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## Reorienting Bayh-Dole's March-In: Looking to Purpose and Objectives in the Public's Interest

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# Reorienting Bayh-Dole's March-In: Looking to Purpose and Objectives in the Public's Interest

## **Keywords**

Patent laws & legislation -- United States; Patent misuse; Inventions -- United States; Public interest -- United States; Commercialization; Patent licenses -- United States

# REORIENTING BAYH-DOLE'S MARCH-IN: LOOKING TO PURPOSE AND OBJECTIVES IN THE PUBLIC'S INTEREST

ABIGAIL AMATO RIVES\*

## ABSTRACT

*Congress passed the Bayh-Dole Act to promote the commercialization of inventions that arise from federally funded research. However, Congress knew there was a potential that private beneficiaries might misuse the Act. To combat that risk and protect the public's interest, Congress included a "march-in" provision. This gives the government an option to intervene when private actors are not making reasonable efforts to realize the benefits of a federally funded invention.*

*So far, the march-in provision has failed to live up to its potential. Although the government has received five march-in petitions, it has never exercised this right. Federal research agencies, interpreting their march-in right, have relied on a narrow interpretation of the statute. This narrow interpretation has meant that agencies are only able to prevent a narrow range of problems. Instead, march-in needs to be an effective safety valve that prevents misuse of Bayh-Dole inventions and protects the public interest without undercutting the overall Bayh-Dole framework.*

*This Article argues that march-in can be a more effective tool for combating misuse, if the government makes minor changes to the process by which it decides whether to march-in. Specifically, the government should consider the purpose and objectives of the Bayh-*

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\* I would like to thank Professor Liza Vertinsky for a year of patience, advice, oversight, and interesting conversations on this topic. I would also like to thank Professor Margo Bagley for shedding new light on these ideas. Finally, I would like to thank Dr. Stuart Nightingale, Christopher Cortez, Kristi North, Katharine Amato, and Albert Rives for helpful feedback and support throughout the drafting process.

*Dole Act and weigh the public's interest when making a march-in decision. Congress should amend the Bayh-Dole Act to establish this new approach to march-in, and the implementing regulations should be revised. Furthermore, federal research agencies should develop official guidance interpreting the march-in provision. Developing this guidance through a public process will give the U.S. taxpayers an opportunity to articulate their goals and expectations for federally funded inventions, while industry interests can ensure that their needs are addressed in future march-in decisions. The guidance can serve as a framework for future agency march-in decisions, and signal to the community circumstances under which a march-in petition would be successful. This approach will allow the government to create the safety valve Bayh-Dole needs without disturbing the successful operation of the Act*

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## INTRODUCTION

In 1988, Abbott Laboratories received a grant from the National Institutes of Health (“NIH”), and the company used these funds to discover ritonavir.<sup>1</sup> Ritonavir, marketed as Norvir, is a potent HIV/AIDS therapy from the class of protease inhibitors.<sup>2</sup> Abbott brought the product to market in 1996, and, by 2003, the average daily price for Norvir was \$1.71.<sup>3</sup> However, in December 2003, Abbott Laboratories abruptly increased the price 400 percent, to \$8.57.<sup>4</sup> Patients and advocates, frustrated by the price increase, came to the government seeking relief.<sup>5</sup> They asked the NIH to exercise its statutory “march-in” right to resolve the access problem caused by this price-hike.<sup>6</sup>

The Bayh-Dole Act gives research institutions, such as universities or private labs, the ability to retain patent rights for inventions that arise from federally funded research.<sup>7</sup> Under the Act, the government also retains the right to “march-in” and issue a license for the patented technology to another party; the government can march-in when patent-holders are not making reasonable efforts to realize the public benefits of a federally funded invention.<sup>8</sup> In the

1. Susan R. Morrissey, ‘*Marching In*’ on NIH-Funded Drugs, CHEMICAL & ENGINEERING NEWS (Sept. 14, 2004), <http://pubs.acs.org/cen/news/8237/8237earlygov1.html>.

2. Zelalem Temesgen, David Warnke & Mary J. Kasten, *Current Status of Antiretroviral Therapy*, 7 EXPERT OPINION PHARMACOTHERAPY 1541, 1546 (2006).

3. *In re Abbott Labs. Norvir Anti-Trust Litig.*, 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008).

4. Carina Marquez, B. Joseph Guglielmo & Jeffrey D. Klausner, *Five Years Later: Re-examining the Financial Burden of Boosting with Norvir*, 22 AIDS 2402, 2402 (2008); Ceci Connolly, *NIH Declines to Enter AIDS Drug Price Battle*, WASH. POST, Aug. 5, 2004, at A04, <http://www.washingtonpost.com/wp-dyn/articles/A40430-2004Aug4.html>.

5. KNOWLEDGE ECOLOGY INTERNATIONAL, REQUEST FOR MARCH-IN ON ABBOTT PATENTS FOR RITONAVIR ON GROUNDS THAT ABBOTT PRIVATE SECTOR PRICES FOR RITONAVIR ARE HIGHER IN USA THAN IN OTHER HIGH INCOME COUNTRIES, AND ABBOTT'S REFUSAL TO LICENSE PATENTS FOR NON-ABBOTT FIXED DOSE COMBINATIONS OF HIV DRUGS 5 (Oct. 25, 2012) [hereinafter NORVIR PETITION 2012], available at [http://keionline.org/sites/default/files/2012\\_Oct25\\_Ritonavir\\_march\\_in\\_complaint.pdf](http://keionline.org/sites/default/files/2012_Oct25_Ritonavir_march_in_complaint.pdf).

6. NORVIR PETITION 2012, *supra* note 5, at 2.

7. 35 U.S.C. § 202 (2006). In 1983, President Reagan extended the reach of the Bayh-Dole Act to cover all organizations that receive federal research funding. Originally, the Bayh-Dole Act only applied to universities and small businesses. After a Presidential memo and Executive Order, agencies revised their regulations to treat all research organizations equally. See Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 22, 1987); Memorandum on Government Patent Policy, 1983 BOOK I PUB. PAPERS 248 (Feb. 18, 1983); National Science Foundation Patent Policy, 45 C.F.R. § 650.2 (2012) (amending NSF regulations to comply with the Presidential directive ordering that Bayh-Dole apply to all research organizations).

8. 35 U.S.C. § 203 (2006).

case of Norvir, if the government exercised this march-in right it would allow competitive manufacturing, lower prices, and new combination HIV/AIDS treatments.<sup>9</sup> Patients have asked for a march-in on the Norvir patent twice; first in 2004 and again in 2012.<sup>10</sup> The agency is currently evaluating the 2012 march-in petition.<sup>11</sup>

Patients and advocates asking for a march-in characterized Abbott's decision as an abusive practice.<sup>12</sup> Norvir is not used as a standalone treatment, but instead prescribed in conjunction with almost all other protease inhibitors to enhance their effectiveness.<sup>13</sup> Abbott raised the price of Norvir to preserve the strong position of Kaletra in the market.<sup>14</sup> Kaletra, another of Abbott's HIV/AIDS products, is a combination pill that contains one of the same active ingredients as Norvir.<sup>15</sup> Abbott had determined that increasing the price of Norvir would be an effective weapon against Kaletra's competition.<sup>16</sup> As a result of the price increase, patients had to choose either an expensive treatment regimen including Norvir or switch to Kaletra, regardless of what treatment worked best for the individual patient.<sup>17</sup>

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9. See *infra* notes 271-275 and accompanying text.

10. ESSENTIAL INVENTIONS, INC., PETITION TO USE AUTHORITY UNDER BAYH-DOLE ACT TO PROMOTE ACCESS TO RITONAVIR, SUPPORTED BY NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES CONTRACT NO. A127220 11 (Jan. 29, 2004) [hereinafter NORVIR PETITION 2004], available at <http://www.essentialinventions.org/legal/norvir-29jan04petition.pdf>.

11. See NORVIR PETITION 2012, *supra* note 5.

12. NORVIR PETITION 2004, *supra* note 10, at 10-11, 17; Krista Cox, *Notes from the March 18, 2013 NIH Call on the Ritonavir March-In Request*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 19, 2013, 7:47 AM), <http://keionline.org/node/1685>.

13. Jana Pokorna, Ladislav Machala, Pavlina Rezacova & Jan Konvalinka, *Current and Novel Inhibitors of HIV Protease*, 1 VIRUSES 1209, 1216-17 (2009).

14. See John Carreyrou, *Inside Abbott's Tactics to Protect AIDS Drug*, WALL ST. J., Jan. 3, 2007, at A1, <http://online.wsj.com/article/SB116778411362865429.html> (describing the tactics Abbott considered when it wanted to protect Kaletra against competition, resulting in the Norvir price increase).

15. *In re Abbott Labs. Norvir Anti-Trust Litig.*, 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008).

16. Carreyrou, *supra* note 14, at A1.

17. See Letter from Michael Weinstein, President, AIDS Healthcare Found., to Tommy Thompson, Sec'y, Dep't of Health and Human Servs. (Jan. 28, 2004), <http://www.ott.nih.gov/policy/meeting/Michael-Weinstein.pdf> (stating that "a ritonavir-containing [sic] regimen [is] much more expensive, unless Abbott's Kaletra is used"); Letter from Lynda Dee, Co-Chair, AIDS Treatment Activists Coal. Drug Dev. Comm., to Mark L. Rohrbaugh, Dir., Office of Tech. Transfer, Nat'l Insts. of Health (Feb. 26, 2004), <http://www.ott.nih.gov/policy/meeting/Lynda-Dee.pdf> (describing how "[t]he disparity in the price of Kaletra versus other Norvir-boosted protease combinations will negatively impact the health and safety of people with HIV/AIDS . . ."); Letter from Benjamin Young, Org. of Healthcare Providers, to Tommy Thompson, Sec'y, Dep't of Health and Human Servs., and Mark Rohrbaugh, Dir., Office of Tech. Transfer, Nat'l Insts. of Health (Mar. 10, 2004), <http://www.ott.nih.gov/policy/meeting/Benjamin-Young.pdf> (noting that the price increase "will have adverse consequences for the care of patients as doctors and

Today, U.S. patients cannot access new, effective HIV treatments, because Abbott refuses to license Norvir.<sup>18</sup>

Congress adopted the Bayh-Dole Act to encourage utilization and commercialization of new inventions by granting private patent rights in federally funded inventions.<sup>19</sup> Abbott exploited this privilege. Instead of promoting utilization of and access to Norvir,<sup>20</sup> the company manipulated the price of the federally funded invention to control the HIV/AIDS treatment market.<sup>21</sup>

Although the government has received five march-in petitions since Congress passed the Bayh-Dole Act, it has never exercised this right.<sup>22</sup> March-in was intended to protect the public interest<sup>23</sup> and

patients will feel pressure to use Kaletra, even when it is not the best treatment for a patient”).

18. See NORVIR PETITION 2012, *supra* note 5, at 6 (describing a new atazanavir/Norvir combination product that is available in developing countries but not in the U.S.); Jean-Michel Molina et al., *Once-daily Atazanavir/Ritonavir Versus Twice-daily Lopinavir/Ritonavir, Each in Combination with Tenofovir and Emtricitabine, For Management of Antiretroviral-Naïve HIV-1 Infected Patients: 48 Week Efficacy and Safety Results of the CASTLE Study*, 372 LANCET 646, 646-47 (2008) (describing how the atazanavir/Norvir combination is better than some of the other protease inhibitor combinations that include Norvir).

19. See *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 28-29 (1979) (statement of Sen. Bob Dole); *id.* at 2-3 (statement of Sen. Birch Bayh).

20. See 35 U.S.C. § 200 (2006) (the purpose and objectives of Bayh-Dole include promoting utilization of inventions and public availability).

21. See Carreyrou, *supra* note 14.

22. Meredith Wadman, *NIH Asked to Grant Open Licence 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>; J. Steven Rutt, *Important Update re: Bayh-Dole Law and Policy: Another “March-In” Petition*, CLEANTECH AND NANO BLOG (Oct. 30, 2012), <http://www.nanocleantechblog.com/2012/10/30/important-update-re-bayh/>. In July 2013, Senator Patrick Leahy sent a letter to NIH requesting that the agency consider march-in with respect to Myriad Genetic’s BRCA gene tests. Tony Dutra, *Leahy Calls for NIH March-in Against Myriad But Some Patents Not Subject to Bayh-Dole*, BLOOMBERG LAW, <http://about.bloomberglaw.com/law-reports/leahy-calls-for-nih-march-in-against-myriad-but-some-patents-not-subject-to-bayh-dole/> (last visited Aug. 8, 2013) (providing perspectives from two scholars on why this march-in request will not be successful, and linking to Leahy’s letter); Donald Zuhn, *Senator Leahy Urges NIH to Use March-In Rights on Myriad BRCA Test*, PATENT DOCS (July 17, 2013, 11:59 PM), <http://www.patentdocs.org/2013/07/senator-leahy-urges-nih-to-use-march-in-rights-on-myriad-brca-test.html> (providing background on the request and a description of patents in question).

23. *E.g.*, 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, 1096 (1999); NAT’L RESEARCH COUNCIL, *MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST* 17 (Stephen A. Merrill & Anne-Marie Mazza eds., 2010) [hereinafter *MANAGING UNIVERSITY INTELLECTUAL PROPERTY*], available at [http://www.nap.edu/catalog.php?record\\_id=13001](http://www.nap.edu/catalog.php?record_id=13001).

prevent misuse of federally funded inventions.<sup>24</sup> As the Norvir experience shows, march-in has not succeeded in achieving these goals. Abbott continues to charge a high price for a federally funded technology, and U.S. patients cannot access some of the best available HIV/AIDS treatment regimens.<sup>25</sup> The high price of Norvir does not reflect the value of the product;<sup>26</sup> it reflects Abbott's desire to maintain power in the market for HIV/AIDS treatment.<sup>27</sup>

Furthermore, march-in was intended to be a valuable deterrent against inventors, universities, and companies misusing Bayh-Dole inventions.<sup>28</sup> However, since march-in has never been used, its "deterrent value has been diminished over time."<sup>29</sup> The march-in decision process needs to change to stop parties from misusing Bayh-Dole and prevent future misuse. This Article argues that we need an effective safety valve in the Bayh-Dole Act that prevents misuse of inventions and protects the public's interest, without undercutting the overall framework of the Bayh-Dole Act.

Academics have not paid much attention to the march-in provision.<sup>30</sup> Many scholars have written about the Bayh-Dole Act, addressing the development of research tools,<sup>31</sup> the role of

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24. See Amy R. Schofield, *The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions*, 32 J.L. MED. & ETHICS 777, 780 (2004) (describing the need to protect the public against certain harms, quoting a Senate Committee Report that march-in "should be a sufficient safeguard to protect public welfare," and citing Senator Russell Long's concern "that march-in rights would be 'ineffective and valueless' in protecting the American public against misuse of government-funded inventions").

25. See sources cited *supra* note 18 and accompanying text.

26. The price of Norvir, before an intentional price increase, was \$1.71/day. *In re Abbott Labs. Norvir Anti-Trust Litig.*, 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008).

27. See Carreyrou, *supra* note 14.

28. See, e.g., McGarey & Levey, *supra* note 23, at 1116 (referring to march-in as "the proverbial sword of Damocles, suspended over the federally-funded invention licensing process, its very presence an incentive for parties to resolve privately would-be cases of march-in"); Mark L. Rohrbaugh & Brian R. Stanton, *Technology Transfer at the National Institutes of Health*, TECHNOLOGY TRANSFER IN BIOTECHNOLOGY: A GLOBAL PERSPECTIVE 35, 43 (Prabuddha Ganguli, Ben Prickril & Rita Khanna eds., 2009) (stating that march-in "is useful as a deterrent . . .").

29. David Halperin, *The Bayh-Dole Act and March-In Rights*, NATIONAL INSTITUTE OF HEALTH OFFICE OF TECHNOLOGY TRANSFER 17 (2001), available at <http://www.ott.nih.gov/policy/meeting/David-Halperin-Attorney-Counselor.pdf>.

30. Select scholarship on the march-in provision includes: McGarey & Levey, *supra* note 23; Schofield, *supra* note 24; 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); 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).

31. See, e.g., Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003); Gary Pulsinelli,



universities in product development,<sup>32</sup> and the problem of anti-commons.<sup>33</sup> Some authors have rejected the idea that Bayh-Dole has even had a beneficial effect.<sup>34</sup> A few authors have suggested major changes in the Bayh-Dole framework.<sup>35</sup> This Article, instead, focuses on public access to products—especially medically or clinically useful products—and offers a practical solution to the misuse of Bayh-Dole inventions through the march-in provision.

This Article will explain how, with a shift in focus and minor amendments to the statute and regulations, march-in can be an effective tool to prevent misuse of Bayh-Dole inventions. Part I provides background on the Bayh-Dole Act, the march-in provision, and how the current approach to march-in is flawed. Part II tells the story of two recent march-in petitions: a more detailed description of the Norvir case and a request for march-in on a treatment for Fabry disease. These stories reveal how beneficiaries of the Bayh-Dole Act can exploit this benefit in ways that are inconsistent with the Act's objectives. This Part also discusses the current landscape of federally funded biomedical research, and illustrates why the government needs to fix the march-in problem. Part III proposes a solution to the current march-in problem. By simply refocusing the march-in process, the government can achieve better results with greater public approval and without damaging the underlying Bayh-Dole framework. Shifting the approach to march-in can be accomplished through a series of policy, statutory, and regulatory actions. Finally, Part IV discusses implications of a change to march-in and explains how this Article's approach is superior to other recent policy suggestions.

## I. THE BAYH-DOLE ACT AND ITS MARCH-IN PROVISION

U.S. research universities drive the generation of new ideas and

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*Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393 (2006).

32. See, e.g., Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217 (2006); Liza S. Vertinsky, *Experimenting with University Innovation Capacity*, 62 EMORY L.J. 741 (2013).

33. See, e.g., Anthony D. So et al., *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLOS BIOLOGY 2078, 2080 (2008).

34. See, e.g., *id.* at 2079; David 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, 101-102 (2001).

35. See Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1439-1443 (2007); Michael Sweeney, Comment, *Correcting Bayh-Dole's Inefficiencies for the Taxpayer*, 10 NW. J. TECH. & INTELL. PROP. 295 (2012); Arno & Davis, *supra* note 30.

innovation.<sup>36</sup> Government sponsored university research led to the invention of global positioning systems, DNA fingerprinting, fetal monitoring, and the algorithm for Google searching.<sup>37</sup> Over the past forty years, federally funded research institutions have invented over 150 new biomedical products or new indications for existing drugs.<sup>38</sup> The Bayh-Dole Act is credited with making these benefits possible.<sup>39</sup>

In recent years, the U.S. government has spent approximately \$140 billion on research and development (“R&D”) annually.<sup>40</sup> The Bayh-Dole Act is the primary statutory foundation for federal technology transfer,<sup>41</sup> and applies to the research sponsored by all federal agencies.<sup>42</sup> The Department of Defense, NIH, Department of Energy, National Aeronautics and Space Administration (“NASA”), and the National Science Foundation are the federal agencies that spend the most on R&D.<sup>43</sup> NIH is the largest funder of biomedical research in the world.<sup>44</sup> This Part will explain the rationale behind the Bayh-Dole Act and describe the march-in provision, both its content and application.

### A. *The Bayh-Dole Framework*

The Bayh-Dole Act was passed in 1980, based on the belief that granting patent rights on federally funded inventions would motivate companies to carry these inventions through development.<sup>45</sup> The purpose of the Act is to promote “utilization of inventions arising from federally supported research or development,” free competition, commercialization of inventions, and the public

36. NAT’L RESEARCH COUNCIL, RESEARCH UNIVS. & THE FUTURE OF AMERICA: TEN BREAKTHROUGH ACTIONS VITAL TO OUR NATION’S PROSPERITY AND SECURITY 1 (2012), available at [http://www.nap.edu/openbook.php?record\\_id=13396](http://www.nap.edu/openbook.php?record_id=13396).

37. *Id.* at 2-3; Jonathan R. Cole, *Can American Research Universities Remain the Best in the World?*, CHRON. HIGHER EDUC., Jan. 3, 2010, <http://chronicle.com/article/The-Clouded-Future-of-Ameri/63353/>.

38. Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEW ENGLAND J. MED. 535 (2011).

39. *See Innovation’s Golden Goose*, THE ECONOMIST, Dec. 12, 2002, <http://www.economist.com/node/1476653>; *see also supra* notes 37-38.

40. JOHN F. SARGENT JR., CONG. RESEARCH SERVICE, FEDERAL RESEARCH AND DEVELOPMENT FUNDING: FY 2013 4 (2013), available at <https://www.fas.org/sgp/crs/misc/R42410.pdf>.

41. McGarey & Levey, *supra* note 23, at 1097.

42. 35 U.S.C. § 200-211, 301-307 (2006); MANAGING UNIVERSITY INTELLECTUAL PROPERTY, *supra* note 23, at 16 (“The Act established a uniform patent policy among federal agencies funding research . . .”).

43. SARGENT, *supra* note 40, at 3.

44. *About NIH*, NATIONAL INSTITUTES OF HEALTH (Jun. 6, 2013), <http://www.nih.gov/about/>.

45. Rai & Eisenberg, *supra* note 31, at 290.

availability of products.<sup>46</sup>

America has a rich tradition of innovation, but in the 1970s, America's R&D productivity was increasing at a slower rate than that of global competitors.<sup>47</sup> Prior to the Act, the government retained ownership of most inventions.<sup>48</sup> The government would only grant companies non-exclusive licenses.<sup>49</sup> Companies found this unattractive, and few products were developed from federally funded research.<sup>50</sup> At the time, only four percent of government-held inventions were successfully licensed<sup>51</sup> and only five percent of government-funded inventions were used.<sup>52</sup> Congress blamed the federal research policy for stifling productivity and withholding inventions from the American public.<sup>53</sup> Seeking to reverse this trend, Congress leveraged traditional patent law incentives in federal research policy to "insure that the fruits of American inventive genius are delivered to the marketplace as quickly as possible. . . ."<sup>54</sup>

An important function of patents in U.S. law is the *ex post* incentive to innovate.<sup>55</sup> The Bayh-Dole Act employs a simple mechanism: it allows institutions that receive federal research funding to retain ownership of patents that emerge from their work.<sup>56</sup> The universities, small-businesses, or organizations ("contractors") that employ federally funded investigators can leverage these patents and grant licenses to private companies ("licensees").<sup>57</sup> The companies that license these inventions will further develop and commercialize the ultimate products.<sup>58</sup> The Bayh-Dole Act allows universities to enter into exclusive licenses for

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46. 35 U.S.C. § 200 (2006).

47. *See The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 1-2 (1979) (statement of Sen. Birch Bayh).

48. *Id.* at 2.

49. *Id.*

50. *Id.*

51. *Id.* at 28 (statement of Sen. Bob Dole).

52. *Id.*

53. *Id.*

54. *Id.* at 3 (statement of Sen. Birch Bayh).

55. CRAIG ALLEN NARD, *THE LAW OF PATENTS* 32-33 (2nd ed., 2011).

56. 35 U.S.C. § 202 (2006).

57. *Id.*; Jerry G. Thursby & Marie C. Thursby, *University Licensing and the Bayh-Dole Act*, 301 *SCIENCE* 1052, 1052 (2003).

58. *See The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 28-29 (1979) (statement of Sen. Bob Dole) (noting the benefits of uniform federal patent policy, including incentivizing private sector product development, creating partnerships that promote practical implementation of inventions, and promoting utilization of inventions).

federally funded inventions.<sup>59</sup> Under some circumstances, this exclusivity is necessary to motivate companies to bring products to market.<sup>60</sup>

The Bayh-Dole Act has been referred to as “the most inspired piece of legislation to be enacted in America over the past century.”<sup>61</sup> It has been applauded for major contributions to the U.S. economy and it is even credited with providing the foundation for the entire biotech industry.<sup>62</sup> However, the Act is not free from criticism.<sup>63</sup> For example, critics argue that the Act requires taxpayers to “double pay” for products.<sup>64</sup> The U.S. taxpayer supports the research underlying an invention and then has to pay again to access the product.<sup>65</sup> Furthermore, the Act is criticized on the grounds that patents are not necessary to achieve commercialization of all federally funded inventions.<sup>66</sup> Critics are also concerned about the ability of the public to access Bayh-Dole subject inventions.<sup>67</sup>

### *B. The March-In Provision: Content and Application*

Within the Bayh-Dole Act, there are oversight provisions that authorize the government to intervene on private parties that are enjoying patent rights.<sup>68</sup> March-in rights are one important way for

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59. Thursby & Thursby, *supra* note 57, at 1052 (for example, “[e]xclusive licensing may be needed when inventions require further development before use”).

60. See Thursby & Thursby, *supra* note 57, at 1052.; see also Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Tale of University Licensing* (Nat’l Bureau of Econ. Research, Working Paper No. 6698, 1998), available at <http://www.nber.org/papers/w6698.pdf> (noting that “unless universities have the right to license patentable inventions, many results from federally funded research would never be transferred to industry”). *But see* Rai & Eisenberg, *supra* note 31, at 301 (“It is also unclear whether such exclusive licenses are necessary to further the Bayh-Dole Act’s goal of promoting commercial product development.”).

61. *Innovation’s golden goose*, THE ECONOMIST, *supra* note 39.

62. *E.g.*, Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, 2 SCI. TRANSLATIONAL MED. 27, 27-29 (2010) (for example, explaining that the Bayh-Dole Act “played a critical role in rejuvenating the entire U.S. economic system”).

63. See, *e.g.*, Rai & Eisenberg, *supra* note 31; Halperin, *supra* note 29; Pulsinelli, *supra* note 31; Michael Sweeney, *Correcting Bayh-Dole’s Inefficiencies for the Taxpayer*, 10 NW. J. TECH. & INTELL. PROP. 295 (2012).

64. See Pulsinelli, *supra* note 31, at 410-11 (describing a fundamental argument against Bayh-Dole—the public paid for the initial research and must pay a second time to purchase a product from a patent holder). *But see* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 15 (2003) (referring to the argument that government should not obtain copyright protection because the public would pay twice – for the creation and subsequent purchase – and stating that “[i]f correct, it would mean that government should never charge a fee for any service”).

65. Pulsinelli, *supra* note 31, at 410-11.

66. See, *e.g.*, Rai & Eisenberg, *supra* note 31, at 302.

67. So, *supra* note 33, at 2081.

68. MANAGING UNIVERSITY INTELLECTUAL PROPERTY, *supra* note 23, at 52-53.

the government to step in to promote general welfare and protect the public interest.<sup>69</sup> The federal agency that funded a Bayh-Dole subject invention can march-in and require the inventor, assignee, or licensee to issue a license under certain circumstances. Essentially, the march-in provision gives the government the right to force a new license in two circumstances: if it is necessary to *achieve practical application* of the invention or if it is necessary to alleviate unmet health and safety needs.<sup>70</sup> Elsewhere, the statute defines “practical application” as manufacturing or practicing an invention such that “the invention is being utilized and that its benefits are . . . available to the public . . . .”<sup>71</sup> To date, the government has received five march-in petitions.<sup>72</sup> All five have been directed to the NIH, and at the time of this Article the fifth one is pending before the Agency.<sup>73</sup>

According to Senator Bayh, the intent of the march-in provision “is to insure that every effort is made to bring a product to market.”<sup>74</sup> In circumstances where “this is not being done, the funding agency can ‘march-in’ and require” a license be issued to someone else.<sup>75</sup> The standard quid pro quo of patent law is a government-granted right to exclude in exchange for invention disclosure.<sup>76</sup> Under the Bayh-Dole Act, march-in compels an additional layer of the quid pro quo. An inventor has an affirmative obligation to practice the invention in exchange for government research funding and patent rights.<sup>77</sup> If a contractor or licensee is not living up to this responsibility, the government can revoke the right to exclude.<sup>78</sup> March-in is the government’s tool to ensure contractors and licensees are living up to

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69. See *supra* note 23 and accompanying text.

70. 35 U.S.C. § 203 (2006).

71. 35 U.S.C. § 201(f) (2006).

72. Wadman, *supra* note 22.

73. Kevin E. Noonan, *Groups Petition for NIH Exercise of March-In Rights Over Abbott Laboratories’ Norvir*, PATENT DOCS (Oct. 31, 2012, 11:59 PM), <http://www.patentdocs.org/2012/11/groups-petition-for-nih-exercise-of-march-in-rights-over-abbott-laboratories-norvir.html>.

74. Senator Birch Bayh, Statement of Senator Birch Bayh to the National Institutes of Health 2 (May 25, 2004), available at <http://www.ott.nih.gov/policy/meeting/Senator-Birch-Bayh.pdf>.

75. *Id.* (“When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions that are the subject of today’s meeting.”)

76. NARD, *supra* note 55, at 31.

77. See 35 U.S.C. § 202(c)(5) (2006) (the government can require periodic reporting on utilization efforts of contractors and licensees); 35 U.S.C. § 203 (2006) (if contractors and licensees are not achieving practical application, the government can march-in and require a rights holder to issue licenses).

78. 35 U.S.C. § 203.

their end of the Bayh-Dole bargain.

When making its first four march-in decisions, NIH relied on the plain statutory text of the march-in provision.<sup>79</sup> The agency only considered whether contractors and licensees were taking effective steps to achieve practical application of an invention<sup>80</sup> and whether march-in would alleviate unmet health and safety needs.<sup>81</sup> This rigid reliance on the text indicates that NIH would only consider these two factors in deciding whether to march-in. With such a precedent set, it appears that NIH will be bound to follow a similar analytical approach for future march-in decisions.<sup>82</sup> If march-in is going to have practical meaning and operate as an effective deterrent,<sup>83</sup> the agency must be consistent in its interpretation of the statute.<sup>84</sup> However, relying narrowly on statutory text in this way makes it hard for the agency to combat all misuses of the Bayh-Dole Act. For example, if NIH employs this approach for the current petition, it is unlikely to march-in on the Norvir patent.<sup>85</sup>

## II. A TALE OF TWO DRUGS

The Introduction briefly described one way in which a company can misuse a Bayh-Dole invention. This Part further develops the

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79. See NATIONAL INSTITUTES OF HEALTH: OFFICE OF THE DIRECTOR, IN THE CASE OF NORVIR® MANUFACTURED BY ABBOT LABORATORIES, INC. 4-6 (July 29, 2004) [hereinafter CASE OF NORVIR], available at <http://www.ott.nih.gov/policy/March-In-Norvir.pdf>. Two major sections of NIH's 2004 march-in decision addressed "practical application" and "health or safety needs." (The agency also mentioned drug pricing, because of the specific request.) The agency ultimately decided not to march-in because exercise of rights was not "warranted in this case within the meaning of 35 U.S.C. § 203." *Id.* at 6. See also *infra* note 81 and accompanying text (NIH employed a similar approach in all the march-in decisions, and NIH always ties its ultimate conclusion back to the language and meaning of 35 U.S.C. § 203, 35 U.S.C. § 203(a) (1), or 35 U.S.C. § 203(a) (2)).

80. 35 U.S.C. § 203(a) (1).

81. 35 U.S.C. § 203(a) (2).

82. NIH has used the same basic framework in all four march-in decisions, based in the explicit language of 35 U.S.C. § 203. See CASE OF NORVIR, *supra* note 79; NAT'L INST. OF HEALTH OFFICE OF THE DIR., DETERMINATION IN THE CASE OF PETITION OF CELLPRO, INC. (Aug. 1997) [hereinafter CellPro], available at <http://www.ott.nih.gov/policy/cellpro-marchin.pdf>; NAT'L INST. OF HEALTH OFFICE OF THE DIR., DETERMINATION IN THE CASE OF XALATAN® MANUFACTURED BY PFIZER, INC. (Sept. 17, 2004) [hereinafter Xalatan], available at <http://www.ott.nih.gov/policy/March-in-xalatan.pdf>; NAT'L INST. OF HEALTH OFFICE OF THE DIR., DETERMINATION IN THE CASE OF FABRAZYME® MANUFACTURED BY GENZYME CORPORATION (Dec. 1, 2010) [hereinafter Fabrazyme], available at <http://www.ott.nih.gov/policy/March-In-Fabrazyme.pdf>.

83. See McGarey & Levey, *supra* note 23, at 1116 (describing the potential for march-in to operate as a deterrent against Bayh-Dole abuses).

84. MANAGING UNIVERSITY INTELLECTUAL PROPERTY, *supra* note 23, at 52.

85. See CASE OF NORVIR, *supra* note 79 (based on the same basic facts, NIH declined to march-in on the Norvir patent in 2004).

concept of misuse through the story of two actual march-in petitions. In these stories, a contractor or licensee leveraged its position as the owner of a federally funded patent for a purpose that is inconsistent with the objectives of the Bayh-Dole Act. For the purpose of this Article, that inconsistent use of a Bayh-Dole invention falls within the scope of “misuse.” The misuses described here would tend to reduce utilization of and access to an invention, instead of promoting those goals.

First, this Part describes the two recent march-in petitions. One is the Norvir situation introduced earlier. This Part elaborates on the story underlying the march-in petitions and the NIH response. The second march-in petition, regarding a treatment for a rare disease, illustrates how universities can also misuse Bayh-Dole inventions. This Part concludes by discussing the potential for misuse more generally—focusing on the misuse of health and medical-related inventions.

#### *A. Norvir—High Price for the Wrong Reason*

In the late 1980s to early 1990s, researchers at Abbott Laboratories invented and patented zidovudine using federal funds.<sup>86</sup> Zidovudine, marketed under the name “AIDS,” is a nucleoside reverse transcriptase inhibitor; nucleoside reverse transcriptase inhibitors are a class of drugs used to combat HIV.<sup>87</sup> After Abbott introduced AIDS onto the market in 1985, it was discovered that AIDS could “boost” the effectiveness of other nucleoside reverse transcriptase inhibitors when the two were used together.<sup>88</sup> Used alone at high doses, AIDS causes unacceptable side effects.<sup>89</sup> But when it is used in conjunction with another nucleoside reverse transcriptase inhibitor, it is effective at lower doses and improves the overall effectiveness of HIV treatment.<sup>90</sup> Because AIDS was used at smaller doses, and was only used to boost the effectiveness

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86. CASE OF NORVIR, *supra* note 79, at 1. It is unlikely that Abbott would have pursued this project in the absence of federal funding. Abbott used the money to recruit a team of scientists to work in the risky area of antiviral drugs to treat HIV. JOHN ERICKSON, ON THE ROLE OF THE US GOVERNMENT IN THE DEVELOPMENT OF NORVIR 2 (May 25, 2004), available at <http://www.ott.nih.gov/policy/meeting/John-Erickson.pdf>.

87. CASE OF NORVIR, *supra* note 79 at 1; *In re* Abbott Labs. Norvir Anti-Trust Litig., 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008).

88. *In re* Abbott Labs. Norvir Anti-Trust Litig., 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008). Norvir is used to “boost” the effectiveness of other drugs. A small dose of Norvir is used in addition to other protease inhibitors (“PI”); this not only makes the other PI more effective, but the other PI can be taken at lower doses and it reduces the rate at which HIV develops resistance to the other drugs. Boosting PIs with Norvir improves the quality of the overall treatment regimen and makes it possible for patients to live longer. *Id.*

89. *Id.*

90. *Id.*

of other treatments, the price of Norvir dropped from \$18 to \$1.71 per day.<sup>91</sup>

In 2000, Abbott introduced Kaletra.<sup>92</sup> Kaletra contains two drugs in a single pill, ritonavir and another protease inhibitor, lopinavir.<sup>93</sup> In 2003, two of Abbott's competitors introduced new protease inhibitors to the market.<sup>94</sup> Both of these new drugs are more effective if they are "boosted" with Norvir,<sup>95</sup> and Norvir was the only product available for this "boosting."<sup>96</sup> For at least some patients, these new protease inhibitors, when boosted with Norvir, were preferable to Kaletra.<sup>97</sup> As a result, sales of Kaletra dropped.<sup>98</sup>

At the time Abbott's competitors were preparing to introduce new protease inhibitors, Abbott's executives were considering how to protect Kaletra's market.<sup>99</sup> Abbott executives knew that if Norvir were less attractive to patients, then the competing protease inhibitors would also be unattractive.<sup>100</sup> Abbott even considered removing Norvir from the market or only selling it in a liquid formulation that tasted like vomit.<sup>101</sup>

In December 2003, Abbott increased the wholesale price of Norvir by 400 percent.<sup>102</sup> At the same time, Abbott kept the price of Kaletra constant.<sup>103</sup> This had the effect of making Kaletra the least expensive boosted protease inhibitor on the market, and essentially increasing the cost of all competitors' products—because the competing protease inhibitors are prescribed along with the more expensive Norvir booster.<sup>104</sup> Patients, advocates, insurance companies, pharmaceutical companies, and retailers have all sued Abbott over the price increase, alleging antitrust violations and anticompetitive behaviors. However, all of those cases have either settled, dropped, or failed.<sup>105</sup>

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91. *Id.* This price drop reflects the price in 1996 (\$18/day) and the price in 2003 (\$1.71/day).

92. *Id.*

93. *Id.*

94. *Id.* GlaxoSmithKline introduced Lexiva. Bristol-Myers Squibb introduced Reyataz.

95. *Id.*

96. NORVIR PETITION 2004, *supra* note 10, at 11.

97. *In re Abbott*, 562 F. Supp. 2d at 1082.

98. *Id.*

99. Carreyrou, *supra* note 14, at A1.

100. *Id.*

101. *Id.*

102. *In re Abbott*, 562 F. Supp. 2d at 1082.

103. *Id.*

104. *Id.*

105. See Carreyrou, *supra* note 14, at A11; *In re Abbott*, 562 F. Supp. 2d at 1082; Karen Gullo, *Abbott Tells Jurors Kaletra was 'Clobbered' by Competitors*,



Because Abbott received an NIH grant to fund the early development of Norvir, the agency has the legal authority to march-in on the invention and issue licenses to other manufacturers.<sup>106</sup> In 2004 and in 2012, interested parties requested a march-in on the federally funded patents for Norvir.<sup>107</sup> In 2004, petitioners requested an open license, to allow generic manufacturers to produce ritonavir while paying a reasonable royalty to Abbott.<sup>108</sup> This license would have opened the door to cheaper, generic versions of Norvir.<sup>109</sup> NIH declined to march-in; the Food and Drug Administration (FDA) had approved Norvir, Abbott was marketing it, and physicians were prescribing it.<sup>110</sup> Based on this evidence, NIH concluded that that march-in was not appropriate<sup>111</sup> because Abbott was satisfying the “practical application” and “health and safety needs” requirements taken directly from the statute.<sup>112</sup>

By 2012, the average retail price for Norvir in the U.S. was as high as \$12.63.<sup>113</sup> On October 25, 2012, a collection of nonprofit organizations submitted a similar petition for march-in on the Norvir patents.<sup>114</sup> These petitioners sought broader policy changes to address the problem of high-priced drugs on the domestic market.<sup>115</sup> NIH has not announced its decision in response to this march-in petition.

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BLOOMBERG (Mar. 1, 2011), <http://www.bloomberg.com/news/2011-02-28/glaxo-seeks-billions-in-aids-drug-monopoly-case-against-abbott.html>; Karen Gullo & Matthew Hirsch, *Abbott Settlement in Norvir Lawsuit Approved by Judge (Update I)*, BLOOMBERG (Aug. 19, 2008), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=acy1SbJAFm00>; Kevin Grogan, *GSK Lovaza Generic Case Settled, Mixed Result in Norvir Lawsuit*, PHARMATIMES ONLINE (Mar. 31, 2011), [http://www.pharmatimes.com/article/11-03-31/GSK\\_Lovaza\\_generic\\_case\\_settled\\_mixed\\_result\\_in\\_Norvir\\_lawsuit.aspx](http://www.pharmatimes.com/article/11-03-31/GSK_Lovaza_generic_case_settled_mixed_result_in_Norvir_lawsuit.aspx) (describing that a jury found that Abbott did not violate antitrust laws, but awarding \$3.4 million in favor of GSK because Abbott breached a license agreement).

106. CASE OF NORVIR, *supra* note 79, at 1.

107. *Id.* at 2; NORVIR PETITION 2012, *supra* note 5, at 2-3.

108. NORVIR PETITION 2004, *supra* note 10, at 2. Petitioners also asked that generic manufacturers contribute to a fund for AIDS research.

109. Carreyrou, *supra* note 14.

110. CASE OF NORVIR, *supra* note 79, at 5-6.

111. CASE OF NORVIR, *supra* note 79, at 6.

112. 35 U.S.C. § 203 (2006).

113. NORVIR PETITION 2012, *supra* note 5, at 5.

114. American Medical Students Association, Knowledge Ecology International, U.S. Public Interest Research Group, and the Universities Allied for Essential Medicines.

115. NORVIR PETITION 2012, *supra* note 5, at 2-3. Petitioners also asked NIH to address a problem that can arise for federally funded inventions that are used concurrently with other products.

*B. Fabrazyme—University Seeking Revenue During a Shortage*

Mt. Sinai School of Medicine owns the patent for the only FDA-approved therapy for Fabry disease.<sup>116</sup> Fabry disease is a rare, inherited disorder that causes fat to build up in the body's cells.<sup>117</sup> As the fat builds up, it causes a range of serious symptoms, and Fabry disease can cause life-threatening complications in the kidneys, heart, and brain.<sup>118</sup> Through NIH funding, investigators at Mt. Sinai invented a form of alpha-galactosidase A—an enzyme replacement therapy for Fabry disease.<sup>119</sup> Mt. Sinai granted an exclusive license to Genzyme for this patent so that the company could develop Fabrazyme, a product to treat Fabry disease.<sup>120</sup>

Starting in June 2009, Genzyme encountered viral contamination in the factory where it manufactures Fabrazyme.<sup>121</sup> The factory was closed for cleaning, resulting in a limited supply of the drug and forcing Genzyme to ration Fabrazyme.<sup>122</sup> In November 2009, the drug shortage got worse when Genzyme suffered additional manufacturing problems; contaminants (including rubber, steel, and fiber) were found in vials of Fabrazyme coming out of the factory.<sup>123</sup> Some patients suffered heart or kidney problems.<sup>124</sup> There are allegations that one or more people died because of the drug shortage.<sup>125</sup> By the middle of 2010, Genzyme was only meeting approximately thirty percent of the demand for Fabrazyme.<sup>126</sup>

There is one other enzyme replacement therapy for Fabry disease

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116. FABRAZYME, *supra* note 82, at 1, 6. Mt. Sinai's patent number "relates to the production of enzymatically active alpha-galactosidase A from a recombinant mammalian cell line." *Id.* at 4.

117. U.S. Nat'l Library of Med., *Fabry Disease*, GENETICS HOME REFERENCE (Aug. 22, 2013), <http://ghr.nlm.nih.gov/condition/fabry-disease>.

118. *Id.*

119. FABRAZYME, *supra* note 82, at 1, 4.

120. FABRAZYME, *supra* note 82, at 1, 6.

121. *Genzyme Halts Production of Two Drugs*, N.Y. TIMES, Jun. 16, 2009, <http://www.nytimes.com/2009/06/17/business/17drug.html> ("Contamination with a virus called Vesivirus 2117 has disrupted production and the plant will be closed for cleaning").

122. *Id.* (Genzyme indicated that it might have to ration the limited supply of Fabrazyme, as well as Cerezyme—a treatment for another rare disease).

123. Andrew Pollack, *Genzyme Says F.D.A. Will Oversee Its Factory*, N.Y. TIMES, Mar. 24, 2010, <http://www.nytimes.com/2010/03/25/business/25genzyme.html>.

124. *Id.*

125. Ed Silverman, *Fabrazyme Shortage Killed My Husband: Widow*, PHARMALOT (Mar. 9, 2012, 9:18 AM), <http://www.pharmalot.com/2012/03/fabrazyme-shortage-killed-my-husband-widow/>.

126. *Genzyme Announces Final Terms of FDA Consent Decree*, BUS. WIRE, May 24, 2010, <http://www.businesswire.com/news/home/20100524006520/en/Genzyme-Announces-Final-Terms-FDA-Consent-Decree>.

available globally. Replagal, a different form of alpha-galactosidase A, is approved for use in forty-five countries, but not the U.S.<sup>127</sup> Shire, a U.K. company, manufactures Replagal.<sup>128</sup> During the Fabrazyme shortage, Shire took steps to make Replagal available to U.S. patients<sup>129</sup> while also satisfying European demand.<sup>130</sup>

Mt. Sinai has claimed that Shire's Replagal infringes its patent for Fabrazyme. In 2003, the Federal Circuit held that Replagal did not infringe Mt. Sinai's U.S. patent.<sup>131</sup> However, between 2010 and 2012, Mt. Sinai pursued patent infringement actions against Shire in Sweden, Germany, and the U.K.<sup>132</sup> Mt. Sinai won the patent infringement suit in Germany.<sup>133</sup> The university promised not to enforce an injunction against Shire during the drug shortage, but it actively pursued these cases during the Fabrazyme shortage.<sup>134</sup>

127. FABRAZYME, *supra* note 82, at 7; Susan Donaldson James, *Fabry Disease Patients Hope for FDA Approval of Drug Replagal*, ABC NEWS (Oct. 28, 2011), <http://abcnews.go.com/Health/fabry-disease-patients-hopeful-fda-approval-shire-drug/story?id=14836161>.

128. *Id.*

129. *See Genzyme Has Announced a Drug Shortage for Fabrazyme*, FOOD AND DRUG ADMIN., <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM187056.pdf> (explaining that Replagal was never approved by the FDA for use in the U.S. Fabry patients in the U.S. were allowed to take Replagal during the shortage either by participating in clinical trials or through unique emergency and single-patient mechanisms authorized by FDA); Deena Beasley, *Shire Withdraws FDA Application for Fabry Drug*, REUTERS, Mar. 14, 2012, <http://www.reuters.com/article/2012/03/14/us-shire-replagal-idUSBRE82D1E720120314>.

130. *See* Press Release, European Medicines Agency, European Medicines Agency Updates Treatment Recommendations Because of Continued Fabrazyme Shortage (July 6, 2010), *available at* [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Press\\_release/2010/07/WC500094245.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2010/07/WC500094245.pdf) (advising doctors to switch Fabrazyme patients to alternative treatments such as Replagal). Before the shortage, approximately 1,000 patients in Europe were treated with Fabrazyme and approximately 500 patients received Replagal. Over 680 patients were switched to Replagal. Gabor E. Linthorst, et al., *Expert Opinion on Temporary Treatment Recommendations for Fabry Disease During the Shortage of Enzyme Replacement Therapy (ERT)*, 102 MOLECULAR GENETICS & METABOLISM 99, 100 (2011).

131. *Genzyme Corp. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1106 (Fed. Cir. 2003) (affirming the grant of summary judgment in favor of Transkaryotic Therapies ("TKT"), the U.S. sponsor of Replagal, in a patent infringement suit brought by Genzyme).

132. SHIRE PLC, ANNUAL REPORT 2011 106 (2012), *available at* [http://ar2011.shire.com/shirear11/uploads/downloads/pdf/Shire\\_AnnualReport2011\\_NotesToTheConsolidatedFinancialStatements.pdf](http://ar2011.shire.com/shirear11/uploads/downloads/pdf/Shire_AnnualReport2011_NotesToTheConsolidatedFinancialStatements.pdf).

133. *Id.* On May 9, 2012, Shire and Mt. Sinai settled all proceedings in connection with Mt. Sinai's European Patent. Mt. Sinai granted Shire a non-exclusive license for the sale of Replagal. Shire plc, Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934; For the Quarterly Period Ended June 30, 2012 (Form 10-Q) 20 (Aug. 8, 2012), *available at* [www.shire.com/shireplc/form.secfilings?type=PDF&id=8752725](http://www.shire.com/shireplc/form.secfilings?type=PDF&id=8752725).

134. *Shire Pharmaceutical Contracts v. Mount Sinai School of Medicine*, [2011]

In 2010, a group of patients with Fabry disease requested that NIH march-in on Mt. Sinai's patent.<sup>135</sup> By issuing a license to another manufacturer, NIH could have, in theory, increased production of this treatment. In reality, any licensee would have faced an up-hill battle to acquire FDA approval before manufacturing the product.<sup>136</sup> Fabrazyme is a biological product; and obtaining FDA approval for a biological product is a lengthy process with several layers.<sup>137</sup>

NIH ultimately declined to march-in, because the proceeding would not address the underlying health needs.<sup>138</sup> Issuing a license to a third party (if one could be identified) would not increase production of the treatment—at least not in the short-term.<sup>139</sup> At the time, Genzyme expected to reach full production by early 2011.<sup>140</sup> Therefore, Genzyme would be at full production well before another company could even enter the market.<sup>141</sup>

By the second quarter of 2012, Fabrazyme patients in the U.S. were able to receive full levels of the drug.<sup>142</sup> Genzyme built a new manufacturing plant, and the FDA approved it in January 2012.<sup>143</sup> In March 2012, Genzyme started shipping Fabrazyme from the new plant.<sup>144</sup>

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EWHC 3492 (Pat) (Dec. 6, 2011), *available at* <http://www.bailii.org/ew/cases/EWHC/Patents/2011/3492.html> (patent litigation was before a London court in 2011 and 2012); Ed Silverman, *Mt. Sinai Struggles with Disputes Over Fabry Meds*, PHARMALOT (Jan. 23, 2012, 8:54 AM), <http://www.pharmalot.com/2012/01/mt-sinai-struggles-with-disputes-over-fabry-meds/>; Robb Fitt, *UK - Shire v. Mount Sinai*, EPLAW PATENT BLOG (Jan. 2, 2012), <http://www.eplawpatentblog.com/eplaw/2012/01/uk-shire-v-mount-sinai.html>.

135. FABRAZYME, *supra* note 82.

136. *See id.* at 5 (describing the process a licensee would have to follow to manufacture Fabrazyme).

137. *Id.*

138. *Id.* at 1 (“Based upon the information currently available, NIH has determined that a march-in proceeding under 35 U.S.C. § 203(a)(2) is not warranted at the present time because any licensing plan that might result from such a proceeding would not, in our judgment, address the problem identified by the Requestors.”)

139. *Id.*

140. *Id.* at 1-2.

141. *Id.*

142. Elena Berton, *Sanofi Starts Shipping Fabrazyme from New Plant*, REUTERS, Mar. 1, 2012, <http://www.reuters.com/article/2012/03/01/sanofiidUSL5E8E18I820120301>.

143. Sten Stovall, *Genzyme Gets Nod From FDA for Plant*, WALL ST. J., Jan. 25, 2012, <http://online.wsj.com/article/SB100014240529702037185045771807827831.html>.

144. Chris Reidy, *Genzyme: New Framingham Plant Begins Shipping Fabrazyme Drug*, BOSTON GLOBE, Mar. 1, 2012, <http://www.boston.com/2012/03/01/fabrazyme/z5Tjifs0TNv8M2FqFU79rO/story.html>.

### *C. The Growing Potential for Misuse of Bayh-Dole Inventions*

Bayh-Dole is widely considered to be a success,<sup>145</sup> but the framework can be misused by the private parties who benefit from the Act. The Norvir and Fabrazyme stories show how companies and universities can take advantage of the benefits afforded under the Bayh-Dole framework.<sup>146</sup> Without a mechanism to oppose this behavior, companies and universities will be able to continue to misuse federally funded inventions. As the landscape of drug development evolves to include more public investment, the potential for misuse will grow.

Bayh-Dole embraces the idea that normal market forces will be effective in bringing products through development and commercialization.<sup>147</sup> In the cases of Norvir and Fabrazyme, government contractors and licensees overstepped this idea, leveraging their patent rights in ways that run counter the Bayh-Dole's objectives. Abbott did not build a better mousetrap. Kaletra was not the best product on the market.<sup>148</sup> Instead of increasing value for the consumer, Abbott took another tactic to counteract competition.<sup>149</sup> Abbott tried to limit patient access to the stand-alone Norvir product.<sup>150</sup> Before the price hike, Norvir cost \$1.71 per day.<sup>151</sup> This is probably an accurate reflection of Norvir's value since this was the price before Abbott's intentional intervention in the market.<sup>152</sup> With federal funding and the promise of patent protection, the opportunity to develop Norvir was appealing enough to Abbott that it invested in the research.<sup>153</sup> This is what Bayh-Dole envisions.

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145. See *supra* notes 37-39 and accompanying text.

146. See *supra* Part II.

147. See Norman J. Latker, Statement Before NIH on Essential Inventions Petition Regarding Norvir (May 25, 2004), available at <http://www.ott.nih.gov/policy/meeting/Norman-J-Latker.pdf> (acknowledging that "market forces would do a far better job of disseminating government sponsored inventions than bureaucracies ever could").

148. See *supra* Part II.A.; *In re Abbott Labs. Norvir Anti-Trust Litig.*, 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008) (observing that studies showed new protease inhibitors were more convenient than Kaletra).

149. See *supra* Part II.A.; Carreyrou, *supra* note 14 (describing tactics Abbott considered to defeat new competition in the HIV/AIDS treatment market).

150. See *supra* Part II.A.; Carreyrou, *supra* note 14 (describing Abbott's decision to force patients away from Norvir).

151. *In re Abbott*, 562 F. Supp. 2d at 1082 ("But the use of Norvir as a booster, and not a stand-alone PI, has also meant that the average daily price of Norvir has plummeted since Norvir was first introduced, because patients need a much smaller daily dose . . . By 2003, the average price for a daily dose of Norvir was \$1.71.").

152. See *id.*

153. See Erickson, *supra* note 86, at 2-3 (describing that federal funding was important when Abbott decided to develop Norvir).

Instead, several years later Abbott increased the price, in an effort to limit patient access and leverage the invention against competitors.<sup>154</sup>

In the case of Fabrazyme, during a drug shortage, Mt. Sinai was setting itself up to extract licenses or halt production of the only other product for Fabry treatment.<sup>155</sup> Instead of helping to solve a serious health problem, the university was pursuing patent infringement suits abroad.<sup>156</sup> The purpose of the Bayh-Dole Act is not to increase university revenue.<sup>157</sup> Mt. Sinai issued an exclusive license to Genzyme, and Fabrazyme reached the market.<sup>158</sup> The only competitor product, Replagal, does not even infringe Mt. Sinai's patent in the U.S.<sup>159</sup> Clearing the market of all potential competitors was not necessary to incentivize the development of Fabrazyme. Mt. Sinai did promise it would not enforce patent rights in Europe during the drug shortage.<sup>160</sup> However, Mt. Sinai was forcing Shire to focus resources on patent litigation.<sup>161</sup> With the infringement victory, Mt. Sinai would be able to shut down Replagal production after the shortage ended if Shire was not willing to pay a licensing fee.<sup>162</sup> Here again, Mt. Sinai's actions would tend to reduce patient access to a federally funded invention, not increase utilization.

Both of these stories reveal misuse of Bayh-Dole inventions even though neither invention was left sitting on the shelf. The Bayh-Dole Act's sponsors were particularly concerned about inventions sitting

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154. See Carreyrou, *supra* note 14.

155. See Silverman, *supra* note 134 (explaining that Mt. Sinai could enforce an injunction in Europe to generate revenue, but will not pursue the injunction because it would harm patients).

156. SHIRE ANNUAL REPORT 2011, *supra* note 132, at 106.

157. See *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 31 (1979) (statement of Sen. Bob Dole) (citing Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST, Apr. 8, 1979) (one of the key issues in early debates about the Bayh-Dole Act was how to prevent universities from receiving windfall profits).

158. FABRAZYME, *supra* note 82, at 6-7.

159. *FABRAZYME Corp. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1106 (Fed. Cir. 2003).

160. Silverman, *supra* note 134.

161. See SHIRE ANNUAL REPORT 2011, *supra* note 132 (describing commitments and contingencies relevant to Shire's financial statements, including the Replagal litigation).

162. Silverman, *supra* note 134. Shire might be deterred from investing in new infrastructure to treat the global Fabry community, because the investment would be wasted if Mt. Sinai won an infringement suit and shut down Replagal production. New manufacturing facilities would be an important component for resolving the shortage, but if Mt. Sinai enforced its patent rights after the shortage ended, Shire would not be able to continue using the infrastructure it had just built. See *supra* Part II.B; Food and Drug Administration, *supra* note 129; European Medicines Agency, *supra* note 130.

on the shelf,<sup>163</sup> and the language of the march-in provision is primarily targeted to protect against contractors and licensees ignoring an invention.<sup>164</sup> Focusing only on this statutory language, however, has not gone far enough to prevent or correct all types of misuse. When denying each prior march-in petition, NIH has looked for indications that a company is close to or already marketing an invention.<sup>165</sup> NIH determined that if a product is already on the market, then a company is not failing to achieve “practical application” within the meaning of 35 U.S.C. § 203.<sup>166</sup> Similarly, if the product has FDA approval (or the FDA is reviewing an application) and/or physicians are prescribing a product, then the company is not failing to achieve health and safety needs within the meaning of 35 U.S.C. § 203.<sup>167</sup> The healthcare market, pharmaceuticals in particular, provides a good illustration of how Bayh-Dole inventions can be misused even when there is a product on the market.

The pharmaceutical industry is different from other industries in many ways.<sup>168</sup> First, a patient may be willing to pay more for a product that significantly improves health.<sup>169</sup> Health is relatively fundamental to everything people do, and therefore we value it highly.<sup>170</sup>

Second, patents afford a legal monopoly, but do not generally afford an economic monopoly.<sup>171</sup> There are usually substitute products on the market to compete with a patented product, so price is subject to normal market forces.<sup>172</sup> Pharmaceuticals have been

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163. Bayh, *supra* note 74.

164. See 35 U.S.C. § 203(a)(1) (2006) (allowing march-in when a contractor is not taking reasonable steps towards practical application of an invention).

165. NIH has looked at regulatory approvals and marketing activity when deciding not to march-in. See *supra* note 81 and accompanying text.

166. See, e.g., CASE OF NORVIR, *supra* note 79, at 4-5.

167. See, e.g., CASE OF NORVIR, *supra* note 79, at 5.

168. F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSPECTIVES 97, 98-99 (1993); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomic Era*, 2001 U. ILL. L. REV. 173, 177-79 (2001).

169. See, e.g., Robert E. Hall & Charles I. Jones, *The Value of Life and the Rise in Health Spending*, 122 QUARTERLY J. ECON. 39, 68 (2007) (showing that the most valuable way to spend additional income is on health).

170. See, e.g., *id.* at 39 (“People value health spending because it allows them to live longer and to enjoy better lives.”).

171. NARD, *supra* note 55, at 2; LANDES & POSNER, *supra* note 64, at 22-23 (explaining that intellectual property protection can create “a monopoly, in the literal sense in which a person has a monopoly of the house he owns,” however it may also create monopoly in an economic sense because there “may be no good substitutes for a particular intellectual work.”).

172. NARD, *supra* note 55, at 2.

identified as one area where patents may confer a unique market power.<sup>173</sup> For one, customers do not have as much incentive to seek out substitute products since the insurance company bears most of the cost.<sup>174</sup> In addition, in order to substitute one product for another, there must be a substitute on the market. A truly innovative drug will not have a substitute.<sup>175</sup>

Third, in healthcare, the consumer/decision-maker is not an individual; the decision to purchase healthcare products is made through a more complex system, not an individual.<sup>176</sup> For common commercial products, the price is generally controlled through the relationship between a willing buyer and a willing seller.<sup>177</sup> However, patients, doctors, and health insurance companies all participate in the decision to purchase a prescription drug.<sup>178</sup> Complicating this further is the fact that none of these entities possesses perfect information.<sup>179</sup> Ultimately, the healthcare consumer is not very price sensitive, because no single party is paying the full price of the drug.<sup>180</sup> This makes the price of drugs less elastic.<sup>181</sup> Coupled with strong demand, this can create something closer to monopoly power for the pharmaceutical company.<sup>182</sup>

Patent law is structured so that firms can recoup the costs of developing and commercializing new products.<sup>183</sup> While the pharmaceutical industry is highly regulated, and the costs of

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173. See Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 MINN. L. REV. 1789, 1814 n. 94 (2003).

174. Rai, *supra* note 168, at 177 n. 14.

175. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 19-20 (1998), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf> (“When a breakthrough drug is introduced, by definition it has no close substitutes on the market.”). This was the case with Norvir and Fabrazyme. Norvir is the only “booster” on the market and Fabrazyme is the only FDA approved drug for Fabry disease.

176. Scherer, *supra* note 168, at 98-99.

177. Jerry Thursby, A Primer on Costs 14-17 (Dec. 2008) (unpublished manuscript) (on file with author).

178. Scherer, *supra* note 168.

179. See *id.*; see also Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. ECON. PERSPECTIVES 45 (2002) (providing a detailed description of factors that control the price of pharmaceuticals).

180. See *id.* at 49-50, 57 (describing how individual patients value a pharmaceutical product and how low out-of-pocket payments and insurance coverage can increase consumption); Rai, *supra* note 168, at 206 (identifying healthcare consumers as “cost-insensitive”).

181. Scherer, *supra* note 168, at 99.

182. Scherer, *supra* note 168, at 99.

183. Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1052 (2005).



development and commercialization are considerable,<sup>184</sup> due to the unique nature of the healthcare marketplace, companies may be able to charge an even greater price than would be necessary to justify R&D investment.<sup>185</sup> Contractors and licensees who benefit from the Bayh-Dole Act received federal funding to offset the costs of R&D. Nevertheless, in the healthcare market, the same forces operate so that companies can still exercise unique market power.

At a time when the public expects government to play a greater role in delivering new drugs and biomedical products,<sup>186</sup> it is increasingly important to address misuse of federally funded inventions. The public is generally dissatisfied with their level of access to biomedical products.<sup>187</sup> The government is responding. Drug discovery and development is changing, and both government and industry would like to see academic investigators (and federal funding) play a greater role in the development of new drugs.<sup>188</sup> The government is making targeted investments in drug discovery research, implementing new funding programs, and exploring novel research partnerships.<sup>189</sup> If these efforts are successful, we will see even more federally funded inventions being commercialized and reaching the clinic. On the other hand, advocates will continue to

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184. See CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 19-25 (1998), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drug-d.pdf> (describing the rising costs of drug development).

185. See Berndt, *supra* note 179.

186. See, e.g., SCI. MGMT. REV. BD., REPORT ON TRANSLATIONAL MEDICINE AND THERAPEUTICS 8 (2010), available at [http://smrb.od.nih.gov/documents/reports/TMAT\\_122010.pdf](http://smrb.od.nih.gov/documents/reports/TMAT_122010.pdf) (describing recent Congressional actions that “underscore the expectation of Congress and the American public that NIH is to play a catalytic role in realizing the promise of translational medicine and advancing human health”).

187. E.g., *Cures Acceleration Network*, PARKINSON'S ACTION NETWORK (2013), <http://www.parkinsonsaction.org/federal-initiatives/national-institutes-health/cures-acceleration-network>.

188. See Francis S. Collins, *Reengineering Translational Science: The Time is Right*, 3 SCI. TRANSLATIONAL MED. 17 (2011) (describing a new Center at NIH focused on translational science, including drug discovery and development); P. Vallance, P. Williams & C. Dollery, *The Future is Much Closer Collaboration Between the Pharmaceutical Industry and Academic Medical Centers*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 525, 527 (2010); Lili M. Portilla, Greg Evans, Benjamin Eng & Terry J. Fadem, *Advancing Translational Research Collaborations*, 2 SCI. TRANSLATIONAL MED. 30, 31-32 (2010); B. Michael Silber, *Driving Drug Discovery: The Fundamental Role of Academic Labs*, 2 SCI. TRANSLATIONAL MED. 16, 18 & 20 (2010).

189. NIH recently established the National Center for Advancing Translational Science (NCTAS) with the mission to “enhance the development, testing and implementation of diagnostics and therapeutics . . .” *About NCATS*, NATIONAL INSTITUTES OF HEALTH, <http://www.ncats.nih.gov/about/about.html> (last visited Aug. 8, 2013).

come to NIH seeking relief when they are dissatisfied with their level of access to biomedical products that were funded by the agency.<sup>190</sup>

March-in is supposed to be a safety valve in the Bayh-Dole Act to prevent against misuse of federally funded inventions.<sup>191</sup> Deterring misuse should promote increased public access and decrease public frustration. If the public sees good outcomes and does not witness misuse, they are likely to continue to support Bayh-Dole.<sup>192</sup> If the public does not support the Bayh-Dole Act, because they are not seeing government action to produce their expected health and safety benefits, there is a risk that the public will pressure Congress to abandon Bayh-Dole altogether.<sup>193</sup> By continuing to deny march-in petitions, the government is letting an important tool languish, and runs an increasing risk of disappointing expectant patients with the structure and implementation of the Bayh-Dole Act.<sup>194</sup>

### III. REORIENTING THE MARCH-IN DECISION TO MAKE IT AN EFFECTIVE SAFETY VALVE

March-in should be the safety valve within the Bayh-Dole framework that protects the public interest.<sup>195</sup> However, it is not working; the government has never exercised march-in rights.<sup>196</sup> This problem will only get worse as NIH focuses on translating more federally funded research into marketable technology.<sup>197</sup> In making previous march-in decisions, NIH maintained a rigid focus on statutory language at 35 U.S.C. § 203.<sup>198</sup> For current and future march-in decisions, NIH should reorient its decision-making process to directly reflect the goals of federal research policy as outlined at 35 U.S.C. § 200—utilization, access, collaboration, and discovery.<sup>199</sup> To achieve this, research funding agencies, the Department of

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190. See *supra* note 82 and accompanying text.

191. See *supra* note 23 and accompanying text.

192. See Halperin, *supra* note 29, at 16-17.

193. *Id.*

194. *Id.*

195. See *supra* note 23 and accompanying text.

196. See *supra* Part II; Wadman, *supra* note 22. This is not to suggest that march-in is not working solely because it has never been used. It would be possible that it was never used because it was never needed. See also Raubitschek & Latker, *supra* note 30, at 154-55 (quoting Donald R. Dunner, Vice President of the American Patent Law Association, rejecting the idea that “march-in rights have been available for 10 years, and they have never been used; ergo, they are a failure”). This Article suggests a needed fix because we have at least two examples, involving Abbott and Mt. Sinai, where Bayh-Dole inventions were misused. Moreover, when declining to march-in, NIH did not explicitly consider the purpose and objectives of the Act.

197. See *supra* Part II.C.

198. See *supra* Part I.B.

199. 35 U.S.C. § 200 (2006).

Commerce, and Congress should promulgate explicit instructions where the purpose and objectives of the Bayh-Dole Act are considered from the outset of the march-in process.

This Part will explain how a new approach to march-in would work and how to implement it. First, this Part will explain why two new questions should be incorporated into the march-in decision. Then this Part will explain how to implement a shift in march-in decision-making, with research funding agencies issuing interpretive guidance, the Department of Commerce revising relevant regulations, and Congress amending the Bayh-Dole Act.

#### *A. How the New Approach to March-In Works*

Upon receiving a petition, a research funding agency should consider two additional factors when deciding whether to initiate the march-in proceeding: (1) are the contractor's or licensee's actions consistent with the purpose and objectives of the Bayh-Dole Act; and (2) would march-in promote or disserve the public's interest?<sup>200</sup> By incorporating these two questions into the initial march-in decision, the government can create the safety valve that Bayh-Dole needs. This approach to making the march-in decision will incentivize behaviors that are consistent with the statutory purpose. This section will explain how and why the march-in process should incorporate these questions.

##### *1. Are the Contractor's or Licensee's Actions Consistent with the Purpose and Objectives of the Bayh-Dole Act?*

Early on in the process, an agency should evaluate the circumstances of a march-in petition and ask whether the contractor or licensee is acting in a way consistent with the purpose and objectives of the Bayh-Dole Act. The Bayh-Dole Act clearly states a purpose and objectives, and these should be used to measure the appropriateness of contractor and licensee actions.<sup>201</sup> Congress passed the Act to promote the utilization and commercialization of federally funded research, foster collaboration between industry and nonprofit organizations, encourage free competition without limiting future discovery, and promote public availability of federally funded inventions.<sup>202</sup> Congress contemplated some level of monopoly prices

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200. The first question refers the agency back to 35 U.S.C. § 200, the purpose and objectives of the Bayh-Dole Act. The second question emphasizes the public motivation behind the Bayh-Dole Act.

201. 35 U.S.C. § 200 (2006).

202. *Id.*

and exclusive licenses under the Bayh-Dole Act.<sup>203</sup> However, at a certain level of price or exclusivity, contractors and licensees go beyond what is necessary to achieve practical application, and then are exploiting the Bayh-Dole privilege.<sup>204</sup> This has the effect of limiting utilization, access, collaboration, and further discovery. Weighing the purpose and objectives of the Bayh-Dole Act in the march-in decision would allow the government to curb this exploitative behavior.

NIH has issued general guidance to help contractors conform to the objectives of Bayh-Dole.<sup>205</sup> The agency should use the march-in mechanism similarly, to encourage contractors and licensees to focus on the Act's objectives. The NIH Best Practices for the Licensing of Genomic Inventions describe how a contractor can craft appropriate intellectual property and licensing arrangements for genomic inventions.<sup>206</sup> The Best Practices encourage contractors to balance the needs of commercialization against the risk that overly restrictive patenting or unnecessarily exclusive licensing may limit public access and future research.<sup>207</sup> Similarly, NIH issued principles and guidelines for Sharing Biomedical Research Resources.<sup>208</sup> This policy statement addresses appropriate implementation of the Bayh-Dole Act,<sup>209</sup> describing how to develop patent and licensing strategies for NIH-funded inventions and encouraging investigators to consider alternate sharing mechanisms and narrowly tailored licenses.<sup>210</sup> NIH should employ this same vision of the Bayh-Dole Act when making march-in decisions.

While this might introduce more subjectivity into the march-in decision, this Article's proposed approach will allow the government to combat misuse of Bayh-Dole inventions. It requires the agency to

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203. To incentivize innovation, traditional patent law allows patent holders and licensees to charge any price for a product. Patent law is structured so that firms can recoup the costs of developing and commercializing new products. LANDES & POSNER, *supra* note 64, at 379-80.

204. See *supra* Part II A-B (discussing how the Norvir and Fabrazyme stories show how companies and universities can misuse Bayh-Dole inventions).

205. MANAGING UNIVERSITY INTELLECTUAL PROPERTY, *supra* note 23, at 53 (listing three guidance documents issued by NIH).

206. Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18,413 (Apr. 11, 2005), available at <http://www.ott.nih.gov/pdfs/70FR18413.pdf>.

207. *Id.* at 18,415.

208. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999), available at <http://www.ott.nih.gov/pdfs/64FR72090.pdf>.

209. *Id.* at 72,093.

210. *Id.*

evaluate a contractor's or licensee's action based on hindsight; looking back on a contractor's or licensee's decisions and deciding whether, at the time, those decisions aligned with the policies underlying Bayh-Dole. Product development is challenging, and it does not proceed along a common, linear path.<sup>211</sup> It is difficult for anyone, whether the government, a contractor, or a licensee, to predict when a patent and/or exclusive license is necessary to encourage innovation.<sup>212</sup> The ultimate price of a product cannot be perfectly predicted; the price depends on the eventual market for the product and the product's actual value.<sup>213</sup> Retrospectively evaluating the reasonableness of these decisions will be difficult. However, this Article's proposed approach will not open up every product development decision to government investigation and interference.

Courts granting equitable relief have successfully navigated a similar problem. Traditional equity provides a safety valve to combat opportunistic behavior.<sup>214</sup> Opportunistic behavior is "done with a view to securing unintended benefits from the system."<sup>215</sup> Just like Bayh-Dole violations, opportunism is identified based on hindsight.<sup>216</sup> Historically, courts have been able to identify this behavior and fashion equitable relief to prevent people profiting from their own wrongs.<sup>217</sup> Moreover, courts are still able to achieve a requisite level of certainty in the law.<sup>218</sup> The safety valve theory of equitable relief emphasizes good faith and notice:<sup>219</sup> when granting equitable relief,

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211. See, e.g., FASTER CURES, CROSSING OVER THE VALLEY OF DEATH 7 (2010), available at <http://www.fastercures.org/assets/Uploads/VOD-Translational Research 2.pdf> ("These are very complex and iterative processes that can frequently be a significant bottleneck in drug development.").

212. See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. at 72,094 (explaining factors and options a federally funded research institution should consider when deciding whether to patent and/or license a technology); *Frequently Asked Questions: Licensing*, NATIONAL INSTITUTES OF HEALTH OFFICE OF TECHNOLOGY TRANSFER, [http://www.ott.nih.gov/faqs/lic\\_faq.aspx](http://www.ott.nih.gov/faqs/lic_faq.aspx) (last visited Aug. 8, 2013) (describing the criteria NIH uses when considering an exclusive license, and how an applicant can justify the need for one).

213. See Thursby, *supra* note 177, at 14-17.

214. Henry E. Smith, An Economic Analysis of Law Versus Equity 4-5 (Oct. 22, 2010) (unpublished manuscript), available at [http://www.law.yale.edu/documents/pdf/LEO/HSmith\\_LawVersusEquity7.pdf](http://www.law.yale.edu/documents/pdf/LEO/HSmith_LawVersusEquity7.pdf); Mark P. Gergen, John M. Golden & Henry E. Smith, *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 237-38 (2012).

215. Smith, Economic Analysis, *supra* note 214, at 9-10.

216. *Id.* at 8.

217. Gergen, *supra* note 214, at 238-40.

218. See Smith, Economic Analysis, *supra* note 214, at 2-4; Gergen, *supra* note 214, at 241.

219. Smith, Economic Analysis, *supra* note 214, at 40-41.

the court considers whether a party is acting in bad faith (or has unclean hands)<sup>220</sup> and whether a party is on notice that an action violates the law.<sup>221</sup> If an actor violates the law in bad faith, equitable relief is appropriate.<sup>222</sup> On the other hand, if an actor is in good faith or did not have notice of a violation, equitable relief is not appropriate.<sup>223</sup>

March-in, as a safety valve to combat misuse of Bayh-Dole inventions, should follow a similar structure. If a party, in bad faith, goes beyond what is necessary to promote commercialization then march-in would be appropriate. Furthermore, the Bayh-Dole Act provides public notice of the statute's policy and objectives.<sup>224</sup> A party may go far beyond what is necessary to promote commercialization, even in good faith. Once a contractor or licensee realizes that its actions are defeating commercialization or availability, it should self-correct. A failure to correct such a problem would also justify march-in. While reasonable efforts to utilize an invention may conflict with public access, obvious or bad faith cases of misuse will be subject to government scrutiny and potential march-in.

## 2. *Would March-In Promote or Disserve the Public's Interest?*

The Bayh-Dole Act was constructed to benefit the public by growing the economy, improving public access to new technologies, and reaping the benefits of public investment in research.<sup>225</sup> Similar to patent law,<sup>226</sup> Bayh-Dole strengthens private rights to promote these public ends.<sup>227</sup> Where a private actor fails to achieve Bayh-

220. See *id.* at 15-16; Gergen, *supra* note 214, at 212.

221. See Smith, Economic Analysis, *supra* note 214, at 20; Gergen, *supra* note 214, at 239-40.

222. Gergen, *supra* note 214, at 243. In granting injunctions, courts leave room for consideration of good faith and bad faith acts in fashioning relief. "If the actor has violated the law in bad faith, and injunction will most likely issue . . . [S]omeone acting in good faith can generally navigate this system, using common sense and minimal knowledge to avoid disaster from an injunction." *Id.*

223. *Id.* at 238-40.

224. 35 U.S.C. § 200 (2006); 37 C.F.R. § 401.6 (2012). The development of additional guidance, as suggested later in this Part, would also support this goal of public notice.

225. *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 29 (1979) (statement of Sen. Bob Dole) (describing the goals of the Bayh-Dole Act).

226. Patent law is motivated by the potential for public benefits. It provides incentives to invent, disclose, and innovate. The law confers technology, knowledge, and economic benefits on society. See JANICE M. MUELLER, PATENT LAW 26-31 (3rd ed. 2009) (describing the benefits of the patent system, and its utilitarian underpinnings); NARD, *supra* note 55, at 28-36.

227. As evidenced in the legislative history, Congress' view was that in the

Dole's purpose and objectives, the government should consider what the consequences of a march-in would be and decide whether a march-in would serve the public's interest. If a march-in is likely to result in a public benefit, then the government should consider proceeding. However, it is possible that a march-in would disserve the public—in which case, the government should avoid it. For example, the government should consider whether march-in would compromise the availability and quality of healthcare.<sup>228</sup>

Courts consider public interest when granting injunctive relief in patent infringement cases.<sup>229</sup> This is consistent with recent scholarship on patent remedies, in which authors question the suitability of using private rights and remedies to achieve the public ends in patent law.<sup>230</sup> They have suggested that new remedies are needed to encourage invention and innovation.<sup>231</sup> March-in, as a sort of “remedy,” destroys a private right in the interest of serving the public.<sup>232</sup> Drawing on patent law scholarship,<sup>233</sup> the government should take a further step and refocus march-in on public interests when private rights fail to achieve their intended goal. This can be accomplished by making public interest explicit in the march-in decision process.

### *B. Implementing the New Approach*

Congress, the Executive Branch, and research funding agencies

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complete absence of private rights and patent protection the public loses out on the benefits of federally funded research. “By obstructing patent rights and innovations, the Government increases the factor of uncertainty in an already uncertain area, that of technology end result. By denying the modicum of protection that the granting of patent rights for a limited period of time would afford, the Government removes the incentive that would stimulate the private sector to develop and market inventions.” *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 28 (1979) (statement of Sen. Bob Dole).

228. Julie A. Burger & Justin Brunner, *A Court's Dilemma: When Patents Conflict with Public Health*, VA. J.L. & TECH., Fall 2007, at 1, 30 (discussing how courts should implement the public interest factor from *eBay v. MercExchange*).

229. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (the Supreme Court instructed courts to consider public interest as one of four factors when deciding whether to grant an injunction for patent infringement).

230. See Ted Sichelman, Purging Patent Law of ‘Private Law’ Remedies (Sept. 23, 2011) (unpublished manuscript), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1932834](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1932834) (arguing that remedies for patent infringement should be tailored to promote innovation, rather than making the patentee “whole”). See also Sarah R. Wasserman Rajec, *Tailoring Remedies to Spur Innovation*, 61 AM. U. L. REV. 733 (2012) (arguing that courts should evaluate the incentives for and access to innovation when deciding whether to grant an injunction in patent infringement cases).

231. See Sichelman, *supra* note 230, at 35; Wasserman, *supra* note 230, at 737.

232. See *supra* Part I.B.

233. See *supra* note 230 and accompanying text.

should all take steps to redirect the march-in decision. While research agencies already have the authority to incorporate the purpose and objectives of the Bayh-Dole Act into march-in decisions,<sup>234</sup> formally announcing a new march-in approach has several benefits, including public notice, public input, predictability, and transparency. Implementing the new approach would involve issuing interpretive guidance, revising current regulations, and/or amending the Bayh-Dole Act. The most obvious and high profile way to accomplish the change is through a statutory amendment. However, the same goal could be achieved by revising the associated regulations or issuing additional guidance regarding the march-in provision. This section will describe how the government should develop the new guidance, regulations, and statute.

### *1. Issuing Interpretive Guidance*

Research funding agencies should issue guidance elaborating on this new approach to march-in. Since biomedical technologies are the focus of this Article, this Part is directed to new NIH guidance. However, any federal agency that funds research could benefit from a similar exercise.<sup>235</sup> Alternatively, research-funding agencies could develop a common guidance through, for example, the National Science and Technology Council's Committee on Science.<sup>236</sup>

A guidance document interpreting the march-in provision and explaining the agency's approach to decision-making could – if implemented as suggested below – serve the two important purposes of public input and notice.<sup>237</sup> First, the agency should develop the

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234. Cf. STEPHEN G. BREYER, ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES 425 (7th ed. 2011) (reproducing a portion of the ABA's Black Letter Statement of Federal Administrative Law, indicating that failure to consider the purpose of a statute is a reason to set aside agency action); see also 37 C.F.R. § 401.6(g) (2012) (after conducting fact-finding, the head of an agency should consider the policy and objectives of the Bayh-Dole Act when deciding whether or not to march-in).

235. Here again, an agency could issue this guidance, even if Congress and the Department of Commerce do not revise the statute or regulations. It is an interpretation of an existing rule, and the guidance would be consistent with the current statute and regulations.

236. See OFFICE OF SCIENCE AND TECHNOLOGY POLICY, CHARTER OF THE COMMITTEE ON SCIENCE, NATIONAL SCIENCE AND TECHNOLOGY COUNCIL (Jan. 31, 2011), available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/CoS-Charter-signed-01-31-11.pdf>.

237. See National Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 682 (D.C. Cir. 1973) (the benefits of the APA's rule-making procedures include the opportunity for people to be heard); see also Nina A. Mendelson, *Regulatory Beneficiaries and Information Agency Policymaking*, 92 CORNELL L. REV. 397 (2007) (providing an overview of the weaknesses and strengths of guidance documents, and discussing ways to ensure that public input and notice are incorporated into guidance



guidance through a public process, providing an opportunity for notice and comment based on a modified version of the requirements at section 553 of the Administrative Procedure Act.<sup>238</sup> This type of participation ensures that all stakeholders have a public forum for articulating their goals and concerns regarding march-in.<sup>239</sup> The process is more democratic, and it is a valuable opportunity for the agency to learn from public suggestions.<sup>240</sup> Since Bayh-Dole and march-in are both structured to protect the public's interest,<sup>241</sup> the guidance development process is an opportunity for the public to actually voice their interests. Similarly, Bayh-Dole relies on attracting interested companies to develop federally funded inventions.<sup>242</sup> These commercial interests would also have a voice in the guidance development process, and companies can explain what they need to see from march-in so that federally funded inventions remain attractive development opportunities.

Second, the guidance would provide notice and certainty. To date, there has not been a successful march-in petition.<sup>243</sup> This can create

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documents).

238. 5 U.S.C. §§ 553(b)-(c) (2006). This guidance would not have to go through the APA's informal rulemaking procedures, and it would not be binding on any party. Rather, it would explain the existing statute and instruct the public on how NIH intends to reach future march-in decisions. The agency would still exercise discretion in reaching individual march-in determinations based on the general statements in the guidance. The guidance, as such, would fall under the "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice" exception to APA rulemaking requirements. 5 U.S.C. § 553(b)(3). *See American Hospital Assoc. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (interpretive rules, excepted from the rulemaking requirements of the APA, are those which "clarify or explain existing law," instruct, and do not have the full force of a substantive rule). NIH could develop this guidance through a modified procedure that provides opportunity for public notice and comment. The agency's public process, relying on the principles embodied in APA, could achieve the benefits of public input without engaging in an overly burdensome process.

239. *See National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 682 (D.C. Cir. 1973) (the benefits of the APA's rulemaking procedures include the opportunity for people to be heard). *But see Mendelson*, *supra* note 237, at 424-34 (describing limitations of policy development through guidance documents, especially from the perspective of regulatory beneficiaries).

240. *FTC*, 482 F.2d at 682.

241. *See, e.g.*, 35 U.S.C. § 200 (2012) (one objective of the Bayh-Dole Act is to "protect the public against nonuse or unreasonable use of inventions . . . ."); McGarey & Levey, *supra* note 23, at 1096 ("[T]he Bayh-Dole Act also includes certain provisions protecting the public interest. One such provision [is] commonly known as 'march-in' . . .").

242. *See The University and Small Business Patent Procedures Act: Hearing on S. 414 Before S. Comm. on Judiciary*, 96th Cong. 2 (1979) (statement of Sen. Birch Bayh) (Bayh-Dole was passed to reverse the problem that companies did not have adequate incentives to develop new federally funded inventions).

243. Wadman, *supra* note 22.

uncertainty for universities and companies wishing to license an invention and wondering what the risk of a march-in is. Could it happen to me? Under what circumstances? There is no precedent.<sup>244</sup> Right now, since the government has never marched-in, the risk seems quite low.<sup>245</sup> A shift in the march-in approach would, however, create more uncertainty about the risk. This proposed guidance would ease uncertainty by informing the community as to the direction of future march-in decisions. Contractors and licensees will know what good behavior looks like and what behaviors to avoid.

The guidance should address four primary aims: (1) reiterate the purpose of the Bayh-Dole Act and the importance of a strong patent right; (2) describe how the agency analyzes the “practical application” and unmet health or safety need provisions; (3) explain that the agency will scrutinize contractor and licensee actions for consistency with the purpose of Bayh-Dole; and (4) develop several case studies.

For the Bayh-Dole Act to encourage innovation there needs to be a strong property right in federally funded inventions.<sup>246</sup> The march-in guidance should acknowledge this and signal that the new march-in approach will not threaten the underlying framework of Bayh-Dole. The new march-in approach should not significantly increase the number of march-in proceedings, so initiating march-in will still be a relatively rare occurrence.<sup>247</sup> The agency should also acknowledge that Congress intended to allow “monopoly prices” and exclusive licenses because they are sometimes necessary to incentivize development.<sup>248</sup> By taking a new approach to the march-in decision, the government will not start second-guessing every drug price or dictating the terms of every license.

The guidance should then describe the existing statutory march-in language, focusing on the definition of “practical application” and unmet health and safety needs. NIH should draw on previous march-

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244. *Id.* Each of the previous four march-in decisions describe the circumstances under which an agency will not march-in. The previous decisions do not describe circumstances under which an agency will march-in. This gives a lower threshold, but not an upper limit. See *supra* note 81 and accompanying text. Since this Article argues for a new approach, the lack of precedent will be even more serious.

245. See *supra* note 82 and accompanying text.

246. See *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 2 (1979) (statement of Sen. Birch Bayh) (observing that without patent rights “there is little incentive for any company to undertake the risk and expense of trying to develop a new product”).

247. See *supra* Part III.A.

248. This policy choice is evident from Congress’s decision to rely on patent law. See LANDES & POSNER, *supra* note 64, at 379-80.

in decisions to describe the features and metrics of product development that might indicate a company is achieving practical application and satisfying needs.<sup>249</sup>

The guidance should also address the new march-in approach, structured around the two questions presented in Part III.A of this Article: (1) are the contractor's or licensee's actions consistent with the purpose and objectives of the Bayh-Dole Act, and (2) would march-in promote or disserve the public's interest?<sup>250</sup> Regarding the first question, march-in petitions result from specific problems of development or access to technology.<sup>251</sup> Petitioners and the agency should identify what actions contractors and licensees are taking that either cause or alleviate identified problems. Then, the agency should evaluate those actions in comparison to the purpose and objectives of Bayh-Dole. Are the contractor's or licensee's actions inconsistent with the goals of utilization, commercialization, collaboration, discovery, and availability?<sup>252</sup> NIH should also draw on existing guidance documents to describe how contractors and licensees are expected to balance the sometimes-competing interests of commercialization, public access, and future research.<sup>253</sup>

Regarding the second question, on public interest, the agency should describe its analytical approach in this guidance document. Upon receiving a march-in petition, the agency should consider the likely outcomes if it does or does not march-in and favor the outcome that promotes public interest.

Finally, the guidance should provide a set of case studies. The agency should describe some scenarios that would and would not warrant march-in, and describe how the decision-making criteria would apply to the hypothetical situations. This is an area where the agency will benefit from public engagement. These scenarios should be subject to broad discussion and scrutiny, so that all members of

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249. *Supra* note 81 and accompanying text.

250. *See supra* Part III.A.

251. *See, e.g.*, FABRAZYME, *supra* note 82 (drug shortage caused by manufacturing problems, coupled with patent infringement lawsuits); CASE OF NORVIR, *supra* note 78 (significant price increase).

252. 35 U.S.C. § 200 (2006).

253. *See, e.g.*, Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18,413, 18,415 (Apr. 11, 2005) (encouraging contractors to balance the needs for commercialization against the risk that overly restrictive patenting or unnecessarily exclusive licensing may limit public access and future research); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,096 (Dec. 23, 1999) (encouraging contractors to craft a patent and licensing strategy for NIH-funded inventions and consider alternate sharing mechanisms and narrowly tailored licenses).

the public can clarify their expectations for march-in against concrete fact patterns.

## 2. *Revising the Regulations*

The regulations governing the exercise of march-in rights are codified at title thirty seven of the Code of Federal Regulations.<sup>254</sup> To implement this Article's approach to the march-in decision, the Department of Commerce should revise these regulations.<sup>255</sup> Currently, the regulations give only limited direction to an agency regarding the substance of a march-in decision.<sup>256</sup> The Department should reorganize the regulations and reemphasize the factors an agency weighs when initiating march-in.

Section 401.6(b) explains that an agency can exercise its discretion when deciding whether to initiate the proceeding.<sup>257</sup> Under current regulations, it is not until after the agency initiates the march-in proceeding that the head of the agency considers the policy and objectives of the Bayh-Dole Act.<sup>258</sup> Section 401.6(b) should instruct agencies to consider the purpose and objectives of the Act and the public interest at the outset—when deciding whether to initiate march-in. Waiting until the end of the march-in proceeding is too late for a consideration of purpose and objectives. 401.6(b) should be amended by adding the following sentence:

The agency should consider the following when deciding whether to proceed with a march-in procedure: the circumstances described at 35 U.S.C. § 203 (a) – (d), the purpose and objectives of the Bayh-Dole Act at 35 U.S.C. § 200, and the public's interest.<sup>259</sup>

The Secretary of Commerce is authorized to issue regulations for the implementation of 35 U.S.C. § 203.<sup>260</sup> This authorization is broad, and the Secretary would be able to propose this regulatory amendment without Congressional intervention.<sup>261</sup> However, the revised regulations would have to go through a public comment

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254. 37 C.F.R. § 401.6 (2012).

255. The Department of Commerce is responsible for issuing regulations to implement the Bayh-Dole Act. 35 U.S.C. § 206 (2006).

256. See 37 C.F.R. § 401.6. The bulk of the regulations define the procedures an agency must follow upon receiving a march-in petition.

257. 37 C.F.R. § 401.6(b).

258. 37 C.F.R. § 401.6(g).

259. This sentence should be incorporated after the second sentence in this section of the regulation, which currently reads: "In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below."

260. 35 U.S.C. § 206 (2006).

261. *Id.*

procedure.<sup>262</sup>

### *3. Amending the Bayh-Dole Act*

Amending the Bayh-Dole Act is the most definitive way to announce a shift for march-in. Congress should revise the Act and instruct agencies, industry, and the public that march-in decisions will be guided by the purpose and objectives of the Bayh-Dole Act and the public's interest. Congress can accomplish this by simply adding another subpart to the march-in provision. The new 35 U.S.C. § 203(c) should read: The Federal agency shall make its determination pursuant to this section to promote the public interest and in accordance with the purposes and objectives of this Act.

Congressional action to revise the statute would send a clear signal to agencies and the public that march-in decisions should be guided by the purpose and objectives of the Bayh-Dole Act. In denying previous march-in petitions, NIH has focused on statutory text.<sup>263</sup> After this proposed revision, research-funding agencies can continue to rely on the statutory text, but incorporate Bayh-Dole purpose and objectives and public interest into the march-in decision.

With this proposed revision, agencies will be confident that their march-in decisions will stand up to judicial review. If an agency decided to exercise march-in rights, contractors and licensees would be able to appeal the decision to the U.S. Court of Federal Claims.<sup>264</sup> An agency, not wanting the court to overturn its decision, will choose to rely on statutory factors when making its initial determination.<sup>265</sup> This Article's proposed amendment makes it clear that Congress intends agencies to use the "public interest" and the "purpose and objectives" of the Bayh-Dole Act as factors when making the march-in decision.<sup>266</sup> With the statutory cover, agencies will be more likely to

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262. *Id.*

263. *See supra* Part I.B.

264. 35 U.S.C. § 203(b) (2006).

265. Section 706 of the Administrative Procedure Act instructs courts to overturn agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (2012). The court will look for whether the agency considered "relevant factors" when it decided to act. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). If an agency relied on factors that Congress did not intend it to, that could be grounds to reject the agency decision. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider. . .").

266. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (acknowledging that agency decisions are arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider. . .").

make march-in decisions consistent with this purpose and these objectives.

#### IV. IMPLICATIONS OF THE NEW APPROACH

This Article's proposal provides a practical solution to the problem that contractors and licensees may misuse Bayh-Dole inventions. If the government adopts this proposal, it can redirect march-in so that it is an effective safety valve to protect public interests. Importantly, this solution will not destabilize the entire Bayh-Dole framework. In addition to improving the outcome of march-in decisions, there are other reasons why this new approach to march-in is a preferred policy solution.

This Part will address the implications of adopting the proposed march-in decision process. This Part will first describe two hypothetical applications of this Article's proposed march-in approach, using Norvir and Fabrazyme as case studies. Then, this Part will explain a common criticism of march-in and how this Article's proposal avoids that problem. Finally, this Part shows how this Article's proposal is a preferred policy option over previous suggestions to address shortfalls in the Bayh-Dole Act and march-in.

##### *A. Test Drive: Applying This New Approach to Norvir and Fabrazyme*

Under this Article's proposed approach to march-in decisions, NIH can and should decide to initiate march-in proceedings against Abbott.<sup>267</sup> Regarding the purpose and objectives of Bayh-Dole, Abbott's decision to increase prices was driven by a desire to steer patients toward Kaletra.<sup>268</sup> Abbott wanted to reduce utilization of and

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267. At the time of this draft, NIH had not announced its decision regarding the most recent march-in petition. The agency was scheduled to come to a decision in December 2012. John T. Aquino, *NIH Exercising "March-In" Rights—Is the Fifth Time the Charm?*, BLOOMBERG BNA (Nov. 6, 2012), <http://www.bna.com/nih-exercising-marchin-b17179870773/>. If the government applies the same reasoning it has in the past, including during the 2004 march-in petition, NIH will probably decline to march-in. See CASE OF NORVIR, *supra* note 79; see also Dennis Crouch & Jason Rantanen, *Should a Patentee with Market Power be Allowed to Charge Monopoly Prices?: March-In Rights and the NIH*, PATENTLYO (Oct. 28, 2012), <http://www.patentlyo.com/patent/2012/10/should-a-patentee-with-market-power-be-allowed-to-charge-monopoly-prices-march-in-rights-and-the-nih.html> (predicting that NIH will reject the petition). However, the agency has been deliberating this request for nearly forty weeks. For previous march-in decisions, the agency has reached a conclusion in fifteen to thirty-five weeks. This indicates that NIH might be reconsidering its standard approach. See *supra* note 81; see also *Notes from the March 18, 2013 NIH Call on the Ritonavir March-In Request*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 19, 2013, 7:47 AM), <http://keionline.org/node/1685>.

268. Carreyrou, *supra* note 14.

access to Norvir.<sup>269</sup> This is directly contrary to the objectives of the Bayh-Dole Act.<sup>270</sup> A march-in on Abbott would signal to the community that the government will not tolerate this misuse of federally funded inventions.

Regarding the public's interest, several manufacturers in other countries produce generic versions of ritonavir.<sup>271</sup> If NIH proceeds with a march-in, these generic products could be available to U.S. patients.<sup>272</sup> It is also likely that brand name competitors would manufacture ritonavir as a component of new, potential single-pill combination therapies similar to Kaletra.<sup>273</sup> These combination products would be easier to use and other companies could adjust dosing to achieve optimal efficacy.<sup>274</sup> The price of Norvir in the U.S. would also drop and come closer in line with the price in other countries (and the U.S. price from 2003) of between \$1-2 per day.<sup>275</sup>

The situation is more complicated when it comes to a march-in on Mt. Sinai during the Fabrazyme shortage. Under this Article's approach, NIH could have initiated march-in proceedings against Mt. Sinai. However, that decision may have run counter to the public's interest. Regarding the purpose and objectives of Bayh-Dole, Mt. Sinai was preparing to extract license revenues from a company during a drug shortage.<sup>276</sup> The purpose of the Bayh-Dole Act does

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269. *See id.*

270. 35 U.S.C. § 200 (2006).

271. *See* Norvir Petition 2012, *supra* note 5, at 11 (noting that five companies are selling generic versions of ritonavir outside the U.S.).

272. FDA has tentatively approved the use of atazanavir/ritonavir combination tablets. They can be used abroad, through the President's Emergency Plan for AIDS Relief (PEPFAR). However, because of the U.S. patent on ritonavir, they are not available domestically. *See* Richard Klein and Kimberly Struble, *Tentative Approval of Atazanavir Sulfate and Ritonavir Fixed Dose Combination Tablets*, U.S. FOOD AND DRUG ADMIN. (Nov. 18, 2011), <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm280673.htm>.

273. *See* NORVIR PETITION 2004, *supra* note 10, at 13-14 (noting that Abbott's price leverage has reduced incentives for competitors to develop new protease inhibitors to be used in combination with ritonavir and describing how the increasing demand for single-pill combinations make them a lucrative product for manufacturers to develop).

274. *See* NORVIR PETITION 2004, *supra* note 10, at 13-14 (noting that the single-pill format simplifies treatment and lowers pill counts for patients, and explaining that varying protease inhibitor types and regimes can reduce side effects and preempt development of resistance).

275. *See In re Abbott Labs. Norvir Anti-Trust Litig.*, 562 F. Supp. 2d 1080, 1082 (N.D. Cal. 2008) (2003 price of Norvir was \$1.71/day). Competition would drive the price of Norvir down. This Article does not suggest exactly how competition would affect the price of protease inhibitors, but it is reasonable to expect that the price in 2003, which is similar to the global price today, is a more accurate reflection of the product's value.

276. *See supra* Part II.B.; Silverman, *supra* note 134.

not include generating revenue for universities.<sup>277</sup> If Mt. Sinai enforced an injunction against Shire during the shortage, that would have further limited the global supply of Fabry treatments.<sup>278</sup>

At the time of the shortage, no companies were interested in receiving a license.<sup>279</sup> Regarding the public's interest, an NIH march-in would not have solved the supply problem for Fabry patients.<sup>280</sup> The march-in would have been little more than a slap on Mt. Sinai's wrist—primarily signaling that the government will not tolerate misuses of Bayh-Dole inventions. This signal, in and of itself, would benefit the public to the extent it deterred similar acts from occurring in the future. Nevertheless, the march-in would not have caused an immediate public health benefit.<sup>281</sup> Furthermore, the march-in could have had costs. After a march-in, Genzyme would have lost its exclusive license for Fabrazyme.<sup>282</sup> It was already losing its position in the global market relative to Shire, as patients in Europe were switching to Replagal.<sup>283</sup> Without an exclusive license, and with Replagal gaining strength, Genzyme could have decided to give up on Fabrazyme and focus resources on a more secure market. This would have been unlikely, because Genzyme was under considerable public pressure to resolve the Fabrazyme shortage.<sup>284</sup> But without an exclusive license, manufacturing Fabrazyme might not be a sufficiently attractive investment.

When considering march-in petitions, NIH should first evaluate circumstances in light of the purpose and objectives of the Bayh-Dole Act. If a contractor or licensee is not acting consistent with the purpose and objectives of the Act, then march-in might be appropriate. But the agency cannot stop there. As the Fabrazyme case study illustrates, even when a party is misusing an invention, a

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277. See *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 31 (1979) (statement of Sen. Bob Dole) (citing Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST, Apr. 8, 1979) (emphasizing that one of the key issues in early debates about the Bayh-Dole Act was how to prevent universities from receiving windfall profits).

278. Silverman, *supra* note 134.

279. FABRAZYME, *supra* note 82, at 2.

280. *Id.* at 1.

281. *Id.*

282. While Genzyme did cