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March-In Rights Under the Bayh-Dole Act

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September 23, 2016

Congressional Research Service
7-5700
www.crs.gov
R44640

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

Congress approved the Bayh-Dole Act, P.L. 96-517, in order to address concerns about the commercialization of technology developed with public funds. This 1980 legislation awards title to inventions made with federal government support if the contractor consists of a small business, a university, or other non-profit institution. A subsequent presidential memorandum extended this policy to all federal government contractors. As a result, the contractor may obtain a patent on its invention, providing it an exclusive right in the invention during the patent's term. The Bayh-Dole Act endeavors to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D).

The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights," codified at 35 U.S.C. §203. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

No federal agency has ever exercised its power to march in and license patent rights to others. In particular, the National Institutes of Health (NIH) has received six march-in petitions and has denied each one. A 2016 exchange of correspondence between Members of Congress and the Department of Health and Human Services suggests a difference of views related to agency authority under the march-in provision. Supporters of the use of march-in rights assert that they provide an unused mechanism for combatting high drug prices and ensuring that U.S. citizens enjoy the benefits of public R&D funding. Others assert that march-in rights do not provide such a broad authority, but rather are limited to four circumstances identified in the statute. They are also concerned that use of march-in rights might discourage private investment in the often considerable effort needed to bring early-stage technologies to the marketplace.

Congress possesses a number of options with respect to march-in rights. If the current situation is deemed acceptable, then no action need be taken. Congress could also consider amending the Bayh-Dole Act by specifying in greater detail the precise circumstances in which march-in rights should be exercised. Congress may also take such steps as transferring authority over the administration of march-in rights, requiring government contractors to submit periodic reports regarding the commercialization of inventions achieved through public funding, creating a centralized database of inventions subject to the Bayh-Dole Act, and taking steps to ensure that patents on inventions developed through government funding are licensed to the most capable enterprise.

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Introduction

Congressional interest in facilitating U.S. technological innovation led to the passage of P.L. 96-517, Amendments to the Patent and Trademark Act.[1] This legislation is commonly referred to as the "Bayh-Dole Act,"[2] after its two primary sponsors, former Senators Robert Dole and Birch Bayh. This 1980 legislation awards title to inventions that government contractors make with federal government support, if the contractor consists of a small business, a university, or other non-profit institution. A subsequent presidential memorandum extended this policy to all federal government contractors.[3] As a result, the contractor may obtain a patent on its invention, providing it with an exclusive right in the invention during the patent's term. The legislation is intended to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D).

The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit.[4] The Bayh-Dole Act also provides federal agencies with "march-in rights."[5] March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

Members of Congress have recently taken note of the fact that march-in rights have never been exercised during the 35-year history of the Bayh-Dole Act.[6] In particular, the National Institutes of Health (NIH) has received six march-in petitions and has denied each one. A 2016 exchange of correspondence between some Members of Congress and the Department of Health and Human Services has suggested a potential difference of views about the appropriate use of march-in rights.[7] Some observers believe that march-in rights should be rarely, if ever invoked due to the significant investment the private sector investment may make to bring early-stage inventions into practical application. These commentators further assert that the use of march-in rights would discourage private enterprise from investing in the commercial development of any invention funded in part by the government.[8] On the other hand, others believe that U.S. taxpayers should be protected from what they view as excessive profiteering on technologies developed with

[1] 94 Stat. 3015 (1980). For further information about this legislation, see CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht.

[2] See, e.g., Fred Reinharta and Stephen J. Susalkaa, "Inspired Bayh-Dole Act Turns 35," *les Nouvelles*, vol. 51 (March 2016), p. 17.

[3] See Memorandum on Government Patent Policy from President Ronald Reagan, to Heads of Executive Departments and Agencies, February 18, 1983, http://www.presidency.ucsb.edu/ws/index.php?pid=40945&st=&st1=.

[4] 35 U.S.C. §202(c)(4).

[5] 35 U.S.C. §203.

[6] See, e.g., William O'Brien, "March-In Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?," *Seton Hall Law Review*, vol. 43 (2013), p. 1403.

[7] See Michael Mezher, "Lawmakers Urge HHS to Exercise 'March-In' Rights to Fight Higher Drug Costs," *States News Service*, January 11, 2016.

[8] Letter from Patricia Harsche Weeks, Immediate Past President, Association of University Technology Managers, to Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH; http://www.autm.net/advocacy-topics/government-issues/advocacy-archives/march-in-rights/autm-response-to-march-in-provisions/.

public funding. They consider march-in rights to constitute a long-available, but entirely unused mechanism for combatting the high and growing cost of health care.[9]

This report reviews the availability of march-in rights under the Bayh-Dole Act. It begins by providing a brief overview of the patent system and innovation policy. The report then introduces the Bayh-Dole Act. The specific details of the march-in authority provided to federal agencies are reviewed next. The report then considers past efforts to obtain march-in authorization from NIH. The report closes with an identification of potential issues for congressional consideration.

The Patent System: An Overview

The Mechanics of the Patent System

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution, which states that "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.... " As mandated by the Patent Act of 1952,[10] U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[11] USPTO officials known as examiners then assess whether the application merits the award of a patent.[12] The patent acquisition process is commonly known as "prosecution."

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[13] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[14] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other state-of-the-art knowledge that is collectively termed the "prior art."[15] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[16]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[17] Those who engage in these acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[18] The patent statute also provides for the award of damages

[9] Amy R. Schfield,"The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions," *Journal of Law, Medicine & Ethics*, vol. 32 (2004), p. 780.

[10] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[11] 35 U.S.C. §111.

[12] 35 U.S.C. §131.

[13] 35 U.S.C. §112.

[14] 35 U.S.C. §101.

[15] 35 U.S.C. §102.

[16] 35 U.S.C. §103.

[17] 35 U.S.C. §271(a).

[18] 35 U.S.C. §283.

"adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[19]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[20] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights are not self-enforcing. Patentees who wish to compel others to observe their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[21] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) possesses national jurisdiction over most patent appeals from the district courts.[22] The U.S. Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[23]

Patents and Innovation Policy

The patent system is intended to promote innovation, which in turn leads to industry advancement and economic growth. The patent system in particular attempts to address "public goods problems" that may discourage individuals from innovating. Innovation commonly results in information that may be deemed a "public good," in that it is both non-rivalrous and non-excludable. Stated differently, consumption of a public good by one individual does not limit the amount of the good available for use by others; and no one can be prevented from using that good.[24]

The lack of excludability in particular is believed to result in an environment where too little innovation would occur. Absent a patent system, "free riders" could easily duplicate and exploit the inventions of others. Further, because they incurred no cost to develop and perfect the technology involved, copyists could undersell the original inventor. Aware that they would be unable to capitalize upon their inventions, individuals might be discouraged from innovating in the first instance. The patent system corrects this market failure problem by providing innovators with an exclusive interest in their inventions, thereby allowing them to capture their marketplace value.[25]

The patent system potentially serves other goals as well. The patent law may promote the disclosure of new products and processes, as each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.[26] In this manner the patent

[19] 35 U.S.C. §284.

[20] 35 U.S.C. §154(a)(2). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[21] 35 U.S.C. §282.

[22] 28 U.S.C. §1295(a)(1).

[23] 28 U.S.C. §1254(1).

[24] See Deepa Varadarajan, "Of Fences and Definite Patent Boundaries," *Vanderbilt Journal of Entertainment and Technology Law*, vol. 18 (Spring 2016), p. 563.

[25] See Gregory N. Mandel, "Innovation Rewards: Solving the Twin Market Failures of Public Goods," *Vanderbilt Journal of Entertainment and Technology Law*, vol. 18 (Winter 2016), p. 303.

[26] 35 U.S.C. §112.

system ultimately contributes to the growth of information in the public domain. Issued patents may encourage others to "invent around" the patentee's proprietary interest. A patent proprietor may point the way to new products, markets, economies of production, and even entire industries. Others can build upon the disclosure of a patent instrument to produce their own technologies that fall outside the exclusive rights associated with the patent.[27]

The patent system also has been identified as a facilitator of markets. If inventors lack patent rights, they may have scant tangible assets to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been disclosed to a prospective licensee might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make transactions concerning information goods more feasible.[28]

Patent protection may also encourage enterprises to commercialize and market existing inventions. Even though a new technology has already been patented, a firm might have to make refinements, construct manufacturing facilities, establish distribution channels, comply with government safety and regulatory requirements, and educate consumers prior to marketing. Second entrants to the market may not have to bear all of the first mover's costs. As a result, the exclusive rights provided by a patent may encourage not just the invention of new technologies, but also their commercialization.[29]

Through these mechanisms, the patent system may act in a more socially desirable way than its chief legal alternative, trade secret protection.[30] Trade secrecy guards against the improper appropriation of valuable, commercially useful, and secret information.[31] In contrast to patenting, trade secret protection does not result in the disclosure of publicly available information. That is because an enterprise must take reasonable measures to keep secret the information for which trade secret protection is sought. Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.

The patent system has long been subject to criticism, however. Some observers have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of innovation. The desire to obtain a lead time advantage over competitors may itself provide sufficient inducement to invent without the need for further incentives. Other commentators believe that the patent system encourages industry concentration and presents a barrier to entry in some markets. Additionally, while the patent incentive encourages the development of new medicines, some assert that it also contributes to the growing costs of healthcare.[32]

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[27] See Herbert Hovenkamp, "Antitrust and the Patent System: A Reexamination," *Ohio State Law Journal*, vol. 76 (2015), p. 467.

[28] Jonathan N. Barnett, "Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation," *San Diego Law Review*, vol. 36 (2000), p. 1029-1030.

[29] Emily Michiko Morris, "The Many Faces of Bayh-Dole," *Duquesne Law Review*, vol. 54, p. 81.

[30] For further information on trade secrets, see CRS Report R43714, *Protection of Trade Secrets: Overview of Current Law and Legislation*, by Brian T. Yeh.

[31] See generally Michael R. McGurk and Jia W. Lu, "The Intersection of Patents and Trade Secrets," *Hastings Science & Technology Law Journal*, vol. 7 (Summer 2015), p. 189.

[32] See, e.g., Dan L. Burk and Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* (2009); James Bessen and Michael Meuer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (2008); (continued...)

Each of these arguments for and against the patent system has some measure of intuitive appeal. However, they remain difficult to analyze on an empirical level. We lack rigorous analytical methods for studying the impact of the patent system upon the economy as a whole. As a result, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation at the lowest social costs.

The Bayh-Dole Act

Even prior to the Bayh-Dole Act, the federal government considered the intellectual property implications of R&D projects financed by public funds.[33] In 1963, the Kennedy Administration called for greater consistency in diverse agency practices regarding the disposition of rights to inventions made by government contractors. This early "Government Patent Policy" generally allowed the U.S. government to retain rights to inventions developed through government contracts.[34] However, the contractor could obtain title in specified circumstances. For example:

> [W]here the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the government, and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental commercial position, the contractor shall normally acquire the principal or exclusive rights throughout the world in and to any resulting inventions, subject to the government acquiring at least an irrevocable non-exclusive royalty free license throughout the world for governmental purposes.[35]

In those situations, the 1963 policy retained significant government rights in privately held patents that resulted from publicly funded projects. In a prelude to today's march-in rights, the 1963 policy further provided:

> Where the principal or exclusive (except as against the government) rights to an invention are acquired by the contractor, the government shall have the right to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract.[36]

The 1980 enactment of the Bayh-Dole Act altered the intellectual property landscape with respect to patents and government-sponsored R&D. Congress instead accepted the proposition that the lack of patent title discouraged private enterprise from advancing early-stage technologies into the marketplace. For example, suppose that a university researcher identifies a promising chemical compound using funds provided by the National Institutes of Health (NIH). Some observers believed that under pre-Bayh-Dole Act practices, a brand-name pharmaceutical company would be unlikely to undertake costly and risky clinical trials in order to convert that

(...continued)

Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What To Do About It* (2004).

[33] Roberto Mazzoleni, "Patents and University-Industry Interactions in Pharmaceutical Research Before 1962: An Investigation of the Historical Justifications for Bayh-Dole," *Journal of High Technology Law*, vol. 10 (2010), p. 168.

[34] "Statement of Government Patent Policy," 28 *Federal Register* 10943, October 10, 1963.

[35] Ibid. at 10945.

[36] Ibid.

early-stage research into a drug approved by the Food and Drug Administration. Absent patent protection, generic firms could quickly introduce competing products. This view accepts that patents provide incentives not just for individuals to invent, but also to commercialize completed inventions.[37]

Under the Bayh-Dole Act, each nonprofit organization (including universities) or small business is permitted to elect within a reasonable time to retain title to any "subject invention" made under federally funded R&D.[38] The institution must commit to commercialization of the invention within a predetermined, agreed upon, timeframe. However, the government may keep title under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter." Additionally, the government may withhold title if the contractor "is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government"; in situations associated with national security; or when the work is related to the naval nuclear propulsion or weapons programs of the Department of Energy.[39]

Certain other rights are reserved for the government. The government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.... "[40] The government also retains "march-in rights" which enable the federal agency to require the contractor to license a third party to use the invention under certain circumstances.[41] This report discusses march-in rights at greater length below.

By its own terms, the Bayh-Dole Act applies only to nonprofit organizations (including universities) and small businesses. However, in a February 1983 memorandum concerning the vesting of title to inventions made under federal funding, then-President Ronald Reagan ordered all agencies to treat, as allowable by law, all contractors within the Bayh-Dole Act framework regardless of their size.[42] This longstanding practice lacks a legislative basis, however.

The Bayh-Dole Act authorizes the government to withhold public disclosure of information for a "reasonable time" until a patent application can be made.[43] Licensing by any contractor retaining title under this act is restricted to companies that will manufacture substantially within the United States. This requirement may be waived if domestic manufacture is not commercially feasible, or if the contractor or its successors made reasonable but ultimately unsuccessful efforts to license domestic manufacturers.[44] The Secretary of Commerce was provided the authority to issue regulations implementing the Bayh-Dole Act.[45]

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[37] See F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," *Minnesota Law Review*, vol. 85 (2001), p. 697.

[38] 35 U.S.C. §202(a).

[39] Ibid.

[40] 35 U.S.C. §202(c)(4).

[41] 35 U.S.C. §203.

[42] Memorandum on Government Patent Policy from President Ronald Reagan, to Heads of Executive Departments and Agencies, February 18, 1983, http://www.presidency.ucsb.edu/ws/index.php?pid=40945&st=&st1=.

[43] 35 U.S.C. §205.

[44] 35 U.S.C. §204.

[45] 35 U.S.C. §206. These regulations may be found at 37 C.F.R. Part 401.

March-In Rights

The Mechanics of March-In Rights

The Bayh-Dole Act provides the government with the ability to "march in" and grant licenses for patents that resulted from publicly funded R&D. In particular, march-in rights allow the federal government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants."[46] If the patent owner refuses to do so, the government may grant the license itself. The terms of the license must be "reasonable under the circumstances."

The Bayh-Dole Act specifies four circumstances under which march-in rights may be exercised. The federal agency that provided the funding arrangement under which the patented invention was made must reach one of the following determinations:

> (1) 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;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement required by section 204 [generally requiring that patented products be manufactured substantially in the United States unless domestic manufacture is not commercially feasible] 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.[47]

With respect to the first of these conditions, the Bayh-Dole Act further defines the term "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."[48]

The Bayh-Dole Act states that any adversely affected "contractor, inventor, assignee, or exclusive licensee" may appeal a march-in rights petition to the United States Court of Federal Claims. The statute further explains that in cases described in paragraphs (1) and (3) above, march-in authority may not actually be exercised until all appeals or petitions are exhausted.[49]

The exercise of march-in rights does not invalidate or void the relevant patent. That patent remains extant and could presumably be enforced against entities that did not enjoy march-in rights. However, march-in rights grant a license—in other words, a permission—to the enterprise identified by the government. That entity may practice the patented invention without concern for

[46] 35 U.S.C. §203(a).

[47] 35 U.S.C. §203(a).

[48] 35 U.S.C. §201(f).

[49] 35 U.S.C. §203(b).

infringement, so long as it satisfies the conditions stipulated in the march-in order, such as the payment of a royalty.

March-in rights should be distinguished from the "nonexclusive, nontransferable, irrevocable, paid-up license" that the Bayh-Dole Act grants the U.S. government elsewhere.[50] This license solely benefits the federal government. Should another entity—such as a generic drug company or other enterprise—wish to practice the patented invention, then march-in rights provide a possible legal mechanism.

March-in rights are also distinct from the workings of another statute, 28 U.S.C. §1498(a).[51] That provision states:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. §1498(a) operates independently of the Bayh-Dole system. That statute applies to the use of a patented invention by the U.S. government, or one of its contractors with the authorization or consent of the U.S. government, without the permission of the patent proprietor. In such a case, the sole remedy for the patent owner is a suit in the U.S. Court of Federal Claims for monetary damages. An injunction is not available to the patent owner in such cases.

Three significant distinctions exist between march-in rights under the Bayh-Dole Act and 28 U.S.C. §1498(a). First, march-in rights apply only to patented inventions that were developed with the support of public funding. 28 U.S.C. §1498(a) applies to every U.S. patent, no matter what the sources of funding were. Second, private enterprises may take the initiative in requesting march-in rights from the government. 28 U.S.C. §1498(a) applies when the federal government practices the patented invention on its own behalf or requests a contractor to do so. Finally, recipients of march-in rights are awarded licenses "upon terms that are reasonable under the circumstances" and would presumably pay royalties to the patent proprietor. In contrast, under 28 U.S.C. §1498(a) the patent proprietor commences litigation and may be awarded damages to compensate for the use of the government or its contractors.

March-In Petitions

March-in rights have never been exercised during the 35-year history of the Bayh-Dole Act. Apparently the only federal agency that has even received a petition is the National Institutes of Health (NIH).[52] In particular, six petitions have been filed requesting that the NIH "march in" with respect to a particular pharmaceutical. Each petition was denied. A common theme of each

[50] 35 U.S.C. §202(c)(4).

[51] See Justin Torres, "The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498," *New York University Annual Survey of American Law*, vol. 63 (2007), p. 315; Bradley M. Taub, "Why Bother Calling Patents Property? The Government's Path to License Any Patent and Maybe Pay For It," *John Marshall Review of Intellectual Property Law*, vol. 6, p. 151.

[52] The author of this report has not located any record of any march-in petition filed at any other federal agency that funds R&D. See U.S. Government Accountability Office, *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*, GAO-09-742, July 2009, http://www.gao.gov/assets/300/293020.pdf (noting that the Department of Defense, Department of Energy, and National Aeronautics and Space Administration "have neither discovered nor received information that would lead them to initiate a march-in proceeding or exercise their march-in authority during the last 20 years.").

of the denials was the agency's views that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights. The six requests were:

> ***CellPro, Inc.*** (1997). CellPro requested that the government exercise march-in rights after being found to infringe patents held by the contractor. Although the NIH recognized that CellPro's device was the only FDA-approved product on the market, the agency observed that (1) the contractor and its licensees had not sought immediately to enjoin CellPro and (2) that they were making reasonable efforts to commercialize their own product. As a result, the agency declined to initiate march-in procedures.[53]
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> ***Norvir/ritonavir*** (2004). The petitioners, which included some Members of Congress, asked the NIH to exercise march-in rights due to perceived concerns over the high price of this HIV/AIDS treatment. The agency declined to initiate march-in proceedings because it deemed Abbott Laboratories, Inc., to have made the drug available to the public on a sufficient basis.[54]
>
> ***Xalatan/latanoprost*** (2004). Petitioners asserted that the price of this glaucoma treatment was higher than that of other nations. The NIH declined to initiate march-in proceedings because the drug was readily available for use by the public.[55]
>
> ***Fabrazyme/agalsidase beta*** (2010). This petition asked the NIH to grant an open license on certain patents relating to this treatment for Fabry disease. According to the petitioners, Genzyme Corporation was encountering difficulties in manufacturing sufficient quantities of the drug. The NIH did not initiate a march-in proceeding because (1) Genzyme was working diligently to resolve its manufacturing difficulties and (2) other enterprises were unlikely to obtain FDA marketing approval on agalsidase beta products before those problems were addressed.[56]
>
> ***Norvir/ritonavir*** (2012). The second petition against this HIV/AIDS drug more specifically requested the NIH to invoke march-in rights when prices in the United States were greater than other high-income nations. The NIH did not initiate march-in right proceedings because, in the view of the agency, such pricing disparities did not trigger any of the four statutory criteria for marching in.[57]
>
> ***Xtandi/enzalutamide*** (2016). The petitioner asserted both that the prostate cancer drug Xtandi had an average wholesale price of $129,269 per year; and that this price was much higher than in other high-income nations. The NIH declined to

[53] Harold Varmus, Director, NIH, *Determination in the Case of Petition of CellPro,Inc.*, August 1, 1997, http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[54] Elias A. Zerhouni, Director, NIH, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.*, July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[55] Elias A. Zerhouni, Director, NIH, *In the case of Xalatan, Manufactured by Pfizer, Inc.*, September 17, 2004, https://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.

[56] Francis S. Collins, Director, NIH, *Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation*, December 1, 2010, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.

[57] Francis S. Collins, Director, NIH, *Determination in the Case of Norvir Manufactured by AbbVie*, November 1, 2013, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

> initiate a march-in investigation because sales of the product were increasing and no evidence suggested that the product was in short supply.[58]

The NIH has offered some observations about the role of march-in rights during these proceedings. In its response to the 1997 CellPro petition, the agency stated its reluctance to undermine the exclusivities offered by the patent system:

> We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.[59]

In the 2004 proceedings regarding Norvir/ritonavir, the agency spoke more specifically about drug pricing:

> Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, 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. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.[60]

The NIH has also observed that another statute, the Drug Price Competition and Patent Term Restoration Act, P.L. 98-417, plays a role in the public availability of medicines.[61] Better known as the Hatch-Waxman Act, this legislation allows generic drug companies to develop their own products without incurring liability for patent infringement. It also allows generic drug companies to market their products prior to the expiration of relevant patents, although if they do so they may incur infringement liability at that time.[62]

Debate over March-In Rights

Concerns over the lack of assertion of march-in rights have been expressed for the past two decades. In 2001, Peter S. Arno[63] and Michael H. Davis[64] published an article in the *Tulane Law*

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[58] Letter from Francis C. Collins, Director, NIH, to Andrew S. Goldman, Knowledge Ecology International, June 20, 2016, http://keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf.

[59] Harold Varmus, Director, NIH, *Determination in the Case of Petition of CellPro,Inc.*, August 1, 1997, http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[60] Elias A. Zerhouni, Director, NIH, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.*, July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[61] Francis S. Collins, Director, NIH, *Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation*, December 1, 2010, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf, p. 9.

[62] CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by Wendy H. Schacht and John R. Thomas, The Hatch-Waxman Act: Over a Quarter Century Later.

[63] Dr. Arno was then a Professor of the Albert Eistein College of Medicine/Montefiore Medical Center.

[64] Mr. Davis was then a Professor of the Cleveland State College of Law.

Review asserting that the Bayh-Dole Act "has had a powerful price-control clause since its enactment in 1980 that mandates that inventions resulting from federally funded research must be sold at reasonable prices."[65] According to Arno and Davis, "the solution to high drug prices does not involve new legislation but already exists in the unused, unenforced march-in provision of the Bayh-Dole Act."[66] Arno and Davis followed this article with a 2002 editorial published in the *Washington Post*, stating in part:

> Although Bayh-Dole has been in place for 20 years, the government has never enforced it—not even once. That, despite the AIDS crisis at home and abroad, despite the millions of elderly and chronically ill Americans in need of affordable prescription drugs and the 40 million others who have no health insurance coverage whatever—and despite the general hand-wringing over the skyrocketing costs of pharmaceuticals.[67]

Former Senators Birch Bayh and Robert Dole, as they were then, responded with an editorial published in the *Washington Post* less than a month later. The editorial states in part:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.... The [Arno and Davis] article also mischaracterizes 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 the 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.[68]

Dialogue over the use of march-in rights was renewed in 2016, resulting in several exchanges between some Members of Congress, on one hand, and the Department of Health and Human Services (HHS) on the other. In an undated letter that was reportedly sent on January 11, 2016, the Honorable Lloyd Doggett, joined by 51 Members of Congress, addressed a letter to Secretary Sylvia Matthews Burwell of HHS and NIH Director Francis S. Collins. The letter in part requested NIH to provide official guidance regarding the situations in which march-in rights should apply.[69]

Secretary Burwell responded by letter on March 2, 2016. Her letter states in part that the Bayh-Dole Act's march-in right was "strictly limited and can only be exercised if the agency conducts an investigation and determines that specific criteria are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of the inventions." She also concluded that "the statutory criteria are sufficiently clear and additional guidance is not needed."[70]

Representative Lloyd Doggett sent an additional letter to Secretary Burwell and Director Collins on March 28, 2016. Signed by eleven other Members of Congress, the letter encourages the NIH

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[65] Peter S. Arno and Michael H. Davis, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research," 75 *Tulane Law Review* (2001), p. 631.

[66] Ibid.

[67] Peter Arno and Michael Davis, "Paying Twice For the Same Drugs," *Washington Post,* March 27, 2002, at A21.

[68] See Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, April 11, 2002, at A28.

[69] Michael Mezher, "Lawmakers Urge HHS to Exercise 'March-In' Rights to Fight Higher Drug Costs," *States News Service*, January 11, 2016.

[70] Letter from Sylvia M. Burwell, Secrtary of Health and Human Services, to The Honorable Lloyd Doggett, U.S. House of Representatives, March 2, 2016, http://freepdfhosting.com/be7532cfc0.pdf.

to conduct a public hearing regarding the request of public interest groups to invoke march-in rights to the cancer drug Xtandi/enzalutamide. The letter explains:

> NIH was recently petitioned to exercise these march-in rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles (UCLA) through taxpayer supported research grants from the U.S. Army and NIH grants. The petition states that a Japanese licensee, Astellas, is charging Americans $129,000 for this drug, which sells in Japan and Sweden for $39,000, and in Canada for $30,000. We do not think that charging U.S. residents more than anyone else in the world meets the obligation to make the invention available to U.S. residents on reasonable terms.[71]

As noted above, the NIH denied march-rights for Xtandi/enzalutamide on June 20, 2016.[72]

Congressional Issues and Options

To date, no bills have been introduced in the 114th Congress to address march-in rights under the Bayh-Dole Act. Therefore, if Congress deems the current situation to be acceptable, then no action need be taken. Other options include clarifications that further stipulate the circumstances under which march-in rights may be invoked, either by statutory amendment or the encouragement of regulatory refinements. Congress could, for example, define with greater clarity the precise circumstances under which a patented invention is deemed "available to the public on reasonable terms."[73] Congress could also define with greater specificity when march-in rights are needed to "alleviate health or safety needs,"[74] particularly with respect to inventions that might be perceived as too costly for many consumers to afford.

Other options include transfer of oversight of administering march-in rights. Currently the Bayh-Dole Act assigns the agency that provided funds that led to the patented invention responsibility for exercising these rights.[75] Another entity might have distinct perspectives than the funding agency and might reach different conclusions on whether to exercise march-in rights.

Transferring decisionmaking authority to a distinct entity might also eliminate any perceived conflicts of interest with respect to march-in rights. Former employees of federal agencies often wish to pursue careers within the private sector and may wish to maintain good relationships with those enterprises. In addition, agency officials may themselves be named inventors on patents to which march-in rights apply.[76] These factors could conceivably lead to a perception of bias against the institution of march-in rights.

Some commentators have also suggested that Congress should establish a centralized database of inventions subject to the Bayh-Dole Act.[77] Such a record would potentially improve the ability of

[71] Letter from Lloyd Doggett, House of Representatives, to The Honorable Sylvia Burwell, Secretary, Department of Health and Human Services, March 28, 2016, http://freepdfhosting.com/1c677ecdfc.pdf.

[72] "Feds Won't Lower Price of Prostate-Cancer Drug," *Seattle Times*, June 21, 2016.

[73] 35 U.S.C. §201(f).

[74] 35 U.S.C. §203(a)(2).

[75] 35 U.S.C. §203(a).

[76] The petition for rehearing of the Fabrazyme march-in decision asserted that NIH Director Francis Collins was named as an inventor on nineteen patents potentially subject to march-in rights. Letter from C. Allen Black, Jr., Attorney at Law, to Mark Rohrbaugh, Office of Technology Transfer, NIH, April 5, 2011, http://patentdocs.typepad.com/files/nih-petition-for-rulemaking-and-rehearing-90.pdf.

[77] Ryan Whalen, "The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?," *Northwestern University Law Review*, vol. 109 (2015), pp. 1111-12.

the public to track its R&D investments and observe the degree to which these investments have resulted in new products for the marketplace. If a further level of monitoring were desirable, one possibility would be to require licensees of patents subject to the Bayh-Dole Act to submit periodic reports disclosing both their efforts at introducing the patented inventions to the public and their pricing policies.

Other commentators also have urged reconsideration of the statutory requirement that in certain cases all judicial appeals be exhausted before march-in authority may actually be exercised.[78] Under current law, even though a federal agency has authorized march-in rights, they may at times not be used until the patent proprietor has taken his case as far as the Supreme Court of the United States. As Arti K. Rai[79] and Rebecca S. Eisenberg[80] assert, "the tolerance for protracted delays inherent in the current process is at odds with the time-sensitive nature of the interests reflected in the substantive standard, such as achieving practical application of the invention 'within a reasonable time' and 'alleviat[ing] health or safety needs.'"[81] This possibility of delay could also possibly discourage march-in petitions in the first instance.

Still other commentators have suggested that Congress should take further steps to ensure that the best candidate receives licenses for patents subject to the Bayh-Dole Act. Under current law, government contractors may choose to license their inventions to anyone. Such a system may not place these inventions in the most capable hands, either from the perspective of the contractor or of the public.[82] Another option might be an open-bidding auction that might better ensure that patents on inventions developed through government funding are licensed to the most capable enterprise.[83]

Concluding Observations

Current dialogue over march-in rights involves a familiar policy debate in intellectual property law. On the one hand, the patent laws are intended to promote the labors that lead to innovation. Critics of the use of march-in rights believe that diluting the patent incentive will discourage private investment and ultimately work against the aims of the Bayh-Dole Act. But others say that the patent laws are also intended to distribute the fruits of those labors to the public. This goal is most visibly achieved when patents expire and previously proprietary technologies enter the public domain. However, some observers believe that march-in rights provide an unused mechanism for discouraging excessive profiteering and providing the public an appropriate return on its R&D investments during a patent's term. Striking a balance between these competing views regarding the commercialization of federally funded research remains a matter of congressional judgment.

[78] 35 U.S.C. §203(b).

[79] Arti K. Rai is the Elvin R. Latty Professor of Law at the Duke University School of Law.

[80] Rebecca S. Eisenberg is the Robert and Barbara Luciano Professor of Law at the University of Michigan Law School.

[81] Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Process of Biomedicine," *Journal of Law and Contemporary Problems*, vol. 66 (2003), p. 311.

[82] Peter Lee, "Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer," *California Law Review*, vol. 100 (2012), p. 1521.

[83] See Whalen, *supra*.

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