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THE BAYH–DOLE ACT & PUBLIC RIGHTS IN FEDERALLY FUNDED INVENTIONS: WILL THE AGENCIES EVER GO MARCHING IN?

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ABSTRACT—For over thirty years, the Bayh–Dole Act has granted federal agencies the power to force the recipients of federal research funding to license the resulting inventions to third parties. Despite having this expansive power, no federal agency has ever seen fit to utilize it. This Note explores why Bayh–Dole march-in rights have never been used, and proposes reforms that would help ensure that, in the instances when they are most required, the public is able to access the inventions it bankrolled.

There have been five documented march-in petitions since the Bayh–Dole Act was passed into law. Each petition was dismissed by the funding agency without progressing to the march-in proceeding stage. Even if one of these petitions had made it to the proceeding stage it is unlikely that a march-in would have occurred. The Bayh–Dole Act's march-in rights are designed in such a manner that makes their effective use highly unlikely. Procedurally, they offer expansive protections for patent holders and few safeguards for those who petition for march-in.

A few minor reforms to the system could help appropriately balance the march-in system's design. Potential reforms include instituting an appeal process, mandating a duty to use "best efforts" to bring subject inventions to the point of practical application and report on those efforts, clarifying the meaning of Bayh–Dole's "reasonable terms" requirement, and instituting a requirement that subject inventions be marketed in the United States at internationally competitive rates. In addition, a requirement that subject inventions be licensed via public auction rather than private negotiation would help ensure that those best suited to commercializing inventions have the chance to secure the rights to them.

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INTRODUCTION

In late 1980, President Carter signed into law an act that gave unprecedented powers to federal agencies,[1] powers that to this day have never been used. The Bayh–Dole Act's passage into law allowed for private patents on inventions arising from publicly funded research while also giving federal funding agencies the power to "march-in" on those patents and grant licenses to third parties.[2] Yet, despite receiving this expansive new power, no federal agency has ever utilized it. Over thirty-three years and hundreds of thousands of patents later, not once has a funding agency seen fit to use its march-in rights. In order to explore this unexpected phenomenon—where government agencies are granted expansive powers that they never use—this Note examines both the design of the Bayh–Dole Act and, for the first time, the details of all of the petitions for march-in brought under 35 U.S.C. § 203. After showing that

[1] Bayh–Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980).

[2] *See* 35 U.S.C. §§ 200–212 (2012).

not only have march-in rights never been used, but that no agency has even seen fit to even commence a formal march-in proceeding, this Note argues that this nonuse is a product of both the provisions' design and the agency's hesitancy to upset the technology transfer incentive system. This Note then details procedural and substantive reforms that would help ensure that march-in rights are exercised in situations where they would serve the public good.

While march-in petitions have been rare,[3] they remain relevant today. For instance, following the recent Supreme Court ruling against Myriad in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[4] Myriad has continued with attempts to assert its remaining rights over its breast cancer gene detection test.[5] Upset at barriers to accessing the test, some have called on the National Institutes of Health (NIH) to force Myriad to license its patented test to other labs.[6] After all, the test that Myriad so zealously protects is based partially on the product of federally funded research.[7]

However, even as the calls to march in on Myriad's patents were raised, informed observers could be almost certain that they would not be heeded.[8] If past performance is any predictor of future behavior, the NIH will likely deny the march-in petitions and refuse to march in on Myriad's gene testing patents.

It is perplexing that, over the course of over three decades, federal agencies have accumulated march-in rights on hundreds of thousands of patents, yet no federal agency has utilized this extraordinary power. This Note argues that Bayh–Dole march-in rights have not been used because the march-in procedure mandated in the Code of Federal Regulations grants agencies wide discretion and leaves those who would benefit from marching-in unrepresented during the proceeding and without recourse to

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[3] Since the 1980 signing of the Bayh–Dole Act, there have been five documented march-in petitions—one in 1997, two in 2004, one in 2010, and one in 2012. *See infra* Part II.

[4] 133 S. Ct. 2107 (2013).

[5] *See* Andrew Pollack, *2 Competitors Sued by Genetics Company for Patent Infringement*, N.Y. TIMES, July 11, 2013, at B3 [hereinafter Pollack, *Competitors Sued by Genetics Company*].

[6] *See, e.g.*, Letter from Patrick Leahy, Chairman, S. Comm. on the Judiciary, to Francis S. Collins, Dir., Nat'l Insts. of Health (July 12, 2013), *available at* http://www.leahy.senate.gov/download/07-12-13-pjl-to-nih-re_-myriad-march-in [http://perma.cc/JWK7-2X8R].

[7] *See* E. Richard Gold & Julie Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S41 (2010). The NIH contributed $5 million in grants to researchers at the University of Utah, which subsequently licensed the technology to Myriad. *Id.*

[8] *See, e.g.*, Meredith Wadman, *NIH Asked to Grant Open License on HIV Drug*, NATURE NEWS BLOG (Nov. 2, 2012, 22:05 BST), http://blogs.nature.com/news/2012/11/nih-asked-to-grant-open-license-on-hiv-drug.html [http://perma.cc/AMX8-GBNC] ("[T]he petitioners will have some convincing to do: in the 32 years that [the] Bayh–Dole Act has been law, the NIH has been asked to exercise march-in rights four times. It has declined all four requests.").

any appeal process. These procedural issues combine with a lack of information about Bayh–Dole subject inventions, the statutory language, and a largely conservative approach to march-in rights by federal agencies, to make it extremely unlikely that agencies will utilize their march-in rights.

Understanding why march-in rights have never been used first requires understanding their unique design and the process by which they are exercised. The march-in process grants federal agencies wide discretion and provides little oversight to ensure it is not abused.[9] At any point in the march-in petition process the funding agency overseeing the matter may decline to exercise its march-in rights.[10] When march-in rights are not exercised, those who could have benefited from a forced license are left unrepresented and vulnerable.

Along with understanding the wide discretion that march-in procedure grants to agencies, appreciating why march-in rights are not used also requires considering the interested groups affected by federal march-in rights. Important players include federal funding agencies, recipients of federal funding, patent licensees, would-be licensees, and the public. Notably, while all of these interest groups have a stake in whether or not march-in rights are used, they are not all present at a march-in proceeding, nor are their interests equally protected by march-in procedure. The federal funding agency plays a gatekeeper role with great discretion as to whether or not march-in rights are used. This wide discretion leaves stakeholders—notably members of the public—unrepresented and without recourse should the agency decline to march in.

There have been few march-in petitions and none have led the funding agency to even commence a march-in proceeding, let alone utilize its march-in rights. Examining the details of these cases shows that the regulations governing the instances in which march-in rights are permitted have the dual effect of making it easy for an agency to justify not marching in while simultaneously making the use of march-in rights harder to justify. In order to adequately protect the public interest, the unbalanced structure of these regulations needs reform.

Potential reforms to rebalance the march-in system include empowering a central overseer for the commercialization of Bayh–Dole subject inventions, modifying the march-in procedure to better protect the rights of petitioners, mandating the maintenance of a user-friendly database of patents that the government holds a march-in right to, instituting a duty

[9] *See* 37 C.F.R. § 401.6(b) (2014).

[10] *Id.*

of "best efforts" to commercialize Bayh–Dole subject inventions, and requiring public auctions on licenses for Bayh–Dole subject inventions.

This Note proceeds in four parts. Part I discusses the background of the Bayh–Dole Act and its inclusion of march-in rights. This background section also examines the march-in rights enabling statute (35 U.S.C. § 203) and the march-in proceeding process circumscribed in 7 C.F.R. § 401.6. Subsequently, because understanding why march-in rights are or are not used requires an understanding of the interest groups affected, it also discusses the various parties implicated by federal march-in rights. Part II then discusses previous march-in petitions and why they failed. Next, Part III discusses why no federal agency has ever used its Bayh–Dole march-in rights. Part IV details potential reforms that seek to both maintain the integrity of technology transfer incentives while also ensuring that the technology produced by publicly funded research is made available in an efficient and equitable manner.

I. THE BAYH–DOLE ACT—BACKGROUND

Congress designed the Bayh–Dole Act (the Act) to address concerns about America's lagging rate of innovation.[11] While 80% of the patents issued by the U.S. Patent and Trademark Office (USPTO) in 1965 went to Americans, by the late 1970s, when the Act was drafted, that number had decreased to 62%.[12] Legislators worried that both confidence in the patent system had declined, and that America was falling behind its foreign competitors.[13]

Also during this time, more than half of domestic scientific research was funded by the federal government.[14] Legislators worried that much of the resulting research output was not being adequately developed and commercialized.[15] Funding agencies had various patent arrangements with research collaborators,[16] but most left the funding agency with ownership of

[11] 126 CONG. REC. 29,897 (1980) ("Technological innovation in the United States is declining at an alarming rate . . . ."); *see also The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 1 (1979) [hereinafter *Senate Hearing*] (statement of Sen. Birch Bayh) (showing concern about the United States losing its technological preeminence).

[12] 126 CONG. REC. 29,897 (1980).

[13] *Id.* (specifically citing concerns about competition from West Germany and Japan).

[14] 126 CONG. REC. 29,898 (1980); William H. Reynolds, *Reforming Patent Law*, N.Y. TIMES, Sept. 15, 1980, at A23.

