

March-in Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?

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I. INTRODUCTION

The economic malaise of the late 1970s was accompanied by what many in the public perceived to be a related “technological malaise.”¹ Much of the responsibility for this perceived innovation stagnation was laid at the doorstep of the nation’s patent policy which, at the time, vested ownership of patents resulting from federally-funded research with the government agency responsible for funding the initial research.² The government was perceived as ineffective at licensing out its patents to private parties,³ causing discoveries derived from federally funded research to rarely make their way to market as commercially useful products.⁴ Addressing these concerns, reformers reasoned that private, not government, ownership of patents resulting from federally-funded research was necessary to motivate investment and transform discoveries into commercially useful products.⁵ These reforms were manifested in the

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¹ See *Innovation’s Golden Goose*, ECONOMIST: TECH. Q., Dec. 12, 2002, available at <http://www.economist.com/node/1476653>.

² *Id.*; see also Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663–64 (1996) (describing the perception of government ownership of patents as a “treacherous quicksand pit in which discoveries sink beyond reach of the private sector”).

³ *Innovation’s Golden Goose*, *supra* note 1 (“Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent.”); Eisenberg, *supra* note 2, at 1664 (“If the results of federally-sponsored research were to be rescued from oblivion and successfully developed into commercial products, they would have to be patented and offered up for private appropriation.”).

⁴ *Innovation’s Golden Goose*, *supra* note 1 (“[W]ithout that [exclusive licensing] few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.”).

⁵ See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of*

Bayh-Dole Act of 1980 (the "Act"), which allowed small businesses and academic institutions receiving federal research funds to own any patents resulting from that research, and to convey exclusive rights to those patents to private firms.⁶

Although the Act's primary concern was to encourage private investment and innovation, the Act's drafters also endeavored to protect the public from harm, which might result from a private firm's nonuse or unreasonable use of an invention that the public had funded.⁷ To that end, the Act contains two significant reservations of government rights.⁸ First, the federal government retains a non-exclusive, non-transferable, royalty-free license to use the patent "for or on behalf of the United States."⁹ Second, the federal funding agency can, under certain legally prescribed circumstances, "march-in" and compel the patent holder to grant a license to a "responsible applicant."¹⁰ The federal funding agency may exercise its march-in rights *sua sponte* or at the request of a third party.¹¹

An agency may march-in if it finds that "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees"¹² or if "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."¹³ Despite this potentially broad statutory language, no

Biomedicine, 68 L. & CONTEMP. PROBS. 289, 290 (2003).

⁶ Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019–28 (1980) (codified as amended at 35 U.S.C. §§ 200–12 (2006)).

⁷ 35 U.S.C. § 200 ("It is the policy and objective of the Congress to promote the utilization of inventions arising from federally supported research or development . . . [and] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and *protect the public against nonuse or unreasonable use* of [those] inventions.") (emphasis added).

⁸ *Id.* § 202(c)(4), § 203(a).

⁹ *Id.* § 202(c)(4).

¹⁰ *Id.* § 203(a).

¹¹ *Id.*

¹² *Id.* § 203(a)(2).

¹³ 35 U.S.C. § 203(a)(1). The Act also provides two other circumstances under which an agency may march-in which are not relevant to this Comment. *See id.* § 203(a)(3) (providing for march-in rights when "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees"); *id.* § 203(a)(4) (providing for march-in rights when "action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204").

federal funding agency has ever exercised its march-in rights.¹⁴ The only agency which has ever been petitioned under the Act's march-in rights provision is the National Institutes of Health (NIH); and, it has declined to do so on four separate occasions.¹⁵ This has raised questions regarding whether there are any circumstances under the Act which would ever prompt the NIH, or another agency, to exercise its march-in rights.¹⁶

The most recent petition was from a group of Fabry disease patients which asked the NIH to use its march-in power to address an emergency drug shortage.¹⁷ Fabry disease is a rare genetic disorder which has only one FDA approved treatment: agalsidase beta, known commercially as Fabrazyme.¹⁸ Fabrazyme is subject to the Act's march-in rights provisions because the NIH funded the initial research that resulted in its discovery.¹⁹ The supply of Fabrazyme was interrupted in June 2009,²⁰ resulting in massive rationing of the drug which has caused a resurgence of the patients' painful symptoms and, allegedly, the deaths of at least three patients.²¹ In response to this health emergency, a group of Fabry disease patients petitioned the

¹⁴ Kevin W. McCabe, Note, *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 (1998) ("The Government's march-in right has existed in relative obscurity—never used and largely forgotten—since 1964.").

¹⁵ See *In re* Fabrazyme, Manufactured by Genzyme Corp., (Nat'l Insts. of Health, 2010) (determination), available at <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf> (last visited Sept. 23, 2013) [hereinafter "Fabrazyme Determination"]; *In re* Norvir, Manufactured by Abbot Laboratories, Inc., (Nat'l Insts. of Health, 2004) (determination), available at <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf> (last visited Sept. 23, 2013) [hereinafter "Norvir Determination"]; *In re* Xalatan, Manufactured by Pfizer, Inc., (Nat'l Insts. of Health, 2004) (determination), available at <http://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf> (last visited Sept. 23, 2013) [hereinafter "Xalatan Determination"]; *In re* Petition of CellPro, Inc., (Nat'l Insts. of Health, 1997) (determination), available at <http://www.nih.gov/news/pr/aug97/nihb-01.htm> (last visited Jan. 29, 2012) [hereinafter "CellPro Determination"].

¹⁶ See generally McCabe, *supra* note 14.

¹⁷ See Fabrazyme Determination, *supra* note 15, at 1.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ See Robert Weisman, *Genzyme Struggles to Recover From Virus*, BOS. GLOBE (Sept. 21, 2009), http://www.boston.com/business/healthcare/articles/2009/09/21/genzyme_struggles_to_rebound_from_virus_setback/.

²¹ See Susan Donaldson James, *Fabry Disease Patients Get Sicker as Drugs Go Overseas*, ABC NEWS (Aug. 30, 2011), <http://abcnews.go.com/Health/fabry-disease-patients-sicker-sue-drug-company-lifesaving/story?id=14403759>.

NIH, requesting that the agency march-in and force the drug's manufacturer, Genzyme Corporation, to grant a non-exclusive open license to a third party who could then begin manufacturing the drug in an attempt to alleviate the shortage.²² The NIH denied the patients' request on the grounds that the circumstances did not meet the legal standard necessary to warrant a march-in under the Act.²³ Although Genzyme initially predicted that the shortage would only last six to eight weeks,²⁴ full production did not resume until March 2012.²⁵

Scholarly literature on the issue of government march-in rights has focused largely on the more amorphous question of whether or not march-in authority can be utilized as a mechanism to enforce drug price controls.²⁶ There is a dearth of literature, however, on the narrower question that this Comment seeks to address: given the NIH's determinations in the Fabryzyme case and other prior cases, what circumstances, if any, would ever warrant a march-in in order to protect the public health and safety? This Comment will argue that the reasoning relied upon in the NIH's Fabrazyme determination is legally incorrect, and, practically speaking, effectively reads march-in rights as a public protection mechanism out of the Act. This Comment will demonstrate that the NIH's interpretation of the Act ignores both the plain legal standard set forth in the Act itself as well as congressional intent.

If the NIH changes its interpretation of its march-in authority, the agency will help to more effectively protect the public in future

²² See Fabrazyme Determination, *supra* note 15.

²³ *Id.*

²⁴ See *Will There Be One Global Recommendation for Supply Allocation of Cerezyme® (imiglucerase for injection) and/or Fabrazyme® (agalsidase beta)?*, GENZYME SUPPLY UPDATE (June 24, 2009), <http://supplyupdate.genzyme.com/weblog/recommendation-for-supply-allocation-of-cerezyme-imiglucerase-for-injection-1.html>.

²⁵ See Sten Stovall, *Genzyme Gets Nod From FDA For Plant*, WALL ST. J. (Jan. 25, 2012), <http://online.wsj.com/article/SB10001424052970203718504577180782783340816.html> (noting that full production is expected to resume in March 2012 given the fact that the FDA approved the company's new production facility on Jan. 24, 2012).

²⁶ Cf. 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 (2005) (arguing that the Act does not require reasonable drug prices); see generally Peter S. Arno & 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 TUL. L. REV. 631 (2001).

cases similar to the Fabrazyme case. This Comment will also address the procedural, regulatory, and political hurdles facing the NIH or another government agency seeking to exercise its march-in authority as a means of protecting the public. These procedural hurdles are great, which makes march-in rights a potentially poor tool for use in an emergency situation such as the Fabrazyme case. The lengthy process may, in fact, cause the NIH to adhere to its mistaken legal interpretation of its march-in authority in future cases where the public health is threatened. This Comment will advocate that reform of the Act's march-in mechanisms is necessary in order to avoid future tragedies similar to the Fabrazyme situation.

The Fabry disease community was forced to endure a dire health emergency for nearly three years. The NIH's abrogation of its legal duty has, at least in part, contributed to the pain, suffering, and death of U.S. citizens who would otherwise have had greater access to a lifesaving drug which was developed with taxpayer dollars. This is more than a mere mistake of legal interpretation; it is a human tragedy. If the protection that the Act's march-in rights provision provides is insufficient to protect our nation's citizens from similar future tragedies, then Congress must reform the Bayh-Dole Act.

Part II of this Comment will detail the history of the Bayh-Dole Act, focusing on the history of march-in rights and the legislative intent behind the Act. Part III will set forth the specifics of the Fabry disease case and present the NIH's reasoning for declining the petition to march-in. Part IV will argue that the NIH's decision in the Fabry disease case was wrong and that a broader reading of the march-in rights provision is legally correct and necessary to protect the public health in similar cases. Part V will examine potential reforms to the Bayh-Dole Act that are necessary to avoid similar tragedies in the future given the likelihood that the NIH will continue to adhere to its mistakenly narrow conception of its march-in authority. Part VI concludes.

II. MARCH-IN RIGHTS AND THE BACKGROUND OF THE BAYH-DOLE ACT

A. *March-In Rights History*

President John F. Kennedy first attempted to standardize the patent policy of various federal funding agencies in 1963.²⁷ He issued a memorandum declaring that the patent rights to all publicly-

²⁷ See Memorandum and Statement of Government Patent Policy, 28 Fed. Reg. 10,943 (Oct. 12, 1963).

funded inventions should generally be vested in the federal government funding agency.²⁸ The memorandum does, however, contemplate narrow situations where it would be in the public interest to vest principal or exclusive rights in the contractor receiving federal funds.²⁹ In the event that a contractor were to retain patent rights, the memorandum noted that the government reserved the right to compel the contractor (or its grantee, licensee, or assignee) to grant a license to a responsible applicant on reasonable terms if such action was necessary “to fulfill health needs, or for other public purposes. . . .”³⁰ This policy of maintaining the ability to compel a patent holder to grant a license based on unmet health or safety needs is a direct precursor to the march-in rights provision contained in the Bayh-Dole Act.³¹ It demonstrates that even before the Bayh-Dole Act, government agencies were expected to take action when the unreasonable use or nonuse of an invention, the development of which was funded by taxpayer dollars, threatened public health and safety.³²

These reservations of government rights notwithstanding, the general policy prior to 1980 was retention of patent rights resulting from federally funded research solely by the federal funding agency.³³ Despite attempts at standardization from both President Kennedy and President Richard Nixon, by 1980 each federal funding agency had different regulations and requirements for licensing out its patents.³⁴ This confusing regulatory scheme, coupled with the general ineffectiveness of federal agencies at licensing patents to private enterprises, resulted in much of the technology derived from government-funded research going unutilized by private industry and never making it to market in the form of publicly useful commercial

²⁸ See *id.* at 10,944.

²⁹ See *id.* at 10,945.

³⁰ *Id.*

³¹ It should be noted that President Nixon issued a memorandum in 1971 largely reaffirming President Kennedy's patent policy, including the retained authority of the government to compel the granting of a license based on unmet health or safety needs. See Memorandum and Statement of Government Patent Policy, 36 Fed. Reg. 16,887 (Aug. 26, 1971).

³² *Id.*

³³ *Id.*; see also James E. Dobkin, *Patent Policy in Government Research and Development Contracts*, 53 VA. L. REV. 564, 568–69 (1967).

³⁴ See Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L. J. 1095, 1097–98 (1999); Eisenberg, *supra* note 2, at 1663–64; Ralph C. Nash & Leonard Rawicz, *George Washington University, Government Contracts, Monograph No. 10, Patents and Technical Data 74–78* (1983).

products.³⁵

These perceived inefficiencies (whether real or imagined), coupled with a perceived innovation stagnation and the overall state of the late 1970s economy, led to calls for reform.³⁶ Reformers in Congress believed that, in order to more effectively develop the results of federally-funded research into commercially useful products, it was necessary to enact a new statutory scheme which vested these patent rights exclusively in the private sector and allowed for the transfer of these rights to other private entities.³⁷ This solution would serve a number of goals. It would: (1) ensure the effective transfer and commercial development of patents resulting from government-funded research; (2) “reinvigorate U.S. industry by giving it a fresh infusion of new ideas[;]” and (3) “ensure that U.S.-sponsored research discoveries were developed by U.S. firms” rather than foreign competitors.³⁸ The resulting legislation is codified as amended at 35 U.S.C. §§ 200–12 (2006) and is commonly known as the Bayh-Dole Act.

The Bayh-Dole Act thus established a government-wide policy that allowed recipients of federal funds to retain ownership of any patents resulting from their research.³⁹ The stated goals of the Act are:

to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit

³⁵ See McGarey & Levey, *supra* note 34, at 1098 n.8 (noting that prior to Bayh-Dole only four percent of all government patents had been licensed). Critics have argued that this view is “elusive at best” and that prior to Bayh-Dole patent rights were available to all on a come-one-come-all basis. See Arno & Davis, *supra* note 26, at 640–41 n.46; see also 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, 239 (2000) (“[I]t is unclear how much, if any, the Bayh-Dole Act has contributed to the successful commercialization of government funded inventions.”).

³⁶ See *Innovation’s Golden Goose*, *supra* note 1.

³⁷ See Eisenberg, *supra* note 2, at 1663–64.

³⁸ *Id.* at 1664–65.

³⁹ 35 U.S.C. §§ 200–12 (2010). Although the Act initially only allowed small businesses and non-profit organizations to retain ownership rights in patents resulting from federally funded research, in 1983 President Reagan expanded the scope of the Act by executive order to cover all federal government contractors, including large corporations. See Presidential Memorandum to the Heads of Executive Departments and Agencies, Subject: Government Patent Policy, 1983 PUB. PAPERS 248 (Feb. 18, 1983). Congress later codified this policy in 35 U.S.C. § 210(c).

organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and *protect the public against nonuse or unreasonable use of inventions*; and to minimize the costs of administering policies in this area.⁴⁰

In terms of stimulating the commercial development of discoveries derived from government-sponsored research, the Act has been “consistently hailed as an unqualified success.”⁴¹ The Act has “fostered a potent four-way partnership between researchers, their institutions, government, and industry . . . creat[ing] a powerful engine of practical innovation, producing many scientific advances that have extended human life, improved its quality, and reduced suffering for millions of people.”⁴² The Act is generally credited with the ten-fold increase in patents granted to universities between 1980 and 1997, compared with a two-fold increase in overall patenting during the same time period.⁴³ Biomedical research in health-related fields accounts for a major share of these university patents, particularly in terms of licensing revenues, a majority of which is publically funded.⁴⁴

While the Act has certainly been successful at its stated goal of promoting increased commercialization of federally funded research,⁴⁵ questions remain as to the ability of the current statutory scheme to effectuate one of the Act’s primary stated goals: that of “protect[ing] the public against nonuse or unreasonable use” of

⁴⁰ 35 U.S.C. § 200 (emphasis added).

⁴¹ Eisenberg, *supra* note 2, at 1708–09. *But cf.* Arno & Davis, *supra* note 26, at 640–41.

⁴² Raubitschek & Latker, *supra* note 26, at 150.

⁴³ See D.C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99, 104 (2001).

⁴⁴ *Id.*

⁴⁵ *Id.* *But cf.* Arno & Davis, *supra* note 26, at 640–41. Many commentators have also questioned the desirability of fostering such close ties between industry and academia and argue that Bayh-Dole has fostered an incentive structure which increasingly encourages universities and other entities to patent “basic research” which is properly left in the public sphere as patents on such research could hinder technological progress in the future. See Rai & Eisenberg, *supra* note 5, at 290.

those inventions.⁴⁶ In order to balance the commercial goals of the Act with the interests of the broader public, the Act contains two significant reservations of government rights over inventions arising from federally funded research.⁴⁷ First, the federal government retains a non-exclusive, non-transferable, royalty-free license to use the patent “for or on behalf of the United States.”⁴⁸ Second, the federal funding agency can, under certain legally prescribed standards, march-in and compel the patent holder to grant a license to a “responsible applicant.”⁴⁹ An agency may take action on its own or upon the request of an interested third party in the form of a petition.⁵⁰

In order to march-in under the Act, one of four legal standards must be satisfied, two of which are relevant for the purposes of this Comment.⁵¹ The two relevant standards provide that an agency may march-in if it determines that such action is “necessary” (1) “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”⁵² or (2) “to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees[.]”⁵³

The plain language of the Act therefore demonstrates that march-in rights, along with the ability of the government to use an

⁴⁶ 35 U.S.C. § 200 (2006).

⁴⁷ See *id.* § 202(c)(4), § 203(a).

⁴⁸ *Id.* § 202(c)(4).

⁴⁹ *Id.* § 203(a).

⁵⁰ *Id.* § 203(b).

⁵¹ See, e.g., *id.* § 203(a)(3)–(4). These provisions allow for a march-in when an agency determines action is necessary (1) “to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees” or (2) “because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.” *Id.* at § 203(a)(3)–(4). Neither of these standards involve public health or safety concerns, and are thus outside the scope of this Comment.

⁵² The Act defines “practical application” as:

to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations *available to the public on reasonable terms*.

35 U.S.C. § 201(f) (emphasis added).

⁵³ *Id.* § 203(a)(2).

invention “for or on behalf of the United States,” are the primary regulatory mechanisms by which the public is to receive protection from the nonuse or unreasonable use of inventions funded by taxpayer dollars.⁵⁴ A review of the bill’s legislative history bolsters this view, as march-in rights were continually referred to as a means of protecting the public during hearings on the bill.⁵⁵ Contemporary legal scholarship has not addressed what minimum protections the act provides,⁵⁶ and has instead focused on the more amorphous question regarding whether or not the Act can be construed to include things such as price controls for drugs.⁵⁷ These questions aside, the Act’s legislative history and plain language conclusively demonstrate, at a minimum, that march-in rights were intended to provide the public with at least *some* level of protection. The issue this Comment seeks to address is just how broadly courts and administrative agencies should read those protections in light of the text of the Act and its aforementioned history.

B. Procedural Hurdles to Exercising March-in Rights

Federal regulations set forth a detailed, multi-step process for

⁵⁴ See *id.* § 202(c)(4), § 203(a).

⁵⁵ See *Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before the Subcomm. on Legis. and Nat’l Sec. of the H. Comm. on Gov’t Operations*, 96th Cong. 135 (1980) (letter from Ralph Nader) (“the present bill relies heavily on such ‘march-in rights’ to protect the public”); *Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before the Subcomm. on Legis. and Nat’l Sec. of the H. Comm. on the Judiciary*, 96th Cong. 355 (1980) (statement of Mr. Bremer, Pres., Society of Univ. Patent Administrators) (“the public is adequately protected through appropriate march-in provisions”); *The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Congress 56 (1980) (letter from Elmer B. Staats, Comptroller Gen. of the U.S.):

The Department [of Energy] believes that march-in rights, although available to the Government for more than 10 years, have not been utilized because [problems arising from granting patent rights to government contractors] are illusory and not actual. *If and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them.* Otherwise DOE believes they will never be used.

(emphasis added).

⁵⁶ See Arno & Davis, *supra* note 26, at 660 (“Congress uniformly viewed march-in rights as the mechanism (along with recoupment provisions) to protect the public.”).

⁵⁷ *Id.* at 640–41 (arguing that the legislative history of the Act demonstrates that march-in rights were intended as a mechanism for enforcing reasonable drug prices). *But cf.* Raubitschek & Latker, *supra* note 26, at 150 (arguing that the march-in rights provision was not intended as a price control mechanism). The NIH resolved this dispute in Raubitschek and Latker’s favor in rendering its decisions regarding the Norvir and Xalatan march-in petitions. See discussion *infra* Part II.C.2.

initiating a march-in proceeding.⁵⁸ The process is lengthy,⁵⁹ potentially making it a poor mechanism to respond to an emergency situation.⁶⁰ The procedure is so time consuming, in fact, that some commentators have suggested that it may effectively defeat the Act's substantive goals of protecting public health and safety—goals which are, by their nature, time-sensitive.⁶¹ Some legislators raised similar concerns regarding the effectiveness of march-in rights as a protection for the public during Congressional debates. One Congressman went so far as to describe march-in rights as “a paper tiger,” and he argued that “we can forget [about march-in rights] as a realistic protection for the public.”⁶²

One should be careful, however, not to conflate concerns

⁵⁸ 37 C.F.R. § 401.6 (2012).

⁵⁹ The regulations require that when “an agency receives information it believes might warrant the exercise of march-in rights” (either on its own or, more likely, upon petition by some party) that the agency “shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter.” *Id.* § 401.6(b). The agency must provide the contractor with thirty days to respond. *Id.* Once the agency receives the contractor's response it may initiate march-in procedures within sixty days. *Id.* Within thirty days after receiving written notice of the proposed march-in proceeding the contractor may submit information opposing the proposed march-in. *Id.* § 401.6(d). If the agency determines that the contractor's information raises a factual dispute it *must* undertake a fact-finding process that gives the contractor the opportunity to appear with counsel, submit documents, present witnesses, and question individuals presented by the agency. *Id.* § 401.6(d), (e). The contractor may request to present oral and written arguments. *Id.* Within ninety days after the completion of the fact-finding or oral arguments the agency must provide a written decision. *Id.* § 401.6(g). If the agency decides to exercise its march-in rights the contractor may appeal to the court of federal claim within sixty days which holds the agency's decision in abeyance. *Id.* § 401.6(j). A decision *not* to exercise march-in rights is not reviewable by the courts. 37 C.F.R. § 401.6 (2012).

⁶⁰ See *Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions*, 2009 WL 2232908, GAO-09-742, 15 (Gov't Accountability Office July 27, 2009) (“march-in authority could have limited utility in an emergency situation, such as an important public health issue” due to the lengthy and time consuming process of exercising those rights) [hereinafter GAO report].

⁶¹ See Rai & Eisenberg, *supra* note 5, at 311 (“The tolerance for protracted delays inherent in the current [march-in] 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.’”) (citations omitted).

⁶² See *Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before the Subcomm. on Legis. and Nat'l Security of the H. Comm. on Gov't Operations*, 96th Cong. 55 (1980) (statement of Rep. Jack Brooks, Chairman, Comm. on Gov't Operations) (“The Government does not use its march-in rights one in a million times. . . . I think that it is a paper tiger. I think we can forget [march-in rights] as a realistic protection for the public.”).

regarding the effectiveness of march-in rights as a protection for the public with the legal standards set forth in the Act which determine if a march-in is warranted. Concerns regarding the march-in rights' procedural hurdles and overall effectiveness as a means of public protection are persuasive evidence in favor of reforming the Act.⁶³ These concerns, however, are distinct from the legal issue of what circumstances should trigger an exercise of the march-in provision and whether the legal standard set forth in the Act has been properly understood and applied by the NIH in the Fabrazyme case and other past march-in petitions.⁶⁴

C. Previous March-in Petitions

1. *In re Cellpro* (1997)

In the 1980s a Johns Hopkins University ("Hopkins") researcher, Dr. Curt Civin, isolated an antibody found only on stem cells known as My-10.⁶⁵ His research was funded in part by the NIH and resulted in three patents which had potential application to the treatment of cancer.⁶⁶ Separately, researchers at CellPro, Inc. isolated a related, but different, antibody known as the 12.8 antibody.⁶⁷ The 12.8 antibody is structurally similar to the My-10 antibody, but has the advantage of being able to link physically to baboon cells, which the My-10 antibody is unable to do.⁶⁸ This advantage enabled CellPro to obtain FDA approval for use of its 12.8 antibody in cancer treatments before Hopkins was able to do the same for its My-10 antibody.⁶⁹ Hopkins subsequently sued CellPro alleging willful infringement of its patents.⁷⁰

Before trial, CellPro petitioned the Secretary of the Department of Health and Human Services, requesting that the Secretary exercise the government's march-in rights.⁷¹ The Secretary forwarded the petition to the NIH because the NIH was the agency that funded the

⁶³ See *infra* text accompanying note 171.

⁶⁴ This Comment will focus on the latter issue. For articles considering the procedural hurdles, see, e.g., Rai & Eisenberg, *supra* note 5; GAO report, *supra* note 60.

⁶⁵ See *Johns Hopkins Univ. v. CellPro, Inc.*, 931 F. Supp. 303, 309 (D. Del. 1996).

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ See *CellPro Determination*, *supra* note 15.

research resulting in the My-10 patents.⁷² In the petition, CellPro sought an order which would require Hopkins to license CellPro the patents, asserting that such action was necessary because of health and safety needs or, in the alternative, because Hopkins had failed to achieve practical application of its patents.⁷³

First, the NIH determined whether Hopkins had taken effective steps to achieve practical application of the patents.⁷⁴ The agency concluded that Hopkins achieved practical applications because its sub-licensee, Baxter Healthcare Corporation, was manufacturing a device based on the patents, despite the fact that the device was still awaiting regulatory approval by the FDA.⁷⁵ The agency also cited the fact that CellPro had failed to negotiate a license from Hopkins, which the agency felt was persuasive evidence that the free market had decided against the need for CellPro's product.⁷⁶ Second, the NIH examined whether a health or safety need existed that Hopkins or its licensees/sub-licensees were not reasonably satisfying.⁷⁷ The agency determined that the fact that CellPro had an FDA-approved medical device on the market was enough to meet the health-need prong of the march-in rights provision, writing that it would be "premature[] and inappropriate for the NIH to substitute its judgment for that of clinicians and patients seeking to avail themselves of an FDA-approved medical device" and that the device "fulfills a health need for those who wish to use it."⁷⁸ Thus, the NIH's bar for what constitutes a "health or safety need" within the meaning of the Bayh-Dole Act's march-in provision is extremely low. There need only be a device or drug on the market that patients wish to use to satisfy that prong, and the NIH will not "substitute its judgment"⁷⁹ for that of clinicians and patients who wish to use the drug or device.⁸⁰

The NIH ultimately determined, however, that the health or safety need was reasonably satisfied in this case.⁸¹ The NIH relied on the district court, in the patent infringement litigation between

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ See CellPro Determination, *supra* note 15.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

Hopkins and CellPro,⁸² which had entered an injunction allowing the continuing sale of CellPro's cancer treatment device until the FDA approved the Hopkins/Baxter product for sale.⁸³ The NIH also relied upon the pledge of Baxter, Hopkin's sublicensee, to increase patient access in clinical trials to its device in the event that CellPro reduced the sale of its device.⁸⁴ Therefore, the NIH reasoned, march-in proceedings were not warranted because Baxter had taken reasonable steps to satisfy the existing health and safety needs created by the existence of CellPro's cancer treatment.⁸⁵

Scholarly reaction to the NIH's CellPro decision has been mixed.⁸⁶ Some have applauded the decision as a proper exercise of restraint, citing the fact that the statutory language of the march-in provision requires that action must be "necessary" in order to justify the exercise of march-in rights.⁸⁷ Others have been more critical, arguing that the NIH's determination "not only flies in the face of the legislative history [of the Act], [but that] it is also flatly inconsistent with the language of the Act itself, the 'policy and objective' of which are explained in the Act's introductory paragraph."⁸⁸

Even if one finds the NIH's decision in the CellPro case convincing, such support by no means compels the conclusion that the NIH was similarly correct in the Fabrazyme case because the facts of the two cases are markedly different and easily distinguishable.⁸⁹ First, the cancer patients at issue in the CellPro case had a multitude of different treatment options available,⁹⁰ whereas Fabrazyme is the only treatment available for Fabry disease patients in the United

⁸² See *supra* text accompanying note 61.

⁸³ See Cellpro Determination, *supra* note 15.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ See, e.g., McGarey & Levey, *supra* note 34, at 1097–98; Arno & Davis, *supra* note 26, at 683; see also Peter Mikhail, Hopkins v. CellPro: An Illustration That Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest, 13 HARV. J.L. & TECH. 375, 388–89 (2000).

⁸⁷ See McGarey & Levey, *supra* note 34, at 1097–98 (describing march-in authority as a "blunt and powerful means to ensure that government funded technology does not languish to the detriment of the public").

⁸⁸ Arno & Davis, *supra* note 26, at 683; see also Mikhail, *supra* note 86, at 388–89 (arguing that the NIH "ignored the link between health needs and usage by hospitals" in assessing whether or not Baxter's device, in clinical trial, could be said to be reasonably satisfying the health need created by CellPro's device).

⁸⁹ Compare CellPro Determination, *supra* note 15, with Fabrazyme Determination, *supra* note 15.

⁹⁰ CellPro Determination, *supra* note 15.

States.⁹¹ Second, there was no evidence that patient access to the CellPro device had been curtailed, as the district court's injunction allowed CellPro to continue selling its device until Baxter achieved FDA approval and Baxter promised to expand access to its device in clinical trials if CellPro reduced production of its device.⁹² By contrast, Genzyme Corporation produces the only drug available in the United States for the treatment of Fabry disease and the drug shortage has limited patient access.⁹³ Finally, in the CellPro case the drug producer petitioned the NIH because of impending patent litigation, whereas in the Fabry disease case a group of patients petitioned due to their lack of access to a lifesaving drug.⁹⁴ Thus, the question presented to the NIH in the CellPro case was a substantially closer question than in the Fabrazyme case. Even if one supports the NIH's decision in the CellPro case, this does not preclude the conclusion that the NIH's determination in the Fabrazyme case was incorrect.

2. *In re Norvir* (2004) and *In re Xalatan* (2004)

Both the Norvir and Xalatan petitions challenged dramatic increases in the price of their respective drugs.⁹⁵ The primary thrust of both petitions was that the high prices of these drugs, especially when considered in light of the already large public investment made in their development, rendered them essentially unavailable to the public on the "reasonable terms" required by the Bayh-Dole Act.⁹⁶ The petitions also argued, in the alternative, that the dramatic increase in prices created a public health and safety issue, necessitating a march-in.⁹⁷

Regarding the allegation that the dramatic increase in prices created a health or safety issue, the NIH's response in both petitions was short and practically identical:

[The drug] has been approved by the Food and Drug

⁹¹ Fabrazyme Determination, *supra* note 15.

⁹² CellPro Determination, *supra* note 15.

⁹³ Fabrazyme Determination, *supra* note 15.

⁹⁴ *Id.*

⁹⁵ See Norvir Determination, *supra* note 15; Xalatan Determination, *supra* note 15.

⁹⁶ See Norvir Determination, *supra* note 15; Xalatan Determination, *supra* note 15. This argument seems to be modeled after the reasonable pricing theory advanced in Arno and Davis's article, discussed *supra* note 26.

⁹⁷ See Norvir Determination, *supra* note 15; Xalatan Determination, *supra* note 15.

Administration as safe and effective and is being widely prescribed by physicians.... No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by [Pfizer/Abbot]. Rather, the argument advanced is that the product should be available at [a lower price/the same price as that charged in other countries], which is addressed below. Thus, the NIH concludes that [Pfizer/Abbot] has met the statutory and regulatory standard for health or safety needs.⁹⁸

The NIH also wrote that “the extraordinary remedy of march-in is not an appropriate means for controlling prices” and that the issue is “appropriately left for Congress to address legislatively,”⁹⁹ which seems to implicitly reject the argument some scholars have advanced—that the march-in rights provision was intended as a price-control mechanism.¹⁰⁰ In coming to this conclusion, however, the NIH did not even bother to address the statutory language of the Act, which requires that results of federal funding be “available to the public on reasonable terms.”¹⁰¹ As in the CellPro determination, the NIH in both the Norvir and Xalatan cases seemed more concerned with upsetting settled expectations of patent holders than in protecting the public interest.

It is certainly debatable, as a legal matter, whether the march-in provision was intended as a price-control mechanism.¹⁰² That said, however, it is worth noting that the NIH did not even mention in its Norvir and Xalatan determinations the possibility that the congressional intent and statutory language of the Bayh-Dole Act may require it to protect the public from high drug prices;¹⁰³ nor did it mention its statutory duty to ensure that the products of publicly-funded inventions are available to the public on reasonable terms.¹⁰⁴

⁹⁸ Norvir Determination, *supra* note 15, at 5; *see also* Xalatan Determination, *supra* note 15, at 5.

⁹⁹ Norvir Determination, *supra* note 15, at 5–6. The NIH’s response in the Xalatan determination was practically identical. *See* Xalatan Determination, *supra* note 15.

¹⁰⁰ *See* Norvir Determination, *supra* note 15; Xalatan Determination, *supra* note 15; *see also* Arno & Davis *supra* note 26.

¹⁰¹ 35 U.S.C. § 201(f) (2006); *see also* Norvir Determination, *supra* note 15, at 4; Xalatan Determination, *supra* note 15, at 4.

¹⁰² *See* discussion *supra* note 57.

¹⁰³ *See* Xalatan Determination, *supra* note 15; Norvir Determination, *supra* note 15.

¹⁰⁴ *See* Xalatan Determination, *supra* note 15; Norvir Determination, *supra* note 15.

Additionally, the NIH wrote off any safety concerns posed by the high price of these drugs in one paragraph.¹⁰⁵ This is persuasive evidence that the NIH has not seriously considered its march-in authority and that it is instead more concerned with ensuring that patent holders' settled expectations remain undisturbed.

III. THE FABRY DISEASE CASE

Fabry disease is a rare, painful, and ultimately lethal genetic disorder.¹⁰⁶ The community of Fabry disease patients recently had to endure a severe health crisis: the only FDA-approved treatment for the disease, an enzyme replacement therapy known as Fabrazyme, went into extremely short supply for nearly three years starting in June 2009.¹⁰⁷ Fabrazyme was developed with federal funds from the NIH and is subject to the provisions of the Bayh-Dole Act.¹⁰⁸ Despite the health emergency that this drug shortage caused, the NIH, responding to a petition by a group of patients in need of greater access to the drug, refused to exercise the primary public protection mechanism entrusted to it by the Bayh-Dole Act: the march-in rights power.¹⁰⁹ The Agency's determination in this case was not only legally incorrect; it also prolonged the ongoing pain and suffering of the Fabry disease community. In order to prevent similar drug shortages in the future, either the NIH must revisit its mistakenly narrow interpretation of its march-in power, or Congress must reform the Act to better effectuate its goal of protecting the public health from the nonuse or unreasonable use of inventions derived from taxpayer dollars.

Fabry disease is a rare X-linked recessive lysosomal storage disease.¹¹⁰ Individuals who suffer from the disease have a deficiency of the enzyme alpha galactosidase, which normally breaks down a

¹⁰⁵ See *Xalatan Determination*, *supra* note 15, at 6; *Norvir Determination*, *supra* note 15, at 5–6.

¹⁰⁶ Julie K. Karen et al., *Angiokeratoma Corporis Diffusum (Fabry Disease)*, 11 DERMATOLOGY ONLINE J. 4, 8 (2005), <http://dermatology.cdlib.org/114/NYU/NYUtexts/0419054.html> (last visited Nov. 6, 2011).

¹⁰⁷ See Susan Donaldson James, *Fabry Disease Patients Get Sicker as Drugs Go Overseas*, ABC NEWS (Aug. 30, 2011), http://abcnews.go.com/Health/fabry-disease-patients-sicker-sue-drug-company_lifesaving/story?id=14403759 (last visited Sept. 18, 2011).

¹⁰⁸ *Fabrazyme Determination*, *supra* note 15, at 4.

¹⁰⁹ *Id.* at 1, 9.

¹¹⁰ Karen, *supra* note 106, at 8.

certain fat known as globotriasylcermide.¹¹¹ The inability to break down this fat causes it to accumulate in the blood vessels, tissues, and organs, impairing their functions and resulting in a wide range of symptoms.¹¹² These symptoms include renal disease, heart disease, dermatological problems, ocular disease, burning extremity pain, tinnitus, and an increased risk of stroke.¹¹³ Fabry disease significantly shortens the life of its sufferers: one NIH study found that fifty percent of those patients not treated by enzyme replacement therapy developed end-stage renal failure by age fifty-three.¹¹⁴ All patients in the study who did live into their fifties eventually developed end-stage renal failure.¹¹⁵

Although there is no cure for Fabry disease, an effective therapy using the biologic agalsidase beta (Fabrazyme) was discovered in 2001.¹¹⁶ While not a cure, regular infusion of the drug can allow normal metabolism and even prevent disease progression.¹¹⁷ The discovery was a direct result of the NIH's funding of grant number DK 34045, awarded to Dr. Robert J. Desnick at the Mt. Sinai School of Medicine.¹¹⁸ The resulting patent was exclusively licensed to Genzyme, Inc., which until 2009 was able to produce enough Fabrazyme to meet the needs of all Fabry disease patients in the United States.¹¹⁹ Fabrazyme is currently the only FDA-approved enzyme replacement therapy for Fabry disease patients in the United States.¹²⁰

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*; see also Petition *In re* Fabrazyme, Manufactured by Genzyme Corp., (Jan. 13, 2010) p. 3, available at http://patentlawyersite.com/files/Download/Fabrazyme_Petition_5_0.doc (last visited Nov. 6, 2011) [hereinafter Fabry Disease Patients' Petition].

¹¹⁴ Fabry Disease Patients' Petition, *supra* note 113, at 3.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 4; see also Fabrazyme Determination, *supra* note 15, at 6; Fabrazyme Approval Letter from Steven A. Masiello, Director of the Office of Compliance and Biologics Quality at the Food and Drug Administration, to Christine Harris, Manager of Regulatory Affairs at Genzyme Corporation (Apr. 24, 2003), available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm128159.htm>.

¹¹⁷ Fabrazyme Determination, *supra* note 15, at 4–5.

¹¹⁸ *Id.* at 4. Fabrazyme is therefore an invention subject to the provisions of the Bayh-Dole Act, which was not disputed by Genzyme or the NIH.

¹¹⁹ *Id.* at 4–5.

¹²⁰ Fabrazyme Determination, *supra* note 15, at 7–9. One other enzyme replacement therapy, agalside alpha (trade name Replagal) is available outside the United States and was seeking FDA approval in the United States, but has since

In June 2009, Genzyme was forced to decrease production of Fabrazyme as a result of a viral infection at its manufacturing plant.¹²¹ In November 2009, Genzyme produced a contaminated batch of the drug.¹²² The FDA initiated action against Genzyme resulted in a consent decree, \$175 million in fines as profit disgorgement, and oversight of the manufacture of Fabrazyme for at least seven years.¹²³ In response, Genzyme instituted a rationing protocol, which allotted Fabry patients with one dose of the drug every other month, compared to the two per month normally prescribed.¹²⁴ Moreover, newly diagnosed patients were not allowed any drug whatsoever.¹²⁵ Genzyme also allocated only thirty-eight percent of what meager supply of Fabrazyme it had been able to produce to U.S. citizens, with the rest being distributed to other countries.¹²⁶

In response to Genzyme's production problems, a group of Fabry disease patients petitioned the NIH requesting that the agency exercise its march-in rights and grant an open license so that a third party could make up the production shortfall.¹²⁷ The NIH denied this request on December 2, 2010.¹²⁸ The primary reason that the NIH cited was the fact that no third party would likely be able to gain regulatory approval to produce a drug similar to Fabrazyme before Genzyme could restart production.¹²⁹ The NIH placed particular reliance upon Genzyme's predication that supply would be fully restored in the first half of 2011 and that a competitor, Shire, was seeking FDA approval of its own enzyme replacement therapy, Replagal.¹³⁰

Despite Genzyme's promises to the NIH and the Fabry disease community that it would resume production in early 2011, on March 23, 2011, the company announced that it was pushing back full resumption of production to the summer of 2011 due to continuing

withdrawn its application. See James, *supra* note 107.

¹²¹ Fabry Disease Patients' Petition, *supra* note 113, at 4.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ See Thomas Gryta, *Genzyme Sees End to Fabrazyme Rationing*, WALL ST. J. (Sept. 16, 2010) <http://online.wsj.com/article/SB10001424052748703743504575494210148662260.html>

¹²⁵ *Id.*

¹²⁶ Fabrazyme Determination, *supra* note 15, at 7.

¹²⁷ See generally Fabry Disease Patients' Petition, *supra* note 113.

¹²⁸ See Fabrazyme Determination, *supra* note 15, at 1–2, 9–10; see also discussion *infra* Part IV.

¹²⁹ *Id.* at 9.

¹³⁰ *Id.*

viral contamination problems.¹³¹ Yet again, on August 26, 2011, production was delayed, with Genzyme issuing an apology to the Fabry disease community.¹³² Moreover, a study by the European Medicines Agency (EMA) concluded that the pattern of adverse events the patients were suffering following lowered doses of Fabrazyme may actually have been an “accelerated[] course of Fabry disease.”¹³³ The EMA thus required that Genzyme provide enough of the drug to allow full doses to Europeans.¹³⁴ Genzyme complied, shifting more drugs overseas and away from U.S. patients, despite the availability of Replagal overseas.¹³⁵ Adding to the shortage crisis, Shire has since withdrawn its application for FDA approval of Replagal, meaning that there is no chance that U.S. patients will be able to access that drug as the NIH predicted in its determination.¹³⁶

In response to these continuing developments, a group of Fabry disease patients requested that the NIH reconsider its decision not to march-in.¹³⁷ The group has also requested that the FDA ban overseas shipment of the drug in order to free up more supply for U.S. patients.¹³⁸ Finally, the patients have sued Genzyme for damages, alleging a novel, implied cause of action arising from the Bayh-Dole Act: that Genzyme unreasonably used a publicly-funded invention to cause public harm.¹³⁹ They allege that some Fabry disease patients have died as a result of Genzyme’s drug rationing during the nearly

¹³¹ See Robert Weisman, *Genzyme Has to Scrap Batch of its Fabrazyme Drug*, BOS. GLOBE (Mar. 23, 2011, 4:30PM), http://www.boston.com/business/ticker/2011/03/genzyme_has_to.html.

¹³² See Alina Selyukh, *Genzyme Apologizes for a Drug Shipment Delay*, REUTERS (Sept. 7, 2011), available at <http://www.reuters.com/article/2011/09/07/genzyme-fda-idUSN1E78613C20110907> (last visited Nov. 6, 2011).

¹³³ See EUR. MEDS. AGENCY, ASSESSMENT REPORT ON THE SHORTAGE OF FABRAZYME 7–8 (2010), available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099241.pdf (last visited Jan. 29, 2012).

¹³⁴ *Id.*

¹³⁵ See Amended Complaint at 9, *Hochendoner v. Genzyme Corp.*, No. 11-0313 (W.D. Pa. Mar. 10, 2011).

¹³⁶ See James, *supra* note 107.

¹³⁷ See Petition for Rehearing and Rulemaking, *In re Fabrazyme* (Dep’t of Health & Human Servs. Apr. 5, 2011), <http://www.patentlawyersite.com/files/Download/NIH%20PETITION%20FOR%20RULEMAKING%20AND%20REHEARING%209.pdf>; see also James, *supra* note 21.

¹³⁸ See Ed Silverman, *Patients Petition FDA over Genzyme Drug Shortage*, PHARMALOT (Jan. 19, 2011, 10:25 AM), <http://www.pharmalot.com/2011/01/patients-petition-fda-over-genzyme-drug-shortage/>.

¹³⁹ See Amended Complaint, *supra* note 135, at 23.

three-year shortage.¹⁴⁰

The patients' request for NIH reconsideration has likely been rendered moot given that Genzyme achieved FDA approval of its new manufacturing facility in January 2012 and resumed full production in March 2012.¹⁴¹ The shortage, therefore, lasted more than a full year beyond Genzyme's initial prediction, on which the NIH heavily relied in its decision.¹⁴²

IV. ANALYSIS OF THE MARCH-IN PETITION AND NIH DETERMINATION

The NIH determined that exercising its march-in power in response to health and safety concerns was not warranted on three grounds.¹⁴³ First, the NIH argued that a march-in proceeding granting license of the Fabrazyme patents to a responsible third party would not increase the supply of Fabrazyme in the short term because it would take years for any third party's production facility to achieve FDA approval.¹⁴⁴ Second, the NIH cited the fact that no third party had presented itself as seeking FDA approval for an alternative to Fabrazyme.¹⁴⁵ In making this point, the NIH anticipated a counter argument—that no third party would conduct clinical trials or seek FDA approval of an alternative to Fabrazyme because this would leave those companies open to a patent infringement suit.¹⁴⁶ The NIH responded by arguing that Genzyme's patents are not an impediment to a third party seeking regulatory approval because clinical trials are exempt from infringement under the Hatch-Waxman statutory safe-harbor provision.¹⁴⁷ Finally, the NIH cited the fact that Genzyme had

¹⁴⁰ *Id.*

¹⁴¹ See Albertina Torsoli, *Sanofi's Genzyme Receives FDA Approval of Framingham Plant*, BLOOMBERG BUSINESSWEEK (Jan. 24, 2012), <http://www.businessweek.com/news/2012-01-24/sanofi-s-genzyme-receives-fda-approval-of-framingham-plant.html>.

¹⁴² See Fabrazyme Determination, *supra* note 15, at 9 (noting that Genzyme predicted full production would resume in the first quarter of 2011).

¹⁴³ See *infra* text accompanying notes 144–49.

¹⁴⁴ Fabrazyme Determination, *supra* note 15, at 1–2. The NIH emphasized the difficult and lengthy process of obtaining FDA approval for a biological product such as Fabrazyme to market, irrespective of any patent rights. *Id.* Specifically, any new biological product must complete FDA Investigational New Drug (IND) and Biologic License Application (BLA) approval processes. See generally 21 C.F.R. §§ 50, 54, 56, 210, 211, 312, 600, 601, 606 (2006) (describing various points of the approval process facing any organization seeking to produce a Fabrazyme competitor).

¹⁴⁵ Fabrazyme Determination, *supra* note 15, at 1–2.

¹⁴⁶ See Fabrazyme Determination, *supra* note 15, at 1–2.

¹⁴⁷ *Id.* at 1. The Hatch-Waxman statutory safe harbor provision exempts companies from liability for patent infringement claims if their use is “reasonably related to the development and submission of information under a Federal law

promised to resume full production of Fabrazyme in the first half of 2011, and that Genzyme was working diligently and in good faith to make good on its promise.¹⁴⁸ The NIH also noted, in a break from the previous three decisions, that it would monitor the shortage of Fabrazyme and re-evaluate its decision if it received information suggesting either that progress toward restoring the supply of Fabrazyme to meet patient demand was not proceeding as represented by Genzyme, or that a third party with a viable plan to obtain FDA approval to market an alternative to Fabrazyme presented itself.¹⁴⁹

The NIH's application of the Bayh-Dole Act's march-in provision to the facts of this case was mistaken for several reasons. First, its reasoning was circular and set up a self-fulfilling prophecy because the Hatch-Waxman statutory safe-harbor provision extends only to actions taken to achieve regulatory approval, *not* to actions taken to bring a product to market.¹⁵⁰ Thus, to bring a product to market, a company would have to be granted a compulsory license by the NIH via a march-in (or perhaps negotiate a license with the patent holder). Second, the agency's decision ignores the plain language of the Act as well as the congressional intent underlying that language. Third, and similarly, the NIH's decision effectively defeats one of the Act's principal goals—to protect the public from the nonuse or unreasonable use of publicly funded inventions—by reading the legal standard in such a way that it can essentially never be met by any set of facts. If the public is to receive any protection from drug shortages resulting from patent monopolies¹⁵¹ then either the NIH must re-evaluate its mistaken legal reasoning, or Congress must amend the Bayh-Dole Act to offer greater public protection—lest the circumstances of the Fabrazyme case be repeated in the future.

The NIH's reasoning in the Fabrazyme determination is circular because it places primary emphasis on the fact that no third party had presented itself as ready to achieve regulatory approval for an

which regulates the manufacture, use, or sale of drugs or veterinary biological products.” See 35 U.S.C. § 271(e)(1) (2006) (commonly known as the Hatch-Waxman Safe Harbor Provision). Thus, as per the NIH's reasoning, a company seeking FDA approval of a Fabrazyme competitor would not have to fear a patent infringement suit brought by Genzyme because they would be protected by Hatch-Waxman while they were developing the drug. See *generally* Merck KGaA v. InTegra LifeSciences I, Ltd., 545 U.S. 193, 202–03 (2005).

¹⁴⁸ Fabrazyme Determination, *supra* note 15, at 1–2.

¹⁴⁹ *Id.*

¹⁵⁰ 35 U.S.C. § 271(e)(1).

¹⁵¹ These are drugs whose development was funded by the public, no less.

alternative to Fabrazyme. But, in refusing to march-in on those grounds, the NIH effectively created a situation where no third party will *ever* present itself—a self-fulfilling prophecy. The NIH argued that a third party should be willing to seek FDA approval of a competing drug even without a march-in because it can do so without fear of a patent infringement suit under the Hatch-Waxman statutory safe-harbor provision.¹⁵² The NIH's reasoning, however, overlooks the fact that simply because a company hypothetically *could* seek FDA approval without infringing upon the Fabrazyme patents and then request a march-in does not by extension mean that a company *will* do so. Indeed, companies will almost certainly not seek regulatory approval of a competing product absent a march-in first because bringing a product to market *is not exempt* from patent infringement suits by the safe-harbor provision.¹⁵³ Although the Hatch-Waxman safe-harbor provision exempts actions that are related to seeking regulatory approval, that safety does not extend to selling the product on the open market after regulatory approval is achieved.¹⁵⁴ Thus, the NIH expects a company to seek FDA approval of a competing (and patent-infringing) drug, and then request that the NIH march-in and compel the granting of a patent license so it can sell its drug on the open market. This asks a company to take on the great risk of investing a large sum of money in achieving regulatory approval and then hoping that the NIH marches-in and grants a compulsory license. Especially in light of the fact that no government agency has *ever* used its march-in authority,¹⁵⁵ it should not be surprising that no company has endeavored to do this, thereby fulfilling the NIH's prophecy.¹⁵⁶

Certainly, a march-in would not guarantee that a third party would immediately present itself as ready and willing to produce a competing product. But marching-in first, before a company decides to seek regulatory approval, dramatically lessens the risk that any

¹⁵² See *supra* text accompanying note 147.

¹⁵³ 35 U.S.C. § 271(e)(1).

¹⁵⁴ See *id.* (exempting companies from liability for patent infringement claims if their actions are “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”).

¹⁵⁵ See McCabe, *supra* note 14, at 649.

¹⁵⁶ Indeed, the NIH's determination seems to implicitly recognize this, stating that it will reconsider its decision “*in the unlikely event*” that they receive information that a third party has presented itself as ready and willing to seek regulatory approval of a competing drug. Fabrazyme Determination, *supra* note 16, at 2 (emphasis added).

company contemplating this course of action would have to take on, and would therefore drastically increase the chances that such a company might present itself. Thus, the NIH's reasoning is circular: by declining to march-in until a third party has presented itself, it has effectively guaranteed that no such party will ever appear. This limits the scope of march-in authority so drastically as to effectively read it out of the Bayh-Dole Act.

The NIH's reasoning also ignores the Bayh-Dole Act's plain language and Congress's intent. As a preliminary matter, the underproduction of Fabrazyme clearly constitutes a "health or safety need[]" within the meaning of the Act.¹⁵⁷ This view is supported by the NIH's determination in the CellPro case, where the agency determined that the choice of any patient or doctor to utilize a particular product creates a health or safety need, and that the NIH will not second guess these decisions.¹⁵⁸ It is also clear that these health and safety needs are not being "reasonably satisfied"¹⁵⁹ by Genzyme, as the underproduction of Fabrazyme has allegedly resulted in an accelerated course of the disease and the deaths of three patients.¹⁶⁰ Although not clearly stated by the NIH, the only limiting language available in the Act to support the view that a march-in is not appropriate is the requirement that action on the part of the federal funding agency be "necessary to alleviate" the unmet health or safety needs.¹⁶¹ The NIH, in stating that it will not march-in absent a third party achieving regulatory approval of a competing drug, is interpreting the Act to require that the agency be the last party to take action in the multi-step process required to bring a competing drug to market. Thus, the NIH is interpreting "necessary" as meaning strictly necessary.

This interpretation of when action is "necessary" is not a valid means of statutory interpretation. Such an interpretation would make action on the part of the NIH both necessary and sufficient to alleviate the unmet health need.¹⁶² Regardless of the fact that there is

¹⁵⁷ 35 U.S.C. § 203(a)(2).

¹⁵⁸ See *supra* text accompanying notes 77–80.

¹⁵⁹ 35 U.S.C. § 203(a)(3).

¹⁶⁰ See Fabry Patients' Petition, *supra* note 113.

¹⁶¹ 35 U.S.C. § 203(a)(2).

¹⁶² Additionally, this author could find no cases in any context which have construed a statute's use of the word "necessary" to mean absolutely necessary. Indeed, in the context of constitutional law the Supreme Court has written that "the word 'necessary' does not mean 'absolutely necessary.'" *United States v. Comstock*, 130 S. Ct. 1949, 1956 (2010) (discussing the Necessary and Proper clause).

no third party, a march-in is still a necessary (though not sufficient) predicate action to allow any third party, whether present or not, to legally produce a Fabrazyme competitor. Without an exercise of the NIH's march-in authority, the health and safety needs of the Fabry community will go unmet, and action by the NIH is "necessary" to alleviate those needs. In fact, considering the history of march-in proceedings since Bayh-Dole's enactment, most third parties would be right to assume that the NIH will never march in, and thus decide not to attempt to produce a Fabrazyme competitor because the chance of receiving a compelled license via a march-in is effectively zero. Therefore, the NIH's granting of an open license under its march-in authority is "necessary" in order to motivate third parties.

The NIH, however, did not engage in such a close examination of the statutory language in deciding the scope of its march-in authority, and instead simply stated that a march-in was not appropriate.¹⁶³ Notwithstanding its limited analysis, its determination still ignored the Act's clear congressional intent. One of the Act's principal goals, expressed in the "Policy and Objective" section, is to "protect the public against the nonuse or unreasonable use of inventions"¹⁶⁴ As noted, the Act's sponsors viewed march-in rights as the primary mechanism to effectuate this goal.¹⁶⁵ The Act's proponents argued that "the public is adequately protected through appropriate march-in provisions."¹⁶⁶ In commenting on the bill, the Department of Energy viewed a march-in as unlikely, but noted that "[i]f and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them."¹⁶⁷ Contemporary legal scholarship,

¹⁶³ See Fabrazyme Determination, *supra* note 15.

¹⁶⁴ 35 U.S.C. § 200.

¹⁶⁵ See discussion *supra* note 55.

¹⁶⁶ *Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before the Subcomm. on Legis. and Nat'l Sec. of the H. Comm. on the Judiciary*, 96th Cong. 355 (1980) (statement of Mr. Bremer, Pres., Soc'y of Univ. Patent Adm'rs) ("the public is adequately protected through appropriate march-in provisions").

¹⁶⁷ *The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Congress 56 (1980) (letter from Elmer B. Staats, Comptroller Gen. of the U.S.). Mr. Staats further elaborated that:

The Department [of Energy] believes that march-in rights, although available to the Government for more than 10 years, have not been utilized because [problems arising from granting patent rights to government contractors] are illusory and not actual. *If and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them.* Otherwise DOE believes they will never be used.

in reviewing the legislative history of the Act, has similarly concluded that march-in rights were viewed as the primary means of protecting the public.¹⁶⁸ In the Fabry case, the unreasonable use of a federally funded invention caused a great health and safety need, but the NIH ignored the primary mechanism inserted into the Act to ensure such need was met. The NIH's interpretation of its legal authority has thus defeated the public protection goal of the Act by ignoring the mechanism intended to further that goal.

The NIH, however, has the ability to correct its mistaken interpretation. The agency has been petitioned by the Fabry patients again, requesting a reconsideration of the march-in determination and a rule clarification.¹⁶⁹ At this point, given that the FDA has cleared Genzyme's new production facility, an NIH march-in is almost certain not to occur. The NIH should, however, issue a rule clarification correcting its prior mistaken determination in order to send a message that the Bayh-Dole Act's public protection measures are functional and to make clear that it will exercise its march-in authority in future drug-shortage cases. The NIH should do so not only because its legal determination was incorrect, but because two factual assumptions upon which it heavily relied (that Genzyme would resume full production in the first half of 2011 and that Replagal would be made widely available in the United States) were proven to be completely wrong.¹⁷⁰ A reconsideration of its determination will at least serve as a reminder to other holders of publically funded patent monopolies that if they abuse the invention which has been entrusted to them by taxpayers the NIH still has the will to march-in. If the NIH adheres to its mistaken view it will have sent a message to pharmaceutical companies everywhere that in the event of a large-scale drug shortage their patents are not in danger.

Id. (emphasis added).

¹⁶⁸ See 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, 218–19 (2000) (arguing that balancing public versus private benefits is a primary concern of the Bayh-Dole Act and that march-in rights exist in order to protect the public welfare).

¹⁶⁹ See *In re Fabrazyme*, *supra* note 137, at 3; see also James, *supra* note 21.

¹⁷⁰ Compare Fabrazyme Determination, *supra* note 15, at 2 (noting that Genzyme had promised to resume full production in the first half of 2011), with Stovall, *supra* note 25 (noting that full production of Fabrazyme will not resume until at least March 2012); also compare Fabrazyme Determination, *supra* note 15, at 7 (noting that Shire was seeking FDA approval for its Fabry disease treatment, Replagal) with James, *supra* note 107 (noting that Shire has withdrawn its application for FDA approval of Replagal).

A return to the Act's original intent will provide additional motivation to holders of publicly funded patent monopolies to avoid the mistakes made by Genzyme.

V. BAYH-DOLE REFORM

Unfortunately, the possibility of the NIH revisiting its determination to correct its mistaken legal interpretation of its march-in authority may fairly be described as unlikely, at best. The NIH's likely adherence to its mistaken interpretation of its legal authority, coupled with the lengthy procedure required to exercise the march-in power, demonstrates the need for reform.

As noted, the lengthy march-in procedure limits its utility in an emergency situation, such as a drug shortage.¹⁷¹ Especially when one considers that FDA approval¹⁷² would have to be satisfied as well as the march-in procedures, the ability of the Act's march-in rights provision to offer adequate public protections in public health emergencies is even more severely curtailed.¹⁷³ The Fabry disease community's plight is a vivid illustration of this. The mistaken determination by the NIH, coupled with the march-in right's limited utility in an emergency situation, served to defeat the ability of the Act to effectuate its goal of protecting the public health and safety. Indeed, it seems as though the fears that the Act's detractors expressed while the Act was before Congress have been wholly realized: march-in rights have become nothing more than a "paper tiger," offering the public nothing more than the appearance of protection from misuse of the inventions it funded.¹⁷⁴ While march-in rights may have previously existed as an existential threat to patent holders after the

¹⁷¹ See *supra* text accompanying note 59 describing the march-in procedure.

¹⁷² See *supra* text accompanying note 144 describing the FDA-approval process.

¹⁷³ See GAO report, *supra* note 60, at 15 ("March-in authority could have limited utility in an emergency situation such as an important public health issue."); McGarey & Levey, *supra* note 34, at 1100–10 ("In a case where march-in was justified by a health care emergency, the administrative process would likely not be expeditious enough to address the situation."); Rai & Eisenberg, *supra* note 5, at 290 ("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 'alleviating health or safety needs.'").

¹⁷⁴ See *Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before the Subcomm. on Legis. and Nat'l Sec. of the H. Comm. on Gov't Operations*, 96th Cong., 55 (1980) [hereinafter *Patent and Trademark Law Amendments of 1980*] (statement of Rep. Jack Brooks, Chairman, Comm. on Gov't Operations) ("The Government does not use its march-in rights one in a million times. . . . I think that it is a paper tiger. I think we can forget [march-in rights] as a realistic protection for the public.").

Fabrazyme decision, it is probably safe for the current holders of publicly funded patents to conclude that they have nothing to fear from the march-in provision—that the provision constitutes nothing more than an empty threat which will never actually be exercised, no matter how egregious the harm being inflicted upon the public health and safety.

While the public derives substantial benefit from the Bayh-Dole Act's success in increasing commercialization of publicly funded research,¹⁷⁵ taxpayers also deserve at least some sort of functional mechanism to protect them from the "unreasonable use" of inventions funded by taxpayer dollars, especially when such use threatens the public health and safety. If the NIH refuses to ever utilize the primary mechanism intended for that purpose—either out of concern for the length of the proceedings or sheer lack of political will—then the public has no such protection. Accordingly, Congress should enact modest reforms of the Act aimed at two goals: (1) specifying with greater clarity what circumstances warrant a march-in; and (2) streamlining the procedural hurdles currently encumbering the decision to move forward with a march-in, especially in cases where the public health or safety is threatened, such as a drug shortage like the Fabrazyme case.¹⁷⁶

In the case of a future drug shortage similar to the Fabrazyme case, Congress should specify whether or not the presence of a third party manufacturer is a necessary pre-condition to a march-in. Additionally, in these cases, Congress should consider putting in place a procedure under which the NIH and the FDA can work cooperatively. In the Fabrazyme case, for instance, the hurdles of achieving FDA approval for an alternative to Fabrazyme likely prevented a third party from seeking a patent license compelled by the NIH via a march-in.¹⁷⁷ In cases where a proven, effective drug already exists but is in short supply, Congress should contemplate enacting a shorter route to FDA approval by a third party who receives a patent license via a march-in in order to restore the drug supply as quickly as possible. This should not raise substantial

¹⁷⁵ See McCabe, *supra* note 14, at 665–66 (arguing that the public receives substantial long term benefits from increased commercialization of publically funded research in the form of greater technological development).

¹⁷⁶ See Rai & Eisenberg, *supra* note 5, at 311 (arguing that the requirement that march-in authority be held in abeyance pending exhaustion of all court appeals by government contractor should be changed).

¹⁷⁷ The route to FDA approval for a biological product "highly similar" to a product already on the market is currently governed by 42 U.S.C. § 262 (2010).

concerns for investors, as march-ins would continue to be rare so long as companies avoid undersupplying the market—something already in their best interest anyway.¹⁷⁸ Additionally, under circumstances like the Fabry disease case, the NIH could attach reasonable royalty terms to any license compelled under a march-in to further defray the risk of lost profits in the event of a drug shortage.

Congress should also streamline the current march-in procedure, at least in cases where the public health or safety is threatened. Indeed, as noted previously, the current procedure actually serves to defeat the Act's goal of protecting the public health and safety.¹⁷⁹ These reforms are modest but would go a long way towards restoring the Act's ability to effectuate its goal of protecting the public. Without these reforms, or the NIH showing greater political will to correct its mistaken legal interpretation of the current march-in-provision, the march-in rights provision can no longer be honestly described "as a realistic protection for the public."¹⁸⁰

VI. CONCLUSION

In retaining march-in rights over federally funded research, Congress endeavored to balance private interests with those of the public. While the Bayh-Dole Act has certainly been successful at one of its primary goals—commercializing the products of federally funded research—the Fabryzyme case demonstrates its failure in effectuating another primary goal: protecting the public health and safety from the nonuse or unreasonable use of inventions funded by taxpayer dollars. This failure is a product of both the NIH's mistaken legal interpretation of the Act and the burdensome nature of the march-in process. The statutory authority does exist for the NIH to march-in in the Fabryzyme case, despite its failure to do so. This case is precisely the type of situation Congress intended to remedy by

¹⁷⁸ See GAO report, *supra* note 60, at 15 (arguing that the potential for an agency march-in is far less important to investors than other risks faced when deciding whether or not to invest in a product, and noting that investors believe that so long as march-ins are rare and licensees are careful to follow the requirements of the Bayh-Dole Act, the flow of federally funded inventions to market should not be negatively impacted).

¹⁷⁹ See discussion *supra* note 61.

¹⁸⁰ See *Patent and Trademark Law Amendments of 1980* (statement of Rep. Jack Brooks, Chairman, Comm. on Gov't Operations) ("The Government does not use its march-in rights one in a million times. . . . I think that it is a paper tiger. I think we can forget [march-in rights] as a realistic protection for the public.").

providing for march-in rights. Accordingly, the NIH should re-evaluate its determination upon the Fabry patients' rehearing request and issue a rule clarification.

Absent such a rule clarification by the NIH, Congress should reform the Bayh-Dole Act to clarify when a march-in is warranted and, most importantly, to streamline the process for doing so. Such reforms would be modest and should be targeted at ensuring that statutorily conferred monopolies over life-saving treatments derived from federally funded research are not withheld from the public again, either intentionally or through negligent mistakes in production. Without these reforms, or a showing of great political will by the NIH to correct its legal mistake, march-in rights will cease to be even a "paper tiger," and will offer the public no greater protection than mere paper.