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Don't Tread on My IP Rights: A Law and Economics Analysis of "March-In Rights" Under the Bayh-Dole Act

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DON'T TREAD ON MY IP RIGHTS: A LAW AND ECONOMICS ANALYSIS OF "MARCH-IN RIGHTS" UNDER THE BAYH-DOLE ACT

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ABSTRACT

The Bayh-Dole Act has been imperative to the development of the United States' dynamic pharma-biotech sector. However, the use of march-in rights under the Bayh-Dole Act has remained controversial. On the one hand, there is the idea of market equilibrium with a need to secure health care for the public. Many believe march-in rights should be used to create this balance by regulating the pricing of drugs that were developed using federally funded research. On the other hand, some advocates recognize that the current relationship between public-sector institutions and business as the developers of basic research, and private-sector biotechnology companies as the producers has proven to be fruitful. Thousands of patents have been issued since the execution of the Bayh-Dole Act in 1980. These advocates fear that the expansion of march-in right usage would result in a chilling effect that destroys the progress made in pharma-biotech research and development.

This Article analyzes "march-in rights" under Section 203 of the Bayh-Dole Act by examining how individuals have attempted to use them and why in over 42 years of existence, march-in rights have never been invoked. It further addresses the current political climate surrounding the regulation of drug pricing and describes the potential consequences of improperly using march-in rights to lower drug prices.

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I. INTRODUCTION

Pharmaceutical companies have widely invoked International Property Rights ("IPRs") on new biotechnology and biomedical products since the 1980s. In the 1980s, numerous changes were made to the IPRs for biomedical products, such as the Supreme Court's ruling in *Diamond v. Chakrabarty*[1] that human-made bacterium is patent eligible subject matter under U.S. patent laws. Furthermore, in 1984 supplementary protection certificates were introduced under the Drug Price Competition and Patent Restoration Act (also known as the "Hatch-Waxman Act.")[2] These monumental changes to the U.S. patent market were beneficial to biomedical companies by granting them market exclusivity for a specific amount of time for their new patented product.

Although the Hatch-Waxman Act and other legislation incentivized the actual creation of new pharmaceutical products, other legislation has been passed to expand upon this industry as a whole by incentivizing research and development ("R&D") of these new products. There are two types of research areas that go into the development of pharmaceutical innovations: basic research and applied research. Basic research is mainly financed by public sector entities such as universities or the National Institute of Health ("NIH"). Basic research is curiosity driven, and involves the acquiring "knowledge for knowledge's sake," but does not have immediate commercial objectives.[3] Applied research takes knowledge gained during basic research and applies it to a specific commercial objective in the form of products, procedures or services.[4] Applied research is largely in the hands of private companies that attempt to invent and patent biomedical products. The period between the beginning of basic

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1 Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980).

2 98 Stat. 1585; codified in 35 U.S.C. § 271(e)(1).

3 C.R. KOTHARI, RESEARCH METHODOLOGY – METHODS AND TECHNIQUES 3 (2nd rev. ed, 2004).

4 *Id.*

research and a finalized pharmaceutical product can be a very long, drawn-out process. For more elaborate and "transformative drugs, there appears to be a twenty-year 'incubation' period (typically in academia) before formal projects begin in pharmaceutical companies."[5]

Although applied research is where the profit is made on patentable products, there is an immense need for basic research to begin this R&D process. Currently, some of the major players in basic research include the NIH, which has twenty-seven different institutes and centers,[6] and both public and private universities, which conduct nearly 50% of basic research nationwide and 13% of all R&D.[7] To incentivize this basic research, the government passed the University and Small Business Patent Procedures Act of 1980, commonly known as the "Bayh-Dole Act."[8] The Bayh-Dole Act:

> [P]ermit[s] contractors, such as universities, small businesses, and nonprofit research institutions, to secure intellectual property rights, often in the form of patents for molecular compounds or biotechnological processes, which in turn may be licensed to private-sector entities, including start-ups and existing biopharmaceutical companies, which then invest the hundreds of millions—often billions—of dollars required to bring safe and effective drugs to market.[9]

By incentivizing private sector development and commercialization of federally funded R&D, the passage of the Bayh-Dole Act led to a drastic increase in issued patents.[10] For example, "patenting in biotechnology has risen significantly, from 2,000 in 1985 to over 13,000 in 2000."[11] Furthermore, the Bayh-Dole Act has "bolstered U.S. economic output by $1.3 trillion, supported 4.2 million jobs, and helped lead to more than 11,000 start-up companies."[12]

While this incentive towards conducting basic research was successful enough for many supporters of the Bayh-Dole Act, others want to expand upon the use of march-in rights codified in 35 U.S.C. § 203 of the Bayh-Dole Act, to give the government

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5 Jonathan Spector, et al., *Fundamental Science Behind Today's Important Medicines*, 10 SCI. TRANSLATIONAL MED. 1, 2 (Apr. 15, 2018).

6 *See Institutes at NIH*, NIH, https://www.nih.gov/institutes-nih (last visited Apr. 15, 2022).

7 *See Academic R&D in the United States*, NAT'L SCI. BD. (Jan. 2020), https://ncses.nsf.gov/pubs/nsb20202/academic-r-d-in-the-united-states.

8 Pub. L. 96–517 (Dec. 12, 1980); codified in Bayh Dole Act, 35 U.S.C. §§200–212.

9 Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOVATION FOUND. 1, 4 (Mar. 4, 2019).

10 John R. Thomas, *March-In Rights Under the Bayh-Dole Act*, CONG. RSCH. SERV. 1, 1 (2016).

11 Justin B. Biddle, *Intellectual Property in the Biomedical Sciences*, ACADEMIA (2014), https://www.academia.edu/1908148.

12 BIOTECH. INNOVATION ORG., THE BAYH-DOLE ACT, https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO_Bayh_Dole.pdf.

more power over pharmaceutical products. Currently, march-in rights exist to prevent businesses from licensing patented products and technologies from publicly funded research and then shelving the product to prevent the products from being commercialized.[13] The government has attempted to mitigate the shelfing of products by requiring a patent owner in certain circumstances to grant "a nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants."[14] However, many advocates are calling for an expanded interpretation of march-in rights to include utilizing them to regulate drug pricing in the United States.[15]

This Article begins by addressing what these march-in rights are and what they mean for patented products. Next, it will analyze the current economic impact march-in right usage has on the pharmaceutical economy. Finally, it will analyze both the legal and economic implications of march-in rights if they are used to regulate drug pricing in the U.S. as many advocates are calling for. This Article asserts that march-in rights should not be used to regulate pharmaceutical drug pricing because it would destroy the careful balance that has been created between federally funded R&D and private commercialization of drugs through the Bayh-Dole Act.

II. MARCH-IN RIGHTS: WHAT ARE THEY AND WHY DO WE HAVE THEM?

Although the Bayh-Dole Act allows patents to be filed for products that result from publicly funded R&D, march-in rights were created within the Act to prevent these products from being "shelved," i.e., not being commercialized. March-in rights are codified in 35 U.S.C. § 203, which states:

> With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to 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 . . . .[16]

This provision could theoretically be used to assign the license of any "subject invention" to any third party, as long as the government does so in a way that is "reasonable under the circumstances." While it seems straightforward to exercise march-in rights, there are many restrictions in place to keep them from being invoked.

The Bayh-Dole Act lists four circumstances where march-in rights may be exercised.

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13 Michael Brodowski & Kuwabo Mubyana, *Changes To March-In Rights Under Bayh-Dole And More?*, GOODWIN (Mar. 21, 2021), https://www.jdsupra.com/legalnews/changes-to-march-in-rights-under-bayh-1121759/.

14 *See* Thomas, *supra* note 10, at 4.

15 *See* Brodowski & Mubyana, *supra* note 13.

16 35 U.S.C. § 203(a).

The first is when "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."[17]

The second circumstance is when "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[18]

The third situation where march-in rights would be "reasonable under the circumstances" is when "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees."[19]

The final circumstance is when "action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204."[20] Section 204 of the Bayh-Dole Act requires that products patented under the Act should be licensed to companies only if those companies will manufacture the product "substantially" within the United States, unless this is not commercially feasible in an individual case.[21]

While the four situations above do seem to be "reasonable" situations in which the government could intervene to prevent publicly funded research from going to waste, there are many other prerequisite events for the government to exercise march-in rights. Pursuant to Section 201 of the Bayh-Dole Act, the Secretary of Commerce has delegated to the director of the National Institute of Standards and Technology ("NIST") the authority to promulgate the implementation of regulations under the Act.[22] The NIST director has done this through a series of rules now codified in 37 Code of Federal Regulations ("CFR") § 401.6 as "exercise of march-in rights."[23] Some of these requirements include: a notice in writing to the contractor that the agency may exercise march-in rights and a specified time for response;[24] thirty days for the contractor to submit an argument opposing the march-in;[25] and that fact-finding, such

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17 *Id.* § 203(a)(1).

18 *Id.* § 203(a)(2).

19 *Id.* § 203(a)(3).

20 *Id.* § 203(a)(4).

21 *See id.* § 204; *see also* Thomas, *supra* note 10, at 7.

22 Kevin Noonan, *The NIST Proposes Clarifications to Bayh-Dole March-In Rights Regulations*, BIOPHARM INT. (Sep. 2, 2021), https://www.biopharminternational.com/view/the-nist-proposes-clarifications-to-bayh-dole-march-in-rights-regulations.

23 *See* 37 C.F.R. § 401.6 (2021).

24 *See id.* § 401.6(b).

25 *See id.* § 401.6(d).

as submitting documentary evidence and presenting witnesses, must be conducted before the head of the agency makes his determination.[26]

Additionally, in 2018, the NIST made revisions to the rules regulating march-in rights in an attempt to "clarify certain definitions, reduce compliance burdens, address co-inventions between funding recipients and federal agencies, and simplify the electronic reporting process."[27] One of these changes was an elimination of the previous sixty-day limit for the government to seek ownership of an invention.[28] Now, the government has an "unlimited time period within which to assert ownership to an invention following the discovery of the contractor's non-compliance with the Bayh-Dole Act's disclosure and election requirements."[29] Furthermore, the revisions specify that the "right to retain title, when invoked, applies to large business contractors as well as small businesses and nonprofit organizations."[30] These changes also clarified the protocol for a situation in which a federal employee is a co-inventor of the subject invention.[31] The amendments stated that the federal employee's agency can file the initial patent application in "consultation with the contractor," and that if the contractor "elects title in this situation, the agency employing the co-inventor retains all ownership rights to which they would otherwise be entitled."[32] As demonstrated below, exercising march-in rights remains extremely cumbersome despite the efforts by the NIST to streamline the process.

III. THE CURRENT ECONOMIC IMPACT OF MARCH-IN RIGHTS

The Bayh-Dole Act as a whole has stimulated innovation by incentivizing closer cooperation between the government, academia, and private sector investment. Such innovation has boosted the national economy. For example, one study found that between 1996 and 2017, academia-private sector patent licensing across all industries bolstered U.S. Gross Domestic Product by up to $865 billion (in 2012 U.S. dollars) and supported up to nearly 5.9 million employees.[33] In the life science industry specifically, federally funded basic research—which can now be patented under the Act—is seen as being complementary to applied research that generates a

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26 *See id.* § 401.6(e)–(g).

27 *2018 Bayh-Dole Update*, NIST (updated Aug. 12, 2021), https://www.nist.gov/tpo/bayh-dole/2018-bayh-dole-updates.

28 *Bayh-Dole Act: Regulations Impacting Ownership of Patent Rights*, UNIV. WIS. RSCH., https://research.wisc.edu/bayhdole/ (last visited Apr. 14, 2022).

29 *Id.*

30 Ronald D. Lee, et. al., *Amendments to Bayh-Dole Act Regulations Tweak Rights to Inventions Made Using Federal Assistance*, ARNOLD & PORTER (May 25, 2018), https://www.arnoldporter.com/en/perspectives/publications/2018/05/amendments-to-bayh-dole-act-regulations-tweak.

31 *See id.*

32 *Id.*

33 LORI PRESSMAN, ET AL., THE ECONOMIC CONTRIBUTION OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996-2017 1, 22 (2019).

commercialized product. Private sector companies spend millions of dollars on applied research and can license patented basic research to use in their commercialized product. In 2018, a national survey conducted by the Association of University Technology Managers ("AUTM") found that "67% of university licenses [were] granted to start-up companies and small businesses, i.e., the type of licensee envisioned by the Act."[34] A majority of these companies were in life sciences and were involved in "developing products and processes that diagnose disease, reduce pain and suffering, and save lives."[35]

Although the Bayh-Dole Act as a whole has stimulated economic growth, Section 203's march-in rights have yet to show any economic advantages or disadvantages since they have never been used in their entire forty-two years of existence. To date there have been eight different petitions filed with the NIH requesting the NIH to exercise march-in rights; all of these petitions have been denied.[36]

The first petition filed was in 1997, when CellPro, Inc. ("CellPro") wanted the government to march-in regarding a patented device owned by John Hopkins University and licensed first to Becton-Dickinson and next to Baxter Healthcare Corporation. CellPro asserted that these contractors did not take reasonable steps to commercialize the technology, and thus that the government should march in.[37] The NIH declined to do so, reasoning that "Hopkins and Baxter have taken effective steps to achieve practical application, as demonstrated by Hopkins' licensing, Baxter's manufacture, practice, and Isolex 300's operation, as well as the device's availability to and use by the public to the extent permitted at this time under applicable law."[38]

In 2004, two more attempts to invoke march-in rights were made. The first included petitioners, including some members of Congress, asking the NIH to march-in on the HIV/AIDS treatment drug Norvir (ritonavir).[39] The second petition included the assertion that the glaucoma treatment "Xalatan/latanoprost" was priced higher in

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34 COUNCIL GOV'T. REL'S., THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1, 9 (2021) (citing AUTM Licensing Survey, Fiscal Year 2018).

35 *Id.*

36 *See Timeline Regard Bayh-Dole March-In Right Requests*, KNOWLEDGE ECOLOGY INT'L, https://www.keionline.org/march-in-rights-timeline (last visited Apr. 14, 2022); *see also* Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, CTR. FOR STRATEGIC & INT'L STUD. (Mar. 24, 2022), https://www.csis.org/analysis/march-rights-and-us-global-competitiveness.

37 *See* DIRECTOR OF NAT'L INST. OF HEALTH, DETERMINATION IN THE CASE OF PETITION OF CELLPRO, INC. 1, 1 (Aug. 1, 1997).

38 *Id.* at 5.

39 *See* DIRECTOR OF NAT'L INST. OF HEALTH, IN THE CASE OF NORVIR MANUFACTURED BY ABBOTT LABORATORIES, INC. 1, 1 (July 29, 2004).

the United States than other nations.[40] Both petitions were denied because the drugs were sufficiently available to the public from the NIH's perspective.[41]

The fourth petition requesting the NIH to march-in was filed in 2010 by Dr. C. Allen Black, Jr. on behalf of his three clients who all had Fabry disease.[42] Dr. C. Allen sought an open license to the cell line producing the drug Fabrazyme (agalsidase Beta), which treats Fabry Disease, in order to expedite production.[43] Allen claimed the drug was in critically short supply due to the contractor Genzyme's manufacturing difficulties.[44] The NIH denied the petition, reasoning that the NIH was in fact concerned about the "urgent health needs of Fabry patients who are unable to obtain the recommended dosage of Fabrazyme" but stated the NIH received no information suggesting a third party is ready to supply the therapy.[45] Furthermore that Genzyme "expressed its commitment to provide a full supply of Fabrazyme in the first half of 2011."[46]

The fifth petition was filed in 2012 on behalf of Knowledge Ecology International, the American Medical Students Association, the U.S. Public Interest Research Group, and the Universities Allied for Essential Medicines asking the NIH to use march-in rights for Norvir (ritonavir), for the second time, with the same argument as in 2004—that prices in the United States for the drug were higher than other high-income nations.[47] The NIH denied the request again, stating that "the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities" and further stated that "pricing policies and pricing disparities between the United States and other countries [do not] trigger any of the four Bayh-Dole march-in criteria."[48]

The sixth petition was filed in 2016, with the petitioner asserting that the NIH should exercise march-in rights to "break the patents on Xtandi, a $129,000/ year federally-funded drug for metastatic prostate cancer that costs the United States 2-4x what other high income countries pay."[49] This request was also denied, with the NIH

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40 *See* DIRECTOR OF NAT'L INST. OF HEALTH, IN THE CASE OF XALATAN, MANUFACTURED BY PFIZER, INC. 1, 1 (Sept. 17, 2004).

41 *See id.*; *see also* Zerhouni, *supra* note 39 at 5.

42 *See* DIRECTOR OF NAT'L INST. OF HEALTH, DETERMINATION IN THE CASE OF FABRAZYME MANUFACTURED BY GENZYME CORPORATION 1, 1 (Dec. 1, 2010).

43 *Id.*

44 *Id.*

45 *Id.* at 9.

46 *Id*.

47 *See* DIRECTOR OF NAT'L INST. OF HEALTH, DETERMINATION IN THE CASE OF NORVIR MANUFACTURED BY ABBVIE 1, 1–2 (Nov. 1, 2013).

48 *Id.* at 6–7.

49 Claire Cassedy, *Bicameral Letter from 6 Senators and 6 Members of the House to NIH*, KNOWLEDGE ECOLOGY INT'L (Mar. 28, 2016), https://www.keionline.org/26480.

stating that no information presented suggested that the drug is, or would be, in short supply.[50] This decision was appealed and subsequently denied once more.[51]

As demonstrated by the outcome of these six petitions, the NIH has proven extremely hesitant to exercise march-in rights. This has led to frustration by many who believe that march-in rights are not being used despite certain products failing to be made "available to the public on reasonable terms." A current ongoing petition requests that these concerns be addressed. The petition was submitted to the U.S. Army in 2019 which again requested the use of march-in rights for Xtandi patents.[52] This petition, filed by Clare Melvin Love and David P Reed, PhD, stated that the price of the drug in the United States is "four times more than the median price in the seven high income countries identified by the U.S. Senate Armed Services Committee in 2017 to determine if the U.S price on a Department of Defense (DoD)-funded drug is reasonable."[53] It further stated that "the price in the U.S. is five times the reimbursed price in Japan, where Astellas is headquartered."[54] In April 2021, Robert Sachs petitioned the Department of Defense to be added to Ms. Love and Mr. Reed's petition.[55] Sachs further requested if the petition was turned down without notification to the public, that his letter be considered as a new march-in request.[56] He argues that the high price of Xtandi in the United States is inconsistent with the obligation to make Xtandi available to the public on reasonable terms.[57] Following Robert Sachs, Eric Sawyer, an HIV activist who is battling prostate cancer, joined the petition.[58] This petition was redirected by petitioners to HHS, and on December 23, 2021, was subsequently referred to the NIH for review.[59] While the outcome of this case is still pending, the petition represents one side of the debate over march-in rights usage.

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50 Letter from Francis C. Collins, Director, NIH, to Andrew S. Goldman, Knowledge Ecology Int'l., DEP'T OF HEALTH & HUM. SERV. at 1 (June 20, 2016), http://keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf.

51 *See* Timeline Regard Bayh-Dole March-In Right Requests, *supra* note 36, at 5–6.

52 Letter from Clare Melvin Love & Davis P. Reed, PhD., to Mark T. Esper, Secretary of the Army at 1 (Feb. 4, 2019), https://www.keionline.org/wp-content/uploads/enzalutamide-march-in-royalty-free-Clare-Love-David-Reed-Army-4Feb2019.pdf.

53 *Id.*

54 *Id.*

55 Letter from Robert Sachs, to Lloyd J. Austin III, Secretary of Defense at 1, 3 (Apr. 12, 2021), https://www.keionline.org/wp-content/uploads/Robert-Sachs-Letter-Xtandi-Petition-Request-12April2021.pdf.

56 *Id.* at 3.

57 *Id.* at 6.

58 *See* James Love, *Clare Love, Robert Sachs and Eric Sawyer respond to Astellas Feb 9 Statement on Xtandi Bayh Dole March In and Government Use Case*, KNOWLEDGE ECOLOGY INT'L. (Feb. 24, 2022), https://www.keionline.org/37446.

59 *See* Peter Arno, et. al., *Will the Biden Administration Use 'march-in' to Protect Prostate Cancer Patients from Excessive Drug Prices?,* STAT (Jan. 3, 2022),

On the other side of the debate stands the NIST and many advocates for life-science R&D such as universities, private sector companies, and research analysts. In fact, last year the NIST proposed changes to further restrict the use of march-in rights.[60] Some of these proposed changes include the following:

- Adding language stating that march-in rights "shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention."[61]

- Adding language to 37 C.F.R. § 401.14 stating that "[a]n invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention."[62] In addition, NIST proposes deleting the language stating that "[s]eparate accounting for the two funds used to support the project in this case is not a determining factor" when deciding whether an invention is a subject invention."[63]

- Modifying 37 C.F.R. § 404.11 so that "a person who may be damaged by a license must also demonstrate that they were damaged by the license specifically by losing the opportunity to promote the commercialization of the licensed invention."[64]

- Revising the regulations to make forfeiture of title discretionary by stating "[a] Federal agency, at its discretion, may waive the requirement for the contractor to convey title to any subject invention."[65]

These changes were included along with many others in the NIST's proposed rule, with the majority of the proposed changes further restricting the ability to exercise

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https://www.statnews.com/2022/01/03/march-in-rights-protect-prostate-cancer-patients-from-excessive-drug-prices/.

60 *See* Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 FED. REG. 35 (proposed Jan. 4, 2021) (to be codified at 37 C.F.R. pt. 401 and 404).

61 Ronald D. Lee & Claire O. Eaton, *Proposed Changes to March-In and Other Bayh-Dole Regulations for Federally Funded Inventions*, ARNOLD & PORTER (Jan. 13, 2021), https://www.arnoldporter.com/en/perspectives/advisories/2021/01/proposed-changes-to-march-in-regulations.

62 *See* Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, *supra* note 60, at 18.

63 KNOWLEDGE ECOLOGY INT'L, KEI OVERVIEW OF NIST PROPOSALS 1, 2 (Mar. 2021).

64 *Id.* at 3.

65 *See* Lee & Eaton, *supra* note 61, at 3.

march-in rights.[66] For example, the NIST's proposal to eliminate the use of march-in rights as a means to regulate drug pricing directly conflicts with the opposition's view demonstrated by the current petition regarding Xtandi, evidencing the tension between the two views of how march-in rights should be exercised.[67] The NIST requested comments to the proposal, and received over 80,000 of them. The number of differing comments which demonstrates the public division on this matter.[68]

Although march-in rights have yet to be exercised and do not produce economic growth on their own, they still generate economic persuasion within the life-science sector.[69] Companies fear losing their right to a patented invention through a government march-in.[70] As a result, licensees of patented biotech and biomedical products attempt to strictly comply with the Bayh-Dole Act's requirements. This is supported by the line of petitions that the NIH has reviewed.[71] None of the petitions filed to exercise march-in rights have come from a situation where a licensee intentionally shelved the patented product. Instead, most petitions involve the pricing of drugs, with the exception of the 2010 petition regarding Fabrazyme.[72] Even in that case, the NIH found the licensee was committed to and attempting to supply the drug.[73] This demonstrates that march-in rights are being exercised exactly as they were intended to be—that is, only being reserved for times where a flagrant disregard of commercializing the product is apparent.[74]

As discussed below, the use of march-in rights as a means of regulating drug prices would upset the current balance that the Bayh-Dole Act maintains between public and private research which could negatively impact the pharmaceutical market economy.

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66 *Id.* at 1.

67 *See* Letter from Clare Melvin Love & Davis P. Reed, PhD., to Mark T. Esper, Secretary of the Army, *supra* note 52, at 1.

68 *See* Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, *supra* note 60, at 24.

69 Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOVATION FOUND. (Mar. 4, 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/.

70 *Id.* at 48–49.

71 *See* Thomas, *supra* note 10, at 12–13.

72 *Id.* at 11–12.

73 *See* Collins, *supra* note 42, at 9.

74 Carolyn L. Treasure, Jerry Avorn, & Aaron S. Keseelheim, *Do March-In Rights Ensure Access to Medical Products Arising From Federally Funded Research? A Qualitative Study*, 93 Millbank Q. 761–87 (2015).

IV. THE LEGAL AND ECONOMIC IMPLICATIONS OF USING MARCH-IN RIGHTS TO REGULATE DRUG PRICING

As the United States and other nations wait to see what changes will be made to march-in rights in the coming years, we can only contemplate what would happen if the Bayh-Dole's march-in rights were used to regulate drug pricing within the life-science sector. The proposed changes to the NIST's regulation of march-in rights came exactly sixteen days prior to the change in presidential administration from Republican President Donald Trump to Democratic nominee Joe Biden.[75] The Trump administration had a "Lab-to-Market Cross Agency Priority," the purpose of which was to "improve the transition of federally funded innovations from the laboratory to the marketplace by reducing the administrative and regulatory burdens for technology transfer and increasing private sector investment in later stage research and development (R&D)."[76] Following these goals, the NIST proposed the change in rules regarding march-in rights.

However, with the change in administration also came a different perspective on the proper way to utilize these rights. On July 12, 2021, President Biden issued an executive order entitled "Promoting Competition in the American Economy," which included the statement:

> (r) The Secretary of Commerce shall: (ii) acting through the Director of NIST, consistent with the policies set forth in section 1 of this order, consider not finalizing any provisions on march-in rights and product pricing in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," 86 Fed. Reg. 35 (Jan. 4, 2021). . . .[77]

This statement, along with others within the President's executive order, was aimed at promoting competition within the United States economy by "asking agencies to crack down on anti-competitive practices in sectors from agriculture to drugs and labor."[78] Under this executive order, the President also created a new agency called the White House Competition Council.[79] The new director of the agency, Brian Deese, ended its inaugural meeting on September 10, 2021 by "outlining how the Competition Council will work together over the coming months and years to restore competition to the

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75 *See* Timeline Regard Bayh-Dole March-In Right Request, *supra* note 36, at 5–6.

76 Daniel Kelly, *NIST On Track To Clarify Bayh-Dole To Ensure High Prices Cannot Be Used As Grounds For Exercising March-in Rights–Or Is It?*, JDSUPRA (June 1, 2021), https://www.jdsupra.com/legalnews/nist-on-track-to-clarify-bayh-dole-to-5516023/.

77 Exec. Order No. 14036, 86 FED. REG. 36987 at 12 (July 14, 2021).

78 David Shepardson, *White House to Hold Second Competition Council Meet On Monday*, REUTERS (Jan. 24, 2022), https://www.reuters.com/world/us/white-house-hold-second-competition-council-meet-monday-federal-officials-2022-01-24/.

79 Statements & Releases, *Readout of the Inaugural Meeting of the White House Competition Council*, THE WHITE HOUSE (Sept. 10, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/10/readout-of-the-inaugural-meeting-of-the-white-house-competition-council/.

heart of American capitalism and deliver concrete benefits to American families."[80] Some commentators are pushing the Biden administration to use the march-in provision to fix the high-pricing of certain federally-funded medicines and believe that this is consistent with the Biden administration's aim of promoting competition.[81] In January of 2022, the White House Competition Council met for the second time.[82] However, the discussion of march-in rights was not continued and there was no mention of using them to regulate drug pricing.[83]

With the change in political administration, there may also be a change in how government organizations such as the NIH respond to petitions to exercise march-in rights. For example, the NIH under this current administration could utilize march-in rights for the first time regarding COVID-19 vaccines. In particular, there has been a large debate surrounding the Moderna COVID-19 vaccine, with the NIH and Moderna battling over whether NIH scientists should be added to the Moderna vaccine's recently filed patent.[84] NIH director Francis Collins, who has denied past requests to utilize march-in rights, is now calling for NIH scientists to be added to the Moderna vaccine patent stating, "Moderna has made a serious mistake here in not providing the kind of co-inventorship credit to the people who played a major role in the development of the vaccine that they're now making a fair amount of money off of."[85] Moderna, however, argues that the messenger ribonucleic acid ("mRNA") sequence it uses in its COVID vaccine to enhance protein synthesis was "selected exclusively by Moderna scientists using Moderna's technology . . . ."[86] If the NIH scientists are not included in the patent, this could lead to the NIH utilizing march-in rights to control who the vaccine is licensed to and for what price.

Although there has been a shift in political agenda within the United States regarding the regulation of drug pricing, as discussed below, using march-in rights to do so would harm the United States economy and is not supported by the law.

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80 *Id.* at 2.

81 Joseph Allen, *President Biden: Don't Misuse Bayh-Dole March-In Rights*, STAT (Sept. 17, 2021), https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/.

82 Statements and Releases, *Readout of the Second Meeting of the White House Competition Council*, THE WHITE HOUSE (Jan. 24, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/24/readout-of-the-second-meeting-of-the-white-house-competition-council/.

83 *Id.*

84 *See* Caitlin Grow, *United States v. Moderna: Explaining the Side Effects of the Patent Battle over the Moderna COVID-19 Vaccine*, SYR. L. REV. (Mar. 3, 2022), https://lawreview.syr.edu/united-states-v-moderna-explaining-the-side-effects-of-the-patent-battle-over-the-moderna-covid-19-vaccine/.

85 *Id.*

86 *See id.* at 2.

A. The Economic Implications of Using March-In Rights to Regulate Drug Pricing

Past precedent demonstrates that utilizing march-in rights to regulate drug pricing could endanger the economy.[87] The regulation of drug pricing has been attempted before and failed. In 1989, the NIH imposed a "reasonable pricing clause for its patent licenses and its cooperative research and development agreements (CRADAs)—R&D pacts between the public sector and a private company—based on progressives' theory of misusing march-in rights."[88] This reasonable pricing clause was repealed in 1995 with the NIH director at the time, Harold Varmus, stating "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [government] scientists without providing an offsetting benefit to the public."[89] A similar result could occur now if the government attempts to use march-in rights to regulate drug pricing. According to the Congressional Research Service, basic research only constitutes "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."[90] While basic research is essential to the R&D process, it only makes up one portion of the knowledge capital associated with commercializing a product. The "other components of the knowledge capital needed to produce and distribute the new drug are generally privately financed."[91] For example, the "legal and marketing divisions of large pharmaceutical companies" contribute their knowledge and expertise in production and distribution of pharmaceutical products to the public.[92] If march-in rights were utilized to take over and control the drug pricing and who these initial products are licensed to, it would cause a chilling effect whereby large pharmaceutical companies would bypass licensing these initial inventions and would instead complete their own basic research.

Using march-in rights as a means of regulating drug prices could also negate progress made by the passage of the Bayh-Dole Act. Before the Bayh-Dole Act passed, the government retained the right to patent inventions discovered by federally funded research, which contributed to the low percentage of private companies licensing these patents.[93] As an example, prior to the Bayh-Dole Act, the government had only licensed less than 5% of its 28,000 patents that focused on "develop[ing]

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87 *See* Allen, *supra* note 81.

88 *Id.*

89 *Id.*

90 PHRMA, THE ROLE OF THE BAYH-DOLE ACT IN FOSTERING TECHNOLOGY TRANSFER AND IMPLICATIONS FOR INNOVATION 13 (PhRMA 2020).

91 Michele Boldrin & David Levine, *Reforming Patent Law: The Case of COVID-19*, 41 CATO J. 773, 779 (2021).

92 *Id.* at 778.

93 Lou Berneman, *There Are Unintended Costs of Federal Efforts to Control Drug Prices*, PENN LIVE (Mar. 26, 2022), https://www.pennlive.com/opinion/2022/03/there-are-unintended-costs-of-federal-efforts-to-control-drug-prices-opinion.html.

embryonic academic discoveries."[94] However, since the passage of the Bayh-Dole Act, according to a twenty-seven year-long study published by *Science*, about 10% of NIH grants generate a patent directly and 30% generate articles that are cited by patents.[95] Universities have used the Bayh-Dole Act to profit from the licensing of new inventions and have reinvested these profits into their organizations through the creation of new labs and retention of highly experienced professors and researchers that help to teach the future generations of science and technology. This progress made in university-funded research stimulates economic growth within R&D and utilizing march-in rights as a means of regulating drug prices would inhibit this economic growth.

B. The Legal Implications of Utilizing March-In Rights to Regulate Drug Pricing

The U.S. Constitution does not explicitly guarantee a right to health care, and furthermore, the Supreme Court has never found an implied right to health care.[96] This also implies that there is no constitutional right to medicines or products that help to maintain one's health. A court would consider this if it were to review the constitutionality of any changes made to march-in right usage in the future. Typically, rules and regulations issued by administrative agencies are subject to judicial review.[97] The standard of review for agency action taken under the Administrative Procedure Act ("APA") is whether the agency's actions decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[98] This standard of review is extremely deferential towards administrative agencies and a reviewing court may not "substitute its own judgment for that of the [agency]."[99] However, the NIST is "a non-regulatory agency and its procedures are often unlike the notice-and-comment procedures of regulatory agencies dictated by the Administrative Procedure[] Act (APA)."[100] This leaves open the question of whether judicial review would occur if the NIST were to change its promulgated rules regarding march-in rights.

If the NIST did promulgate the proposed rules from the Rights to Federally Funded Innovations and Licensing of Government Owned Inventions, a court could potentially determine whether restricting the use of march-in rights even further is

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94 *Id.*

95 Danielle Li, et al., *The Applied Value of Public Investments in Biomedical Research*, 356 SCIENCE 76, 78 (2017).

96 *See* KATHLEEN S. SWENDIMAN, CONG RSCH. SERV., R40846, HEALTH CARE: CONSTITUTIONAL RIGHTS AND LEGISLATIVE POWERS 2 (2012).

97 *See* JONATHON M. GAFFNEY, CONG, RSCH, SERV., LSB10558, JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT 1 (2020).

98 5 U.S.C. § 706(2)(A).

99 *See* U.S. Postal Serv. v. Gregory, 534 U.S. 1, 6–7 (2001).

100 Megan L. Brown & Kathleen E. Scott, *NIST Plays Increasingly Prominent Role in Privacy Policy*, WILEY (Mar. 12, 2015), https://www.wiley.law/alert-3496.

arbitrary and capricious. It is likely that a court would not find this to be the case, since the government's interpretation of what march-in rights should be used for has historically rejected their use for the regulation of drug pricing. But if the NIST were to change its rules to allow march-in rights to be used for this reason, a reviewing court may find this to be an abuse of discretion as there is no constitutional right to health for those who cannot afford health care services or medicines. In both instances, it is more likely that a judiciary would leave the question of how march-in rights should be exercised up to the legislature since "[s]triking a balance between these competing views regarding the commercialization of federally funded research remains a matter of congressional judgment."[101] This has led to somewhat of a bypass as to how march-in rights should be used because some members of Congress support the use of march-in rights as a means of regulating drug pricing, while others believe that it would defeat the purpose of the Bayh-Dole Act.

Uncertainty also surrounds the issue of whether or not the use of march-in rights to regulate drug pricing is a legal issue that a court could rule upon. To date, U.S. courts have not reviewed the NIH or any other government agency's decision allowing the government to "march in" because these organizations have yet to exercise them. However, the U.S. Court of Federal Claims ("USCFC") does have jurisdiction to review any federal agency's granting of march-in rights. According to the language of the march-in provision of the U.S. Code:

> [A]ny contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency.[102]

If a federal agency such as the NIH were to allow march-in rights to be utilized to control drug pricing, the USCFC still may reverse this decision under the authority of the current march-in rights provisions. Most arguments that have been made to support the use of march-in rights for lowering the cost of a drug's price have fallen under Section 203(a)(3). This section states that "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[103] The burden of proof falls onto the petitioner to demonstrate that the manufacturer of the drug has not met the health or safety needs as required under the Bayh-Dole Act. This task has proven difficult since the NIH, as the only agency to have issued decisions regarding march-in rights, has consistently found that the marketing and production of a drug is sufficient to meet the "health or safety needs" of the public and that the drug's price has not caused a drug manufacturer to fail to meet this requirement.[104] As a reviewing court, the USCFC similarly may find that a

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101 Thomas, *supra* note 10, at 13.

102 35 U.S.C. § 203(b).

103 35 U.S.C. § 203(a)(3).

104 *See e.g.*, Zerhouni, *supra* note 39, at 5; *see also The Role of Federally Funded University Research in the Patent System*: Hearing Before the S. Comm. on the Judiciary, 110 Cong. 167

drug's price cannot support a finding that a drug manufacturer failed to meet the Bayh-Dole Act's health and safety needs requirement because there is no constitutional right to health care.[105] Thus, the use of march-in rights to regulate drug pricing likely has no support under the language of the statute. Furthermore, if the court were to look to the legislative intent of the statute because Congress has not enacted any legislation that supports the use of march-in rights as a means of regulating drug pricing, the court likely would not find that the legislature intended to use march-in rights as a way of regulating drug pricing. As a result, it is unlikely that the USCFC would uphold an agency's decision to exercise march-in rights in this way.

V. CONCLUSION

The debate over how march-in rights should be used is ongoing. Although they have never been invoked, march-in rights still have persuasion over how the public-private R&D relationship works in the pharma-biotech sector. While many are pushing for march-in rights to be exercised to control drug pricing, this has the potential to cause a chilling effect and undermine the progress the Bayh-Dole Act has made in this industry. With this in mind, both the NIST and Congress must consider the legal and economic implications revisions to march-in rights will have on the nation and find an alternative way to reach the goal of lowering drug prices other than undermining the Bayh-Dole Act's years of progress.

(2008) (stating "Pfizer has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of latanoprost and the drug's availability and use by the public").

105 *See* SWENDIMAN *supra* note 96.