[15] *Senate Hearing*, *supra* note 11, at 2 (statement of Sen. Birch Bayh) (stating that "less than 4 percent" of the government's patent portfolio is ever licensed); 126 CONG. REC. 29,896 (1980) (statement of Rep. McClory) ("The funding agency is rarely in a position to develop these inventions.").

[16] In 1979 there were over twenty different arrangements governing ownership of inventions arising from federally funded research. *Senate Hearing*, *supra* note 11, at 2.

any patentable rights "even if the Federal Government ha[d] provided only a small percentage of the total money involved."[17]

Legislators hoped that providing patent rights to private firms would encourage greater commercialization of inventions developed with the assistance of federal funding.[18] The Act's supporters knew that providing private rights for publicly funded research output might be seen as a wealth transfer to the private sector.[19] However, they hoped that the improved rate of development and commercialization these private rights offered would generate a net social benefit.[20] The hope was that, although the public may be temporarily deprived of access to some inventions it had funded, more inventions would be fully developed and brought to market and thus the public would be better off than they would have been with free access to otherwise undeveloped federally funded inventions.

Congress anticipated that patent rights for firms would not only improve the commercialization rates of government funded research, but it also hoped that the new collaboration paradigm would encourage even more research and development agreements.[21] Offering the possibility of patent rights made federal research funding more attractive economically because firms were more likely to be able to profit from any resulting research output, and so Congress expected more firms to apply for federal research funding. Legislators also hoped that the Act would address small firm hesitancy to engage in federally funded research and development (R&D).[22] Prior to the Bayh–Dole Act, these firms hesitated to use federal research funding because it complicated the ownership of much of their intellectual property. Previous arrangements not only did not offer firms the potential for patent rights, but accepting federally funded R&D contracts potentially endangered background rights to the firms' previously patented inventions.[23]

A. March-in Rights Before the Bayh–Dole Act

March-in rights were not a novel development of the Bayh–Dole Act. In earlier iterations of patent policy, proposals to privatize the product of

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[17] 126 CONG. REC. 29,896 (1980).

[18] Senator Dole justified the Act by arguing that, without patent protection, firms would be reluctant to engage in the development process because they would not be able to protect potential earnings that the costly development process might lead to. *Senate Hearing*, *supra* note 11, at 28.

[19] 126 CONG. REC. 29,898 (1980).

[20] *Id.*

[21] *Id.* at 29,896.

[22] *Id.*

[23] *Id.* This was because many agencies had policies requiring firms sign away rights to related patents as a condition of receiving federal research funding. *Id.*

federally funded research were often accompanied by march-in rights provisions.[24]

As early as 1945, Vannevar Bush's[25] postwar report to the President on scientific research policy proposed patent reforms similar to those that would eventually come to be included in the Bayh–Dole Act.[26] This proposal would have allowed recipients of federal research funds to patent resulting inventions, with the provision that the government could assign those rights to protect the "public interest."[27]

The 1947 Attorney General's Report on Patent Practices and Policies inverted Bush's proposals by advocating a default that would entitle the government to invention rights.[28] Under this proposed policy, agency heads would be empowered to make emergency exemptions to the default policy and allow contractors to patent resulting inventions.[29] However, these exceptions would allow the government to march in on the resulting patents if the rights owner did not adequately commercialize the invention within a designated period.[30]

Presidential memos in the 1960s and 1970s also advocated for march-in rights when agencies choose to allow private ownership of publicly funded research output.[31] The Kennedy memo of 1963 noted that agencies had developed a variety of policies regarding rights to inventions developed with federal funding and advocated for more uniformity.[32] Kennedy's policy required that any contractor retaining more than a nonexclusive license in federally funded research would be required to bring the invention to the point of practical application.[33] Should the contractor fail to take effective steps to practice the invention within three

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[24] *See* John H. Raubitschek & Norman J. Latker, *Reasonable Pricing – A New Twist For March-in Rights Under The Bayh–Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 151–52 (2005).

[25] Bush had been head of the U.S. Office of Scientific Research and Development during World War II and was influential in developing postwar innovation policy. *See generally* G. PASCAL ZACHARY, ENDLESS FRONTIER: VANNEVAR BUSH, ENGINEER OF THE AMERICAN CENTURY (1997).

[26] *See* VANNEVAR BUSH, U.S. OFFICE OF SCIENTIFIC RESEARCH & DEV., SCIENCE: THE ENDLESS FRONTIER (1945).

[27] *Id.* at 31–32.

[28] U.S. DEP'T OF JUSTICE, INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICES: REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT 4–5 (1947).

[29] *Id.* at 5.

[30] *Id.*

[31] *See* Raubitschek & Latker, *supra* note 24, at 151–52.

[32] Government Patent Policy, 28 Fed. Reg. 10,943 (Oct. 10, 1963).

[33] *Id.*

years, the government would retain the right to force it to license the patent on reasonable terms.[34]

Unlike the Kennedy memo, the Nixon memo of 1971 advocated for a more flexible approach that would allow individual agencies to design their own patent policies.[35] The Nixon policy retained similar government rights, granting the funding agency the ability to require the rights owner to grant nonexclusive licenses if it had not taken effective steps towards practical application within a three-year period.[36]

It was in the context of this flexible agency-by-agency approach to technology transfer that President Carter signed the Bayh–Dole Act into law on December 12, 1980.[37] In doing so he cited the nation's economic health as a motivating concern for the reforms.[38] Initially, the Bayh–Dole Act—or the University and Small Business Patent Procedures Act as it was known at the time—focused on the funding agreements between federal agencies and universities, nonprofits, and small businesses. Earlier efforts to pass similar reforms that included patent protections for larger corporations had faced overwhelming resistance, and so Senators Bayh and Dole offered the more narrowly tailored act in 1979.[39] However, only three years after the Bayh–Dole Act came into effect, President Reagan expanded its scope via presidential memorandum to treat all federal research fund recipients the same, regardless of whether they were small businesses, universities, or large corporations.[40]

B. The Bayh–Dole Act's March-in Rights

The Bayh–Dole Act's march-in rights provisions are detailed in 35 U.S.C. § 203. They allow the funding agency to force the contractor or licensee to grant a license to "a responsible applicant or applicants."[41] These forced licenses can run the gamut from nonexclusive to exclusive, potentially precluding the contractor or licensee's own rights to use the

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[34] *Id.*

[35] Government Patent Policy, 36 Fed. Reg. 16,887 (Aug. 23, 1971).

[36] *Id.* at 16,890.

[37] Patent and Trademark System Reform, 16 WEEKLY COMP. PRES. DOC. 2803 (Dec. 12, 1980).

[38] *Id.*

[39] *See* Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST, Apr. 8, 1979, at M1.

[40] *See* Memorandum on Government Patent Policy, 1 PUB. PAPERS 248 (Feb. 18, 1983).

[41] 35 U.S.C. § 203(a) (2012).

invention.[42] If the rights owner refuses to grant the license, the agency may grant a license itself.[43]

This forced licensing ability is the core power of the march-in rights provision and is available in four instances. The first instance arises if the rights owner "has not taken, or is not expected to take . . . effective steps to achieve practical application" of the invention.[44] This echoes the requirements in both the Kennedy and the Nixon memos,[45] and reflects longstanding concerns that the product of federally funded research might linger undeveloped and unused. Second, forced licensing is also available if the agency deems it is necessary to "alleviate health or safety needs which are not reasonably satisfied" by the invention's current owner or licensee.[46]

The third and fourth instances in which march-in rights may be used are relatively specific compared to the first two. The third allows for forced licenses if "action is necessary to meet requirements for public use specified by Federal regulations."[47] The final instance allowing forced licenses arises if the contractor or licensee does not comply with the § 204 requirement that the product of federally funded research be manufactured domestically.[48]

While 35 U.S.C. § 203 spells out the rules as to when an agency may march in on a contractor's patent rights, the process for doing so is described in 37 C.F.R. § 401.6.[49] However, the Code of Federal Regulations leaves march-in proceedings largely to the discretion of individual agencies. The first stage of the process requires agencies to notify the rights-holding contractor if it "receives information that it believes might warrant the exercise of march-in rights."[50] The regulations do not clarify what sort of information might warrant the exercise of march-in rights, but past experience suggests that petitions from would-be licensees or even the public might qualify.[51] The contractor has a thirty-day

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[42] *Id.*

[43] *Id.*

[44] *Id.* § 203(a)(1).

[45] *See supra* Part I.A.

[46] 35 U.S.C. § 203(a)(2).

[47] *Id.* § 203(a)(3). This method of march-in allows for public use march-in justifications to be specifically defined in federal regulations. *Id.*

[48] *Id.* § 203(a)(4). Section 204 stipulates that licenses to Bayh–Dole subject inventions must require that "any products embodying the subject invention . . . be manufactured substantially in the United States." *Id.* § 204.

[49] These regulations are promulgated by the National Institute of Standards and Technology, a sub-agency of the Department of Commerce. *See* Redelegations of Authority Resulting From the America COMPETES Act, 78 Fed. Reg. 4764 (Jan. 23, 2013).

[50] 37 C.F.R. § 401.6(b) (2014).

[51] *See infra* Part II.

right of response after agency notification.[52] After the contractor's response, or after thirty days in the absence of a response, the agency then has discretion to initiate a march-in proceeding.[53]

Formal march-in proceedings begin with a written notice from the agency to the contractor and its assignee or licensee as appropriate.[54] This notice must state the reasons for the proposed march-in and the field in which it is considering requiring a license.[55] After the notice, the rights holder has thirty days in which to submit its opposition.[56] If the agency head or the agency head's designee[57] determines that this opposition raises a genuine dispute over material facts, the proceeding will then move to a fact-finding stage.[58] This leaves a single individual with complete discretion over whether or not the agency should continue with a march-in proceeding.

If the proceeding reaches the fact-finding stage, fact-finding is to be "conducted in accordance with the procedures established by the agency."[59] The Code of Federal Regulations requires that these procedures allow for the assistance of counsel, the submission of evidence, and the presentation and confrontation of relevant witnesses.[60] Portions of the proceeding that include evidence about the rights holder's utilization or attempted utilization of the invention are closed to the public.[61]

After the facts have been established and submitted to the agency head or designee adjudicating the march-in proceeding, the rights holder has thirty days to submit written arguments or make requests for oral argument.[62] The adjudicator will then take into account the facts found, information and arguments submitted by the contractor and agency representatives, and other information on the administrative record.[63] The agency head or designated adjudicator has ninety days to provide written

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[52] 37 C.F.R. § 401.6(b).

[53] *Id.* Note the discretion at this stage of the process. Even if a contractor does not respond to a march-in petition, an agency may decline to initiate a march-in proceeding, and indeed no march-in petition has ever made it past this stage of the process. *Id.*

[54] *Id.* § 401.6(c).

[55] *Id.*

[56] *Id.* § 401.6(d).

[57] The C.F.R. does not describe who may or may not be a designee. Presumably this too is left to the agency's discretion.

[58] *Id.* § 401.6(d).

[59] *Id.* § 401.6(e).

[60] *Id.*

[61] *Id.*

[62] *Id.* § 401.6(f).

[63] *Id.* § 401.6(g).

notice of whether march-in rights will be exercised.[64] If the agency does decide to march-in, which has never happened, the rights holder may appeal the decision to the Court of Federal Claims, which has the power to affirm, reverse, remand, or modify the agency's decision.[65]

Parties advocating for an exercise of march-in rights are not officially represented at the proceeding, nor do they have any right of appeal. Furthermore, at any time during the process the agency may terminate the march-in proceeding "if it is satisfied that it does not wish to exercise its march-in rights."[66]

The design of these march-in rules and procedures offer some insight into why no agency has ever marched in on a Bayh–Dole subject patent. Simply put, the process is stacked against the petitioners. Agencies have almost complete discretion to rule as they prefer, while petitioners are neither represented at the hearings, nor are they able to appeal the outcomes. When agencies consider the various interests at play, these rules and procedures make marching in an unlikely outcome. The contractor has a distinct procedural advantage when compared to the other parties implicated by march-in rights.

C. Parties Implicated by March-in Rights

Understanding why march-in rights have never been used requires a discussion of the various parties with interests in inventions that are the subject of march-in petitions. March-in rights implicate federal funding agencies, recipients of federal research funds, parties that license patents arising from federally funded research, parties that wish to use patented inventions arising from federally funded research, and the public. These parties have different and often conflicting interests in who controls federally funded inventions.

1. Funding Agencies.—Federal agencies are concerned about march-in rights not only because they are the primary recipients of march-in petitions and initially decide whether or not they will be granted, but also because the outcome of march-in petitions may have follow-on effects for the research environment more generally. This situation presents agencies with a balancing dilemma: they must balance the potential good that might come from allowing greater access to a patented invention against the

[64] *Id.*

[65] 35 U.S.C. § 203(b) (2012); 37 C.F.R. § 401.6(j).

[66] 37 C.F.R. § 401.6(h).

potential harm that such access by fiat might cause to the incentive system for research, development, and commercialization.[67]

If the individuals charged with assessing the merits of march-in applications had perfect information and were able to accurately balance this tradeoff so as to maximize the public good, this balancing dilemma would not present an issue. In reality, bureaucrats have access to imperfect information and much of their analysis depends upon conjecture or assumptions. In discussing why a Bayh–Dole march-in petition has never been granted we must note that the ideal of perfectly rational bureaucratic decisionmaking does not reflect reality.[68] Institutional actors are better understood as bounded-rational actors, subject to imperfect information, limited resources, and emotional attachments that lead to satisficing approaches to decisionmaking.[69]

2. Recipients of Federal Research Funding.—Federal research funds go to five types of organizations: universities, industry, the federal government (i.e., in-house research), nonprofits, and federally funded research and development centers.[70] The march-in rights issue is most relevant to the nongovernmental entities such as universities, industry, and nonprofit research institutions.[71]

These nongovernmental recipients of federal research funding have a number of organizational interests related to the federal government's retained march-in rights. They have an interest in maintaining the continued flow of research dollars. They also have an interest in ensuring the continued value—whether it be by licensing or self-commercialization—of the intellectual property that arises from federally

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[67] The concern here is that if a march-in proceeding leads to a forced license, contractors will be less likely to pursue federally funded research in the future because of the uncertain intellectual property rights they would have over any resulting inventions. For a discussion on the importance of property rights in incentivizing investments in intellectual property, see F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 717–36 (2001).

[68] *See* Bryan D. Jones, *Bounded Rationality and Political Science: Lessons from Public Administration and Public Policy*, 13 J. PUB. ADMIN. RES. & THEORY 395 (2003); Herbert A. Simon, *Bounded Rationality and Organizational Learning*, 2 ORG. SCI. 125 (1991).

[69] Satisficing occurs when individuals choose a course of action not because it is the best, but because it suffices or satisfies the demands made of them. *See* 14 OXFORD ENGLISH DICTIONARY 504 (2d ed. 1989) ("To decide on and pursue a course of action that will satisfy the minimum requirements necessary to achieve a particular goal.").

[70] CONG. BUDGET OFFICE, PUB. NO. 2927, FEDERAL SUPPORT FOR RESEARCH AND DEVELOPMENT 18 (2007), *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/82xx/doc8221/06-18-research.pdf [http://perma.cc/V5XV-YUWE].

[71] This is because the government generally retains ownership of the product from federal research centers and thus does not need march-in rights over these inventions. *See* 37 C.F.R. § 501.6 (2014) ("The Government shall obtain . . . the entire right, title and interest in and to any invention made by any Government employee . . . .").

funded research. In addition, some recipients may also have a mission-oriented or ideologically-inspired interest in promoting the spread and utilization of knowledge.

It is important to note that funding recipients' primary interest—ensuring the continued flow of research dollars—leaves them with little bargaining power during a march-in petition. Regardless of whether the funding agency chooses to march in, academic institutions and, to a lesser extent, industry partners, are likely to keep lining up for research dollars. For many of these institutions there are few alternative funding sources, and none that would fulfill the role the government plays in funding basic research.[72]

3. Licensees.—Entities that license the product of federally funded research include startups, established businesses, and patent monetization firms. There is no shortage of firms licensing technology that might implicate Bayh–Dole march-in rights. In 2012, universities alone executed over 5000 licenses on their patents.[73] While the licensees that use these patents may have diverse business interests, their interests in the patents that they license unite them as general opponents to the application of any march-in rights petition. The current status quo, where the use of march-in rights is unprecedented, suits the interests of those whose licensed inventions would be at greater risk of competition should the government change its tune.

4. Would-be Licensees.—Would-be licensees have interests diametrically opposed to those of established licensees. These entities wish to utilize the product of federally funded research despite existing license arrangements that prevent them from doing so. Historic examples include CellPro, a firm that petitioned the NIH to march in on patents owned by Johns Hopkins University and licensed to Baxter Healthcare.[74] More recently firms like Ambry Genetics that have been sued by Myriad—the owner of a breast cancer susceptibility screening test produced using federally funded research—for infringement stand to benefit if the government were to exercise its march-in rights.[75]

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[72] *See* JOHN F. SARGENT JR., CONG. RESEARCH SERV., R42410, FEDERAL RESEARCH AND DEVELOPMENT FUNDING: FY2013 (2013).

[73] ASS'N. OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING ACTIVITY SURVEY HIGHLIGHTS (2012), *available at* http://www.autm.net/AM/Template.cfm?Section=FY2012_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=11435 [http://perma.cc/4MZW-8JFJ]. While the 5130 licenses reported by the AUTM do not all necessarily implicate Bayh–Dole Act rights, the majority of university research is funded from federal sources and does so. *See id.*

[74] *See infra* Part II.A.

[75] *See* Pollack, *Competitors Sued by Genetics Company*, *supra* note 5.

These entities hope the Bayh–Dole Act's march-in provisions will help them either avoid infringement suits that their current behavior may be susceptible to, or allow them to expand their operations into an area currently occupied by an entity using a Bayh–Dole subject invention. As discussed below, the absence of would-be licensees can doom a march-in petition if it is brought by a public interest group.[76]

5. The Public.—When it comes to march-in rights, the general public has perhaps the most complex set of interests to balance. Balancing these interests is further complicated by the public's lack of information regarding what patents are potentially at issue, who the interested parties are, and how the approval of march-in petitions might affect technology availability now and in the future.

In theory, the public's interest is aligned with funding agencies' interests. That is to say, each wishes to maximize both innovation and access to technology. The public and the government, in the form of its funding agencies, see limited monopolies over patented technologies as a compromise used to provide incentive for innovation at the short-term expense of access.[77] However, the theory of aligned interests between the public and its representatives does not perfectly reflect reality. In reality, agencies, as institutional actors, have independent interests. Furthermore, the bureaucrats that run funding agencies have their own careers to consider both in public service and potentially in subsequent transfer to the private sector.

In addition, the public is not a unitary actor. There are distinct groups that may benefit more than others from the use of march-in rights on any given technology. For instance, in the case of Fabrazyme, those individuals suffering from the relatively rare Fabry's disease stood to gain from a proposed march-in on Genzyme's license, while the interest of the public at large may have been better served by not marching in and potentially interfering with drug commercialization incentives.[78]

This difference in interests between the public and its representatives is a potential breakdown point in the effectiveness of the Bayh–Dole march-in provisions. Because the public has both limited information and

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[76] *See infra* Part II.B–C.

[77] For more on the general theory of intellectual property law and incentives, see Stanley M. Besen & Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSP. 3 (1991).

[78] *See* Andrew Pollack, *Patients Want Patent Broken on Genzyme Drug*, N.Y. TIMES (Aug. 2, 2010, 4:37 PM), http://prescriptions.blogs.nytimes.com/2010/08/02/patients-want-patent-broken-on-genzyme-drug/?_r=0 [http://perma.cc/5LYY-8XHE] [hereinafter Pollack, *Patients Want Patent Broken*]; *infra* Part II.D.

limited access to the march-in process, the results of any given march-in petition may not adequately represent the public's best interest. Furthermore, and perhaps more importantly, the lack of information about the potential patents at issue may result in march-in petitions not even being initiated when they might otherwise be justified.

The difficulties in balancing the interests in march-in rights share similarities with challenges faced in patent law more generally. It is hard to know when it would be best to march in because it is unclear what result marching in would have on the technology transfer system. Ultimately it is difficult to know how to most efficiently allocate rights to both maximize innovation and access to it. In fact, these challenges are likely one of the reasons march-in rights were included in the Bayh–Dole Act.

D. Why Include March-in Rights?

March-in rights were included in the Bayh–Dole Act both to placate potential criticism about the government shifting wealth to firms licensing the product of federally funded research, and to provide the government with a policy tool it could use to try and ensure adequate commercialization and protect the public interest.

At the time of drafting the Bayh–Dole Act, Congress was aware that granting private ownership to the product of publicly funded research ran the risk of appearing as a wealth transfer to private interests.[79] Retaining march-in rights over these inventions was a way for the government to nuance this property transfer, making it less offensive to potential critics. Earlier drafts of the Act included even more protections against this perceived wealth transfer. The "Return of Government Investment" section would have required entities profiting from products that embodied Bayh–Dole subject inventions to share a portion of those profits with the government.[80] This provision would have ensured that the government recouped much of the cost of subsidized research when that research led to commercialized products. Ultimately, however, the Bayh–Dole Act relied on march-in rights as the chief protection of the public's interest in federally funded research.

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[79] *See* 126 CONG. REC. 29,898 (1980) (statement of Rep. Brown) ("I am aware of the concern that granting contractors exclusive rights to federally funded inventions is a 'give-away' of the taxpayers' property."); 126 CONG. REC. 8738 (1980) (statement of Sen. Long) ("It is dismaying, therefore to find that S. 414 provides for contractors . . . to receive gifts of ownership of taxpayer-financed research, and according to S. 414's chief sponsor, this is to be only a first step.").

[80] S. 414, 96th Cong. § 204 (1980); *see also* 126 CONG. REC. 8739 (1980) (statement of Sen. Dole) ("The Government payback provision guarantees that the Government's investment, paid for by the taxpayers of this country, is returned to the Federal coffer.").

Instead of granting outright unencumbered title to the resulting inventions, march-in rights enabled agencies to maintain the public's right to access the inventions it funded. Their inclusion was framed as a way to "diffuse the danger of monopolies."[81] It is unclear whether Bayh–Dole's drafters envisioned that the provisions would ever be used, or, if their inclusion was more strategic in nature, intended to preemptively counter allegations of wealth transfer. Regardless, as is detailed below, the design of the Act makes it highly unlikely that they will be effectively used as they are currently implemented.

In addition to serving as a response to potential criticisms about public-to-private wealth transfer, march-in rights help ensure patented inventions are used and thus serve a functional role in supplementing the Bayh–Dole Act's incentive structure.[82] One of the Bayh–Dole Act's objectives was to create a technology transfer system that brought to market inventions that had previously remained underdeveloped because no firm was willing to invest in them without a guarantee of exclusivity.[83] The drafters hoped that these patents would provide incentives to help spur innovation.[84] However, by granting patents on these inventions, the Act also risked allowing private parties to withhold the inventions from their competitors and the public. March-in rights address this concern by retaining the right to force licenses, should the patenting entity or its licensee not use the invention.

March-in provisions provide a tool to protect the public's interest by enforcing practical application of Bayh–Dole subject patents. As such, they can be thought of as a method to allow for public input in an intellectual property regime that rarely invites public involvement. Other elements of the patent system at times privilege the patent holders' interests above competing interests. For instance, the establishment of a specialized patent appeal court in the Federal Circuit is thought by many to have strengthened patent rights and led to more findings of infringement than would otherwise

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[81] 126 CONG. REC. 8739 (1980) (statement of Sen. Dole).

[82] Much of the rhetoric used to justify the Bayh–Dole Act accentuated the fact that many products of federally funded research were never commercialized. *See* 125 CONG. REC. 2407 (1979) (statement of Sen. Bayh) ("Of the 30,000 patents that the Government presently holds, less than 4 percent are ever successfully licensed."); Dear Colleague Letter from Sen. Birch Bayh et al. (Feb. 7, 1979) (stating that "[t]he bill addresses a serious and growing problem: hundreds of valuable . . . discoveries are sitting unused under government control") (on file with author).

[83] *See supra* notes 14–17 and accompanying text.

[84] *See* Birch Bayh, *Remarkable Benefits, Remarkable Breakthroughs*, TECHCOMM, Apr.–May 2005, at 12, 29 ("The Bayh–Dole Act was designed to inject the incentive of the free market into what had become a slumbering U.S. patent system.").

have occurred.[85] This specialized court with potential pro-patent leanings privileges inventors over the general public. Similarly, the USPTO provides few opportunities to include the public in its deliberations, and some even suggest that it treats patent applicants as clients and is thus more responsive to their needs than the needs of the public.[86]

This role as a potential entry point for the public voice in matters concerning access to technology is an especially important element of the Bayh–Dole technology transfer system both because of pro-patent tendencies in other areas of the patent system, and because it is part of the bargain that the public strikes with inventors who accept public research funding. Regardless of whether the principle motivation for including march-in rights was to make the Act less offensive to opponents, or whether the drafters intended march-in rights to be used to protect the public interest and encourage commercialization, very few attempts have actually been made to use the provisions.

II. PREVIOUS MARCH-IN ATTEMPTS

Apart from the current Myriad case, there have been five documented petitions for federal agencies to march in on Bayh–Dole subject inventions. All of these petitions were aimed at the NIH and are detailed below.[87] Each of these denials shows the NIH's hesitancy to use march-in provisions. We also see a body of march-in precedent building up over time as the NIH has begun to cite denials of previous march-in petitions to support subsequent denials. In order to demonstrate how the Bayh–Dole march-in provisions have played out in application, the sections below will discuss each of these previous march-in attempts.

A. John Hopkins University v. CellPro

CellPro's march-in petition arose following a legal dispute with Johns Hopkins University over patented inventions that Johns Hopkins had

[85] Jon F. Merz & Nicholas M. Pace, *Trends in Patent Litigation: The Apparent Influence of Strengthened Patents Attributable to the Court of Appeals for the Federal Circuit*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 579, 581 (1994).

[86] Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1984–88 (2009).

[87] That the NIH has been the sole recipient of march-in provisions is likely a product of its very large research budget—and thus oversight over a very large number of Bayh–Dole subject inventions—and the fact that the technologies it oversees are often important both economically and to individuals' health and wellbeing.

developed with funding assistance from the National Institutes of Health.[88] The patents related to technologies used to identify and separate bone marrow stem cells from other cells.[89] CellPro had developed and brought to market two devices used to purify stem cells that Johns Hopkins claimed infringed on its patents.[90]

After losing the infringement suit, CellPro submitted a petition to the NIH, supported by Senator Bayh, requesting that the NIH use its march-in rights to grant licenses that would allow CellPro to continue selling its cell purification devices.[91] In its petition, CellPro argued that Hopkins's licensee Becton Dickinson (Becton) and Becton's sub-licensee Baxter Healthcare (Baxter) were not sufficiently practicing the invention, having not even applied for FDA pre-market approval until thirteen years after filing their patent application.[92] Meanwhile, CellPro had brought a device to market and attained FDA approval for its use.[93] This first line of reasoning used to justify its march-in petition relied on the Bayh–Dole Act's § 203(a)(1) "practical application" requirement.[94] CellPro also argued that the march-in should be allowed for public health reasons,[95] relying on the Act's § 203(a)(2) "public health" march-in allowance.[96]

Harold Varmus, the Director of the NIH at the time, ultimately rejected CellPro's petition.[97] He reasoned that the practical application argument failed because Baxter had achieved regulatory approval in Europe for its stem cell purification device and was in the process of seeking the same in the United States. Varmus held that Hopkins's vigorous protection of its patents and Baxter's pursuit of an active FDA approval application were sufficient to fulfill the Bayh–Dole Act's requirement that patent holders and assignees take "effective steps to achieve practical application" of the technology in question.[98]

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[88] *See* Determination in the Case of Petition of CellPro, Inc., Harold Varmus, Nat'l Insts. of Health, Office of the Dir. 1 (Aug. 1 1997), *available at* http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf [http://perma.cc/YBJ7-BNNL] [hereinafter CellPro Determination].

[89] *See* Johns Hopkins Univ. v. CellPro, 931 F. Supp. 303, 312 (D. Del. 1996).

[90] *Id.*

[91] Tamsen Valoir, *Government Funded Inventions: The Bayh–Dole Act and the* Hopkins v. CellPro *March-in Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211, 223 (2000).

[92] *Id.*

[93] *Id.*

[94] *See* 35 U.S.C. § 203(a)(1) (2012).

[95] Valoir, *supra* note 91, at 223.

[96] 35 U.S.C. § 203(a)(2).

[97] CellPro Determination, *supra* note 88, at 1.

[98] § 203(a)(1); CellPro Determination, *supra* note 88, at 5.

Similarly, Varmus rejected CellPro's health or safety need argument.[99] He held that the district court order allowing CellPro's interim production of its devices until alternative devices attained FDA approval was sufficient to protect public health and safety.[100]

B. Norvir

In 2004, members of the public and Congress petitioned the NIH to march in on Abbott Laboratories' ritonavir (trade name Norvir) patent.[101] The petition arose after Abbott increased the price of Norvir by more than 500%.[102] Petitioners advanced various theories as to why Abbott's price increases justified a statutory march-in,[103] with one of the dominant theories being that Abbott's pricing violated the Bayh–Dole Act requirement that inventions be brought to market under reasonable terms.[104]

Finding that none of the explicit statutory justifications for march-in were present in this case, the NIH rejected the petition and opted not to commence a march-in proceeding.[105] The NIH claimed that Bayh–Dole march-in proceedings were an inappropriate remedy for drug pricing disputes, preferring instead that the Federal Trade Commission pursue the issue as a possible violation of antitrust law.[106]

In 2012 NGOs again petitioned the NIH to march-in on the Norvir patent.[107] This second petition relied on similar justifications as those used

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[99] *See* CellPro Determination, *supra* note 88, at 6.

[100] *See id.* at 1. This order required CellPro to make royalty payments to Baxter. *Id.* at 7.

[101] Determination in the Case of Norvir, Elias A. Zerhouni, Nat'l Insts. of Health, Office of the Dir. 3–4 (July 29, 2004), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf [http://perma.cc/MK5T-7RF8] [hereinafter Norvir Determination I].

[102] *See* David Brown, *Group Says U.S. Should Claim AIDS Drug Patents*, WASH. POST, May 26, 2004, at A04.

[103] Norvir Determination I, *supra* note 101, at 3.

[104] Brown, *supra* note 102; *see also* Petition to use Authority Under Bayh–Dole Act to Promote Access to Ritonavir from Essential Inventions, Inc. 9 (Jan. 29, 2004), *available at* http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf [http://perma.cc/7BDT-KM5K] (arguing that "reasonable terms" include reasonable prices). The requirement that inventions be brought to market under reasonable terms is found in the definitions section of the Bayh–Dole Act in its explication of the meaning of "practical application." 35 U.S.C. § 201(f) (2012); *see also* 37 C.F.R. § 401.2(e).

[105] Norvir Determination I, *supra* note 101, at 4–6.

[106] *Id.* at 6.

[107] *See* Request for March-in on Abbott Patents for Ritonavir from Am. Med. Students Ass'n et al. (Oct. 25, 2012), *available at* http://keionline.org/sites/default/files/2012_Oct25_Ritionavir_march_in_complaint.pdf [http://perma.cc/NTM3-9TY2] [hereinafter Ritonavir Petition from AMSA et al.]. This second petition was brought by four NGOs: the American Medical Students Association, Knowledge Ecology International, U.S. Public Interest Research Group, and the Universities Allied for Essential Medicine. James Love, *Four NGOs Ask NIH to Grant Open Licenses to Ritonavir Patents under Bayh-Dole March-in Provisions*, KNOWLEDGE ECOLOGY INT'L (Oct. 25, 2013, 10:39), http://keionline.org/node/1573 [http://perma.cc/95PE-B4MM].

in the first. Petitioners raised the international price differences as their chief concern and proposed two rules to govern patented inventions that benefited from federal funding. The first proposed rule would have tied American drug pricing to prices in other high-income countries.[108] The second rule proposed mandatory licensing of patented inventions that benefited from federal funding, provided the use was medical in nature.[109]

Unsurprisingly, relying on much the same reasoning as in its 2004 determination, the NIH rejected this second petition.[110] Because Abbvie (Abbott's pharmaceutical spin-off) was able to show widespread availability and use around the world, the NIH found it had achieved the practical application requirement.[111] The NIH also found no risk to health and safety and thus rejected a § 203(a)(2) march-in.[112]

The petitioners also raised a § 203(a)(3) march-in argument[113] by arguing that the Americans with Disabilities Act (ADA) and the Patient Protection and Care Act (PPACA) required that the NIH march in.[114] The NIH rejected this line of reasoning, arguing that this march-in avenue is available "when a statute or regulation . . . specifically requires the use of a patented technology."[115] Because neither the ADA nor the PPACA specifically require the use of Norvir, the NIH determined that march-in would be inappropriate.[116]

In ruling not to begin a march-in proceeding on Norvir, the NIH also rejected petitioners' two rule proposals.[117] The director of the NIH, Francis S. Collins, seems to suggest that the NIH's statutory authority requires case-by-case analysis to determine whether any of the four Bayh–Dole march-in criteria are met.[118] Pronouncing rules like those proposed by the

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[108] Ritonavir Petition from AMSA et al., *supra* note 107, at 16–17.

[109] *Id.* at 18.

[110] *See* Determination in the Case of Norvir, Francis S. Collins, Nat'l Insts. of Health, Office of the Dir. 2, 4–6 (Nov. 1, 2013), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf [http://perma.cc/HK52-FRVJ] [hereinafter Norvir Determination II].

[111] *Id.* at 4.

[112] *Id.* at 4–5.

[113] This section allows for march-in "to meet requirements for public use specified by Federal regulations." 35 U.S.C. § 203(a)(3) (2012).

[114] *See* Norvir Determination II, *supra* note 110, at 5. Petitioners argued that the pricing was prejudicial against those with HIV and thus contravened the ADA's prohibition of discrimination against those with disabilities, and that the high price for Norvir was tantamount to a preexisting condition limitation in violation of the PPACA. Ritonavir Petition from AMSA et al., *supra* note 107, at 14.

[115] Norvir Determination II, *supra* note 110, at 5.

[116] *Id.*

[117] *Id.* at 6.

[118] *Id.*

petitioners would extend march-in power beyond that allotted by the Bayh–Dole Act.

C. Xalatan

The latanoprost (trade name Xalatan) case shares many similarities with the first Norvir petition. Both petitions were made by Essential Inventions, a Washington-based nonprofit organization.[119] Pfizer marketed Xalatan to treat Glaucoma but charged different prices across markets.[120] The petitioners argued that Pfizer's American pricing for Xalatan was excessive, as evidenced by lower pricing in Canada and Europe.[121]

In its response to the Xalatan march-in petition, the NIH argued that the case did not fall under any of the § 203 march-in categories.[122] When assessing the § 203(a)(1) "practical application" requirement, the NIH drew on the precedent it had established in the CellPro and Norvir cases. The Director argued that, as in the previous cases, manufacturing the product and making it available to the public is sufficient to fulfill the practical application requirement.[123]

When assessing the possibility of a § 203(a)(2) health and safety march-in, the NIH argued that petitioners had brought forth no evidence to suggest that marching in would alleviate any health or safety concerns.[124] The fact that Xalatan was a widely prescribed FDA-approved drug seemed to weigh in its favor.[125]

As in the case of Norvir, the NIH again argued that pricing was not an appropriate justification for a Bayh–Dole march-in.[126] Expressing concern about the potential implications for the "market dynamics" of products

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[119] Lisa Richwine, *US Firm Seeks License for Pfizer, Abbott Drugs*, REUTERS, Jan. 28, 2004, *available at* Factiva, Doc. No. LBA0000020040128e01s0084w; *see also* Petition to Use Authority under Bayh–Dole Act to Promote Access to Latanoprost from Essential Inventions Inc. (Jan. 29, 2004), *available at* http://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf [http://perma.cc/9CFC-DBYZ].

[120] Richwine, *supra* note 119.

[121] Determination in the Case of Xalatan, Elias A. Zerhouni, Nat'l Insts. of Health, Office of Dir. 1 (Sep. 17, 2004), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf [http://perma.cc/YSR2-BQUB] [hereinafter Xalatan Determination].

[122] *Id.* at 4–6.

[123] *Id.* at 4–5.

[124] *Id.* at 5.

[125] *Id.* In addition to dismissing the practical application and public health and safety justifications for march-in, the NIH avoided discussing the other two prongs of the march-in analysis (the Federal Regulations stipulation and domestic manufacture requirements) based on similarity with the Norvir Determination I, *supra* note 101, where they were held to be "clearly not relevant." Xalatan Determination, *supra* note 121, at 5 nn.5–6.

[126] Xalatan Determination, *supra* note 121, at 6.

developed under licenses subject to the Bayh–Dole Act, the NIH opted instead to leave the issue of drug pricing to Congress.[127]

D. Fabrazyme

In 2010 three individuals with Fabry's disease petitioned the NIH to march in on Genzyme's patent for Fabrazyme, the only approved treatment for the disease.[128] The petitioners grounded their plea for a march-in proceeding in § 203(a)(2), arguing that forced licensing was "necessary to alleviate health or safety needs."[129]

NIH-funded research at Mount Sinai School of Medicine had led to the development of Fabrazyme. Mount Sinai subsequently sold an exclusive license for the related patents to Genzyme.[130] Genzyme's monopoly on Fabrazyme production resulted in shortages when its plant became contaminated with a virus and had to be shut down for decontamination.[131] This shortage in turn led to treatment rationing for those suffering from Fabry's disease.[132] In order to remedy the drug shortage, the Fabry disease sufferers petitioned for a march-in that they hoped would lead to an open license on the Fabrazyme patents and payment of a "reasonable royalty" to Genzyme.[133]

As in the four previous petitions, the NIH declined to commence a march-in proceeding.[134] Based on the information available at the time, the NIH reasoned that granting a march-in on the Fabrazyme patents would not alleviate the drug shortage because no competitors were at the time expecting "imminent FDA approval of a competing version."[135] Even if it had granted licenses, any Fabrazyme competitors would have had to go through the lengthy FDA approval process.[136] Genzyme was scheduled to

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[127] *Id.*

[128] *See* Petition to Use the Bayh–Dole Act to Promote Access to Fabrazyme from C. Allen Black, Jr. (Aug. 2, 2010), *available at* http://keionline.org/sites/default/files/fabrazyme_petition_2aug2010.doc [http://perma.cc/8JA9-MGTM] [hereinafter Fabrazyme Petition]; Pollack, *Patients Want Patent Broken*, *supra* note 78.

[129] Fabrazyme Petition, *supra* note 128, at 6 (quoting 35 U.S.C. § 203(a)(2)).

[130] Pollack, *Patients Want Patent Broken*, *supra* note 78.

[131] Victor Bethencourt, *Virus Stalls Genzyme Plant*, 27 NATURE BIOTECHNOLOGY 681, 681 (2009).

[132] Pollack, *Patients Want Patent Broken*, *supra* note 78.

[133] Fabrazyme Petition, *supra* note 128, at 12 (quoting 35 U.S.C. § 203(a)(2)).

[134] Determination in the Case of Fabrazyme, Francis S. Collins, Nat'l Insts. of Health, Office of the Dir. 1 (Dec. 1, 2010), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf [http://perma.cc/8SAG-S772] [hereinafter Fabrazyme Determination].

[135] *Id.*

[136] *See* 21 C.F.R. pt. 314 (2014).

have resumed full production before any competitor could possibly have been approved for commercialization.[137]

The NIH also pointed out that, despite the petition's request to also provide alternate manufacturers with the Fabrazyme cell line and Genzyme's technical know-how, the Bayh–Dole Act march-in powers only apply to the subject inventions, not the associated "tangible materials or unpatented technical know-how."[138]

In April 2011, following the NIH's decision not to commence march-in proceedings, the Fabry's patients petitioned the Department of Health and Human Services (HHS) asking for a rehearing of their original petition and a rulemaking to clarify when Bayh–Dole march-ins should be initiated.[139] After Genzyme had revised their original goal of rectifying the supply problem from the first half of 2011 to the second half, petitioners argued that Genzyme's predictions were unreliable and that the NIH should thus grant patent licenses to other manufacturers.[140] The petitioners also argued that Genzyme's redirection of some Fabrazyme stock to Europe, where approved alternatives existed, also supported a march-in to protect American health and safety.[141]

Along with their petition for a rehearing, the petitioners requested the promulgation of new regulations to clarify march-in procedure and encourage more third parties to petition for march-in licenses.[142] The suggestions included stricter regulations of manufacturers, forcing them to notify the NIH of potential shortages; publicization of potential shortages to encourage third parties to seek march-in licenses; a duty on contractors and licensees to report on use and distribution of the invention; and a lower bar to granting march-in licenses when there is a clear threat to human health.[143]

In February 2013, the NIH again declined to commence a march-in proceeding, and closed the file on the Fabrazyme march-in petition.[144] In

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[137] Fabrazyme Determination, *supra* note 134, at 1–2.

[138] *Id.* at 2.

[139] Petition for Rehearing and Rulemaking Regarding In the Case of Fabrazyme from C. Allen Black, Jr. 2 (2011), *available at* http://www.patentlawyersite.com/files/Download/NIH%20PETITION%20FOR%20RULEMAKING%20AND%20REHEARING%209.pdf [http://perma.cc/5EQ2-JJZD] [hereinafter Petition for Fabrazyme Rehearing].

[140] *Id.* at 6.

[141] *Id.* at 8–9.

[142] *Id.* at 18–19.

[143] *Id.* at 19–21.

[144] Fabrazyme March-in Close-out, Mark L. Rohrbaugh, Nat'l Insts. of Health 2 (Feb. 13, 2013), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/Fabrazyme-CABlack.pdf [http://perma.cc/342J-6L37].

support of the outcome, Dr. Rohrbaugh stated that by late 2012 Genzyme had restored full dosing to all patients, and that the NIH had received no requests from third parties wishing to license the Fabrazyme patents.[145]

E. Summary of March-in Petitions

The above Sections detail each of the five past Bayh–Dole march-in petitions.[146] Every one of these petitions came to the same end, with the NIH declining to commence a march-in proceeding. Table 1 summarizes these previous petitions, the § 203 causes of action that they raised, and the reasons that the NIH used to justify not commencing march-in proceedings.

TABLE 1: MARCH-IN PETITIONS & OUTCOMES

	Argument for March-in	**Reason for Declining**
CellPro (1997)	Practical application – § 203(a)(1) Public health and safety – § 203(a)(2)	Application imminent; Interim usage allowed following patent infringement case.
Norvir (2004)	Unreasonable pricing	Unreasonable pricing not an enumerated march-in justification
Xalatan (2004)	Unreasonable pricing	Unreasonable pricing not an enumerated march-in justification
Norvir II (2012)	Unreasonable pricing	Unreasonable pricing not an enumerated march-in justification
Fabrazyme (2010)	Public health and safety – § 203(a)(2)	March-in deemed incapable of timely alleviating drug shortage

III. WHY MARCHING IN IS UNPRECEDENTED

The complete lack of not only a successful march-in petition, but even the commencement of a march-in proceeding, is due to both the rare nature of march-in petitions and the nature of the Bayh–Dole Act and its enforcement. There have been few opportunities for federal agencies to exercise their march-in rights. With only five recorded petitions and determinations, it is not surprising that a march-in has never occurred. In addition, Bayh–Dole's emphasis on property rights to encourage commercialization makes agencies wary of trammeling on those rights out

[145] *Id.* at 1.

[146] To my knowledge, these five examples represent the entire population of Bayh–Dole march-in petitions submitted since the Act came into effect in 1980.

of fear that this might upset the technology transfer incentives that have thus far proven successful.

A. Lack of Petitions

In the over thirty years since the Bayh–Dole Act went into effect, there have been only six notable march-in petitions targeting only five separate inventions.[147] There are two possible explanations for this phenomenon: either the federal technology transfer system works so well that all useful inventions are used and more march-in petitions would be inappropriate or no one is submitting petitions in instances where march-ins would be appropriate.

Given that federal funding agencies have had march-in rights over hundreds of thousands of inventions, it is difficult to believe that none but the five noted above were viable march-in targets. For this to be the case it would require every other invention that has arisen from federally funded research to have been fully used to the extent of its utility and the demand for it in the marketplace. It is highly unlikely that this has been the case. This strongly suggests that there *are* possible march-in target inventions that no one is petitioning for.

There are three nonexclusive explanations for the lack of petitions on inventions that might merit one: potential petitioners may be unaware of the inventions or the government's march-in right (an information gap); alternately, it could be that there is insufficient market demand for the inventions and thus no incentive to petition for a march-in (insufficient demand); finally, it is possible that, even in cases with sufficient information and demand, the low chance of success discourages parties from investing in march-in petitions (perceived futility). From a technology transfer policy perspective, the information gap and perceived futility explanations raise concerns that merit special consideration, while the insufficient demand explanation mirrors a challenge common to patent law more generally.

The information gap explanation would suggest that there are potentially useful inventions that, but for some party's ignorance of either the existence of the invention or the government's march-in rights over it,

[147] These are the five listed *supra* Part II and the recent Myriad petition. To the best of my knowledge these six are the totality of serious petitions received by federal funding agencies. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 9 (2009) *available at* http://www.gao.gov/new.items/d09742.pdf [http://perma.cc/A2AX-PSW7] [hereinafter GAO REPORT] (explaining that the DOD, DOE, and NASA have never received march-in petitions, while, as of 2009, the NIH had received only three).

would otherwise be commercialized.[148] Similarly, the perceived futility explanation suggests that there may be inventions that would attract march-in petitions and potentially justify a march-in were it not for the current pro-property-right design of the technology transfer system. On the other hand, the insufficient demand explanation raises no concerns that are peculiar to technology transfer law. The challenges faced in developing low-demand inventions are well-known and would not be best dealt with by technology transfer statutes.

Some argue that the lack of march-in petitions is emblematic of market forces that will naturally lead to a dearth of Bayh–Dole march-ins. For instance, shortly after the CellPro decision, some argued that market forces will preempt the use of march-in rights.[149] This argument assumes a perfectly functioning market in which potentially profitable inventions will always be developed while unprofitable inventions will not attract march-in petitions.[150] That said, given the sheer number of inventions that arise from federally funded research, there are almost certainly Bayh–Dole subject inventions that are not commercialized in the most efficient manner. March-in rights should be honed so that they can be used to minimize delays in the commercialization of these sorts of inventions.

B. The Nature of the Bayh–Dole Act and its Enforcement

Along with the lack of petitions, the nature of the Bayh–Dole Act itself and the way it is implemented by federal funding agencies offers another explanation for why march-in proceedings are unprecedented.

1. The Act's Intent.—Congress intended the Bayh–Dole Act to increase the commercialization of federally funded inventions.[151] This statutory intent discourages marching in by federal funding agencies because the specter of forced licenses would act as a disincentive to investment in commercialization. Granting forced licenses would leave inventors or their licensees uncertain about the degree of market exclusivity they might enjoy and thus less likely to invest in commercializing inventions that may ultimately be made available to their competitors.

This line of reasoning reflects the general belief in the value of strong property rights as an integral facet of effective innovation policy.[152] In some

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[148] *See infra* Part IV.A.

[149] *See, e.g.*, Kevin W. McCabe, *Implications of the CellPro Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-in Right?* 27 PUB. CONT. L.J. 645, 649 (1997).

[150] *Id.* at 662.

[151] *See* 35 U.S.C. § 200 (2012).

[152] *See* Kieff *supra* note 67; GAO REPORT, *supra* note 147, at 8.

ways, the Bayh–Dole Act represents the culmination in the postwar trend towards greater protections for intellectual property because, while it creates march-in rights, they are designed in a manner that makes it highly unlikely that they will be successfully used.

2. Agency-by-Agency Interpretation and Lack of Oversight.—The lack of a standard Bayh–Dole interpretation among funding agencies and potential conflicts of interest at agency technology transfer offices present another set of issues that may discourage effective march-in petitions. While agencies rely on Department of Commerce regulations on the Bayh–Dole Act's implementation of march-in rules, each agency is free to interpret the Act itself to determine whether or not it should exercise march-in authority.[153] Furthermore, there is no central body monitoring the outcome of march-in petitions to ensure that agencies are applying the rules in a consistent manner. Admittedly, this has been a nonissue as the NIH has been the only agency faced with applying the rules, but it nonetheless injects a potential point of ambiguity into the federal technology transfer system. Possible march-in petitioners cannot be sure that other agencies will approach the march-in issue in a manner similar to that used by the NIH. This uncertainty makes potential petitioners less likely to invest the time and resources necessary to pursue a petition.

3. Possible Conflicts of Interest.—The role played by agency officials charged with assessing march-in petitions offers another potential point of ambiguity in the march-in system. There is some concern that, at least in the NIH's case, these officials may have some conflict of interest in applying the Bayh–Dole Act.[154] Dr. Francis S. Collins, the director of the NIH at the time of the Fabrazyme march-in petition, is listed as an inventor on at least nineteen inventions to which Bayh–Dole provisions apply.[155] This raises the concern that he may have some interest in the development of the NIH's Bayh–Dole precedent because the value of the statutory royalties he receives may be affected should the NIH begin to grant march-in licenses. The concern here is that the NIH appears to be building a set of march-in precedent as it relies on previous determinations to inform petitions.[156] If that precedent is informed by individuals with a pecuniary interest in not granting march-in petitions it may end up being more anti-march-in than it otherwise might have.

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[153] GAO REPORT, *supra* note 147, at 7.

[154] Petition for Fabrazyme Rehearing, *supra* note 139, at 17–18.

[155] *Id.* at 17.

[156] *See* Norvir Determination II, *supra* note 110.

This raises the related issue of regulatory capture.[157] The lack of oversight over federally funded inventions leads to concerns that agencies charged with managing public rights in Bayh–Dole subject inventions advance the interests of researchers and patent rights holders, rather than making decisions that advance the public interest. There are numerous reasons to think that this concern is warranted. The fact that agencies often have repeat relationships with funding recipients suggests they may be more likely to reach decisions favorable to those parties so as to maintain good relations. Similarly, the "revolving door" problem of agency employees pursuing subsequent careers in the private sectors they were once charged with regulating is a potential concern for federal technology transfer managers.[158]

4. Procedural Design Stacked Against Petitioners.—The march-in procedure's design is another factor that discourages successful march-in petitions. The procedure, as detailed in 37 C.F.R. § 401.6, gives complete discretion to funding agencies over the process and allows no appeal right to petitioners. The degree of discretion enjoyed by funding agencies starts petitioners off from a point of great uncertainty. Initially, the funding agency in question has complete discretion as to whether or not it will even commence a march-in proceeding[159]—indeed we saw above that all petitions thus far have resulted in the NIH using this discretion to opt not to commence a proceeding. Furthermore, even if an agency does commence a proceeding, it can terminate the proceeding at any point if it decides it does not wish to exercise its march-in rights.[160] The scope of this complete discretion may discourage possible petitioners from submitting march-in petitions because there is little to ensure that their petition will be granted a thorough review on the merits.

The fact that petitioners have no right of appeal compounds this complete agency discretion. Should a proceeding commence and the agency come to a decision "unfavorable to the contractor" (i.e., should the agency opt to exercise its march-in rights), the decision will be held in abeyance for sixty days, giving the patent rights holder an opportunity to file an appeal with the United States Court of Federal Claims.[161] Petitioners have no such right. If and when agencies decline to exercise their march-in

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[157] *See generally* Ernesto Dal Bó, *Regulatory Capture: A Review*, 22 OXFORD REV. OF ECON. POL'Y 203 (2006); Jean-Jacques Laffont & Jean Tirole, *The Politics of Government Decision-Making: A Theory of Regulatory Capture*, 106 Q. J. OF ECON. 1089 (1991).

[158] For a discussion of the "revolving door" phenomenon, see Dal Bó, *supra* note 157, at 214–15.

[159] 37 C.F.R. § 401.6(b) (2014).

[160] *Id.* § 401.6(h).

[161] 35 U.S.C. § 203(b) (2012); 37 C.F.R. § 401.6(j).

rights there is no right to an appeal. This bias towards protecting intellectual property rights reflects the general tenor of the Bayh–Dole Act, but the result is that potential petitioners may be discouraged from investing in petitioning for a march-in when the procedure so clearly favors the patent holders.

The reasons discussed above—information gaps, perceived futility of petitioning, lack of standard Bayh–Dole precedent, potential conflicts of interest, and a procedural design stacked against petitioners—all combine to make the effective use of march-in rights highly unlikely. This is a concern because march-in rights provide one of the key tools to protect the public's interest in accessing inventions that it bankrolled. In order to ensure that march-in rights can effectively serve this function, some reforms are needed.

IV. REFORMS TO PROTECT THE PUBLIC INTEREST

The final section of this Note proposes a variety of procedural and substantive reforms that will help ensure that the Bayh–Dole march-in provisions effectively protect the public interest in publicly funded inventions. Procedural reforms include shifting the balance of the march-in proceeding to better represent the interests of the petitioner and public as well as establishing central oversight of federal agencies' application of Bayh–Dole transfer. Substantive reforms suggested include a more stringent interpretation of the Act's "practical application" requirement and instituting an open bidding process for Bayh–Dole subject invention licenses.

A. Procedural Reforms

Instituting an appeal process for petitioners and further centralizing the execution of Bayh–Dole are both attainable procedural reforms that would help ensure the public interest is protected by the Bayh–Dole march-in provisions.

The march-in procedure is currently slanted in favor of funding recipients at the expense of those who would have federal agencies march in on Bayh–Dole subject inventions.[162] At the least, this imbalance could be corrected by granting petitioners an appeal right equal to that granted to contractors in 37 C.F.R. § 401.6(j). This would ensure that, if a march-in proceeding ensues and the petition is subsequently denied, the petitioners would be entitled to an appeal to ensure that the correct conclusion was reached.

[162] *See supra* Part III.

To further balance the procedure, the National Institute of Standards and Technology (NIST) could provide a centralized second-look service when agencies decline to commence march-in proceedings after they are petitioned to do so. This would help ensure that there is a check on the currently unchecked discretion that agencies enjoy in deciding whether or not to commence a march-in proceeding. The NIST is already tasked with maintaining the march-in procedure regulations.[163] Having the NIST also monitor march-in petitions and ensure that agency determinations are not abuses of agency discretion would help protect the public interest in publicly-funded inventions.

The NIST could serve other functions as a centralized regulator of the march-in process. In addition to serving as a check on agency discretion, the NIST could maintain a centralized database of Bayh–Dole subject inventions. This would help alleviate the information gap that may contribute to the lack of march-in petitions.[164] Such a database would document all of the inventions that federal agencies have march-in rights over. Providing this sort of centralized record of all Bayh–Dole subject inventions would allow the public to better monitor its investment in research and development to ensure that these inventions are appropriately developed and utilized.

The NIST could also more closely monitor problematic inventions to ensure that their commercialization is proceeding in an acceptable manner. More active monitoring would provide further incentive for effective commercialization. Under the status quo, any signs of commercialization, or intent to commercialize in the future, can be interpreted as sufficient to withstand a § 203(a)(1) practical application march-in petition. Closer monitoring of especially important inventions or inventions that petitioners have indicated as problematic in their commercialization would act as a signal to the contractor or licensee encouraging them to commercialize or risk losing their exclusivity over the invention.

This monitoring could take the form of scheduled reports from those who license Bayh–Dole subject inventions.[165] If licensees have a duty to

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[163] *See* Redelegations of Authority Resulting From the America COMPETES Act, 78 Fed. Reg. 4764 (Jan. 23, 2013).

[164] *See supra* Part III.A.

[165] This is not an entirely novel suggestion. In fact, early after the Bayh–Dole Act was implemented, at least one agency wished to see plans for the "development and marketing" of products before agreeing to extend licenses on Bayh–Dole subject inventions. *See* Letter from Donald Ian MacDonald, Acting Assistant Sec'y for Health, Dep't of Health & Human Servs., to Alan R. Bennett (June 3, 1986) (on file with author). However, the bill's drafters opposed this policy and the 1984 amendments were intended "to make it a matter of routine for contractors to grant exclusive licenses to licensees" for the life of the patent without requiring any showing of intent to commercialize. Letter

report their progress on commercializing subject inventions to the NIST, it will allow not only for NIST oversight to ensure that patents are not being licensed and shelved for strategic reasons, but it could also provide more information to help close the information gap described above. If these reports were public, groups interested in certain inventions and competitors who may benefit from a march-in would be able to use the commercialization reports to monitor inventions of interest and perhaps inform march-in petitions.

Some might argue that a duty to report on the progress of commercializing Bayh–Dole subject inventions adds an unnecessary administrative burden to the process of dealing with federal funding agencies. While it is true that it would somewhat increase administrative costs for the patent rights holders, it is also true that they are the recipients of very large sums of public money and if adding a duty to report commercialization progress will help ensure that the public's resources are well-used, then a minor administrative burden is tolerable.

B. Substantive Reforms

Along with the procedural reforms proposed above, the substance of Bayh–Dole march-in law could be changed to ensure that the public's interest remains protected. By recasting "practical application" to more stringently police commercialization, and by mandating auctions for licenses on Bayh–Dole subject inventions, Congress could improve the efficiency of the federal technology transfer system.

The Bayh–Dole Act's practical application requirement requires that subject inventions are made "available to the public on reasonable terms."[166] Petitioners raised this argument as justification for march-in in the Norvir and Xalatan cases.[167] Each time petitioners raised this argument, the NIH responded by suggesting that the FTC or Congress would be better suited to regulate drug pricing.[168] Congress could do so by clarifying the

from Sen. Bob Dole to Otis M. Brown, Sec'y, Dep't of Health & Human Servs. (Apr. 8, 1986) (on file with author).

[166] 35 U.S.C. § 201(f) (2012).

[167] Ritonavir Petition from AMSA et al., *supra* note 107, at 9; Petition to use Authority Under Bayh–Dole Act to Promote Access to Ritonavir from Essential Inventions, Inc. 9 (Jan. 29, 2004), *available at* http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf [http://perma.cc/PU2C-ZBAS]; Petition to Use Authority Under Bayh–Dole Act to Promote Access to Latanoprost from Essential Inventions, Inc. 6 (Jan. 29, 2004), *available at* http://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf [http://perma.cc/VQW5-UTXN].

[168] *See* Norvir Determination I, *supra* note 101, at 5–6; Xalatan Determination, *supra* note 121, at 6.

meaning of the "reasonable terms" that Bayh–Dole subject inventions must be brought to market under.

The Bayh–Dole Act attempts to balance the commercialization of federally funded inventions with the right of the people to access the fruits of publicly funded research. When the fruits of that research are available to citizens of foreign nations—who have not subsidized the cost of the research—for much lower prices, it suggests that the balance has not been adequately struck. To correct this imbalance, Congress could amend the Bayh–Dole Act to mandate a most-favored-nation status requiring that subject inventions be brought to market in the U.S. on terms at least as amendable as the terms in similarly economically developed countries. Petitioners in the second Norvir march-in petition argued for a similar rule that would bar U.S. prices from exceeding the prices in seven peer countries, or exceeding the median peer country price by more than 10%.[169]

Adoption of a most-favored-nation pricing rule for Bayh–Dole subject inventions would help discourage profiteering off of public research. As discussed above, in their current state, march-in rights are an ineffective price regulation tool. The result is that when contractors or their licensees have an invention with few close substitutes, they may engage in monopoly pricing. In the case of Norvir, when researchers discovered that the dosage could be reduced and the drug combined with other protease inhibitors, Abbott increased Norvir's price by over 500%.[170] Despite the fact that the federal government provided Abbott with $3.5 million in research funding that helped lead to Norvir's invention,[171] the federal technology transfer policy as it is currently implemented does nothing to regulate this sort of pricing behavior.

Beyond the drug-pricing concern, Congress could also clarify the practical application requirement in a manner that would set minimum standards for commercialization efforts. The five unsuccessful march-in petitions detailed above suggest that the NIH uses a relatively forgiving interpretation of practical application. It seems likely that if a licensee can show any efforts at development, regardless of their efficacy, the NIH is hesitant to march in because it fears upsetting the incentives for licensees to license and develop inventions.

Congress could increase incentives to commercialize effectively by requiring that licensees use "best efforts" to bring inventions to the point of practical application. Instead of allowing those holding rights in Bayh–

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[169] Ritonavir Petition from AMSA et al., *supra* note 107, at 16–17.

[170] *See* Brown, *supra* note 102.

[171] *Id.*

Dole subject inventions to meet the practical application bar by showing any activities aimed at using the invention, a best efforts standard would require rights holders to be diligent in their efforts to bring the invention to the point of practical application.[172] This heightened standard would leave licensees at risk of a march-in if they were to neglect the Bayh–Dole subject inventions that they license. Given the importance of effective commercialization that underpins the Bayh–Dole Act, this increased focus on efforts to develop licensed inventions is commensurate with the Act more generally and with the public's interest in ensuring efficient use of public research funding.

In addition to altering its treatment of the practical application requirement, Congress could further encourage commercialization by establishing rules that help ensure the best candidate licenses Bayh–Dole subject inventions. This could be done by requiring public auctions for licenses on Bayh–Dole subject inventions. Under the current system, licenses can be granted in any manner the rights owner desires. There is no assurance that patents are shopped to various licensees, or even shopped at all. While one might expect rational recipients of federal funding to diligently seek out the most lucrative licenses possible, there is evidence to suggest that this often does not occur.[173] A mandatory auction system with publicity requirements would help ensure that all parties interested in commercializing an invention get the opportunity to license it.

CONCLUSION

The Bayh–Dole Act attempts to balance incentives to commercialize with access to federally funded research. The march-in provisions are meant to provide assurance that inventions arising from federally funded research are adequately commercialized. However, the march-in process is currently designed in such a manner that it will almost certainly never be effectively used.

As currently designed, march-in procedure is unbalanced. It protects the rights of patent holders much more thoroughly than it protects the public's right to access federally funded inventions. Agency discretion is unchecked, and there is little oversight to ensure that the march-in process

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[172] *See* E. Allan Farnsworth, *On Trying to Keep One's Promises: The Duty of Best Efforts in Contract Law*, 46 U. PITT. L. REV. 1, 8 (1984) ("Best efforts is a standard that has diligence as its essence and is imposed only on those contracting parties that have undertaken such performance.").

[173] *See* Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503, 1521 (2012) (arguing that "licensing markets for university inventions are strikingly 'thin' and that personal relationships between industry and university personnel—including faculty inventors—are critical").

is effectively managed. In addition, there is a dearth of information about which inventions are subject to the Bayh–Dole Act, leaving the public uncertain about when march-in rights are even an option.

A few minor reforms to the system could help ensure that march-in petitions are given the attention they deserve and that federally funded research is commercialized on reasonable terms. Potential reforms include instituting an appeal process that would allow petitioners to appeal agency decisions not to march in on Bayh–Dole subject inventions, mandating a duty to use "best efforts" to bring subject inventions to the point of practical application and to report on those efforts. In addition, Congress should clarify the meaning of Bayh–Dole's "reasonable terms" requirement, and consider instituting a requirement that subject inventions be marketed in the United States at internationally competitive rates. Finally, a requirement that subject inventions be licensed via public auction rather than private negotiation would help ensure that those best suited to commercializing inventions have the chance at securing the rights to them. These reforms would help ensure that the effective federal technology transfer system implemented by the Bayh–Dole Act remains a robust contributor to American innovation for the foreseeable future.