the government within a “reasonable time” after it becomes known to contractor personnel responsible for the administration of patent matters. The Act does not define “reasonable time,” but the regulations implementing the Act generally provide that this disclosure should be made within two months of learning that a patentable invention has been made.<sup>32</sup> Further, a contractor must require its employees, in writing, to timely disclose any subject inventions to the contractor's patent administration function and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions.<sup>33</sup>
- **Elect to Retain Title:** After disclosure, a contractor must timely elect title to the subject invention, which typically must be done within two years of the initial disclosure.<sup>34</sup> However, if publication, sale, or public use of the invention has occurred, election must be made within 60 days after initial disclosure.<sup>35</sup>
- **File a Patent Application:** A contractor must file its initial U.S. patent application **within** one year of electing title and before the end of any statutory period during which patent protection may be obtained.<sup>36</sup> If the contractor files a provisional patent application as its initial application, the contractor must file a non-provisional application within ten months of filing its provisional application.<sup>37</sup> This regulation requires a contractor to decide whether to file a non-provisional application and to file such an application at least two months before the twelve-month pendency for a

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<sup>32</sup> 37 C.F.R. § 401.14(j)(1).

<sup>33</sup> See 37 C.F.R. § 401.14(f)(2).

<sup>34</sup> See *id.* at 401.14(c)(2).

<sup>35</sup> See *id.*

<sup>36</sup> See *id.* at 401.14(c)(3).

<sup>37</sup> See *id.*

provisional patent applications ends.

- **Provide Periodic Reporting:** The Act requires the contractor to periodically provide the funding agency with reports concerning the “the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify.”<sup>38</sup>
- **Include Government Rights Statement:** A contractor must include within the specification of a United States patent application disclosing a subject invention and any patent issuing thereon, a statement specifying that the invention was made with government support and that the government has certain rights in the invention.

### C. March-In Rights & Obligations

In addition to the contractor obligations discussed above, contractors (and their licensees) must sufficiently commercialize and/or disseminate the subject invention so as not to provide the funding agency with a statutory basis for marching-in on the contractor’s exclusive right to the subject invention. That is, contractors must:

1. achieve or take steps to achieve practical application of the subject invention;<sup>39</sup>
2. make the subject invention to meet health or safety needs of the public;<sup>40</sup>

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<sup>38</sup> 37 C.F.R. § 401.14(h); see 35 U.S.C. § 202(c).

<sup>39</sup> 35 U.S.C. § 203(a)(1). As previously discussed, the Act defines ‘practical application’ as “to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.” 35 U.S.C. § 201(f).

<sup>40</sup> 35 U.S.C. § 203(a)(2). Although not the primary focus of arguments for use of march-in to control drug prices, at least three petitions to NIH have argued that if a drug is not reasonably priced, it is not meeting the health and safety needs of the patient population.

3. make the subject invention to meet the requirements for public use specified by federal regulations;<sup>41</sup> and,
4. substantially manufacture the subject invention in the United States if the subject invention is exclusively licensed.<sup>42</sup>

Failure to meet any of these obligations provides the funding agency with the authority to intrude upon the exclusive right of the title holder. This authority to intrude is distinct from an unbounded compulsory license as it derives from the limited terms set forth in section 203 of the Patent Act. To our knowledge, march-in rights have never been exercised, and no court has ever provided an interpretation of the meaning of any of the statutory bases for march-in.

The guidance that exists came into being as a result of third-party petitions to the National Institutes of Health to march-in on patents implicated by the Bayh-Dole Act that are relevant to certain drug products. Somewhat ironically, the rise of these third-party petitions and accompanying arguments that Bayh-Dole limits the price a contractor or licensee may charge for the subject invention was spurred by the very result Bayh-Dole sought: medical innovation. The 1990s saw the rapid scientific advancement that created new therapeutic areas for drug treatments. This resulted in an unprecedented number of new drug approvals.<sup>43</sup> However, these advancements in

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<sup>41</sup> 35 U.S.C. § 203(a)(3).

<sup>42</sup> 35 U.S.C. §§ 203(a)(4), 204.

<sup>43</sup> Austin Frakt, [Something Happened to U.S. Drug Costs in the 1990s](#), N.Y. TIMES (Nov. 12, 2018).

therapies were accompanied by an increase in government drug spend.<sup>44</sup>

In 2001, Professors Peter S. Arno and Michael Davis published an article positing that Bayh-Dole’s march-in provision includes a strict price-control mechanism.<sup>45</sup> The article appears to largely assume that the “reasonable terms” referred to in the definition of “practical application” includes a “reasonable price” without any engagement with the statutory language and history of the Bayh-Dole Act, or any discussion of what “reasonable” may mean in the context of Bayh-Dole’s legislative history.

Professors Arno and Davis followed up publication of their academic article with an opinion piece in *The Washington Post*.<sup>46</sup> The piece prompted a near immediate rebuttal by Senators Bayh and Dole. Senators Bayh and Dole stated that “[a]s co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law...Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional...”<sup>47</sup> Senators Bayh and Dole also directly addressed the

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<sup>44</sup> *Id.*

<sup>45</sup> Peter S. Arno and Michael Davis, [Why Don’t We Enforce Existing Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research](#), 75 TULANE L. REV. 631, 647 (2001).

<sup>46</sup> Peter Arno and Michael Davis, [Paying Twice for the Same Drugs](#), WASH. POST (Mar. 27, 2002).

<sup>47</sup> Birch Bayh and Bob Dole, [Our Law Helps Patients Get Drugs Sooner](#), WASH. POST (Apr. 11, 2002).

Arno-Davis characterization of march-in rights, stating that, “[t]he article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.”<sup>48</sup>

Despite the authors of the bill directly rebutting the argument of practical application as price control, the argument resurfaced three years later in a third-party petition to NIH requesting the agency to march-in on Norvir<sup>®</sup> based on the price of the therapy.<sup>49</sup> Once again, Senator Birch Bayh characterized the use of march-in provisions to “attempt to control drug prices” as “flagrantly misrepresent[ing] the legislative history supporting Bayh-Dole”<sup>50</sup> and stated that such use of the march-in provisions in the Bayh-Dole statute would require Congress to amend the statute.<sup>51</sup> NIH declined to institute proceedings on the basis of price, and drug price control advocates have submitted three additional petitions, including a second on Norvir<sup>®</sup>,

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<sup>48</sup> *Id.*

<sup>49</sup> Dr. Elias Zerhouni, Nat’l Institutes of Health Office of the Director, [In the Case of Norvir](#) at 1 (July 29, 2004) (“*Norvir I*”).

<sup>50</sup> Birch Bayh, *Statement of Senator Birch Bayh to the National Institutes of Health* at 3 (May 15, 2004).

<sup>51</sup> *Id.* at 2 .

to march-in on the basis of price over the past decade.<sup>52</sup>

NIH has consistently interpreted the practical application requirement of the Act as not requiring Bayh-Dole inventions to be offered at a “reasonable price.” NIH has opined that practical application is evidenced by its “manufacture, practice, and operation” of the invention and the invention being available for purchase in the commercial marketplace<sup>53</sup> and that health and safety needs are met when a Bayh-Dole drug product is safe, effective, and widely prescribed by physicians for its approved indications.<sup>54</sup>

The scope of march-in rights remains a topic of interest. Recently, the U.S. Department of Commerce’s National Institute of Standards and Technology (NIST)<sup>55</sup>—the overseeing agency for Bayh-Dole regulations—announced that it was seeking comments on proposed changes to Bayh-Dole regulations including a proposal to add “a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial

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<sup>52</sup> Dr. Elias Zerhouni, Nat’l Institutes of Health Office of the Director, [In the Case of Xalatan \(“Xalatan”\)](#) (Sept. 17, 2004) (finding that the drug had reached practical application as it was widely available for and utilized by patients); Dr. Francis Collins, Nat’l Institutes of Health Office of the Director, [Determination in the Case of Norvir](#) (Nov. 1, 2013) (“*Norvir II*”); see Dr. Francis Collins, Nat’l Institutes of Health Office of the Director, [Determination in the Case of Xtandi](#) (June 20, 2016).

<sup>53</sup> *E.g.*, *Norvir I* at 5–6.

<sup>54</sup> See *supra* at n.40, *Norvir I* at 5; see also Dr. Harold Varmus, Nat’l Institutes of Health Office of the Director, [Determination in the Case of Petition of CellPro, Inc.](#) at 5 (Aug. 1, 1997) (“*CellPro*”).

<sup>55</sup> AUTM, Research Funding Grows: 2019 U.S. Survey — Key Findings, <https://autm.net/surveys-and-tools/surveys/licensing-survey/2019-licensing-survey> (last accessed May 26, 2021).

goods and services arising from the practical application of the invention.”<sup>56</sup> NIST received over 81,000 comments.<sup>57</sup> However, the Biden Administration issued an Executive Order directing the Secretary of Commerce, through the Director of NIST, to “consider not finalizing any provisions on march-in rights and product pricing in the proposed rule.”<sup>58</sup> The ultimate fate of the final rulemaking remains unknown.

### III. BAYH-DOLE AND A NEW ERA OF PHARMACEUTICAL INNOVATION

The balance of interests between public and private actors in drug development has never been more important. The global pandemic arising from COVID-19 has demonstrated both the importance of public-private collaboration and how successful such partnerships can be when artificial barriers are removed.<sup>59</sup>

And yet, to the extent any Bayh-Dole subject inventions might have been developed to treat or prevent COVID-19, the statutory history of the Act indicates that this is *exactly* the type of collaboration that should be celebrated as a success of the Act—harnessing the collective power of government support, innovative research, and the commercial resources needed to ensure rapid commercialization of essential

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<sup>56</sup> 86 Fed. Reg. 35, 37 (Jan. 4, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-04/pdf/2020-27581.pdf>.

<sup>57</sup> NIST, [Noticed of Proposed Rulemaking – Rights to Federally Funded Inventions and Licensing of Government Owned Inventions](#), RIN 0693-AB66.

<sup>58</sup> [Executive Order on Promoting Competition in the American Economy](#) (July 9, 2021).

<sup>59</sup> Moreover, this unprecedented time has underscored that not all inventions arising from public/private collaborations are implicated by the Bayh-Dole Act as agreements enacted under certain kinds of statutory authority utilized during the coronavirus pandemic are not subject to the Bayh-Dole rights and obligations. *See, e.g.*, 10 U.S.C. § 2371b (providing other transaction authority for the Department of Defense).

new products by the private sector to ensure that the public has access to needed therapies as soon as possible.

The Bayh-Dole Act was meant to balance incentives for funding agencies and private industry in order to kick-start U.S. innovation and ensure that innovative technologies that were supported by federal dollars were made commercially available—as evidenced by its legislative history and post-enactment statements by the drafters. Thus, U.S. innovation statistics demonstrate that the Bayh-Dole Act is an unqualified success. For those who don't accept that the public interest is served by the efficient transfer of intellectual property resulting from government-funded research to the private sector for further development without pricing restrictions, the debate over the scope of march-in rights continues. Any potential revision to U.S. technology transfer policy must be approached cautiously so as not to chill future U.S. innovation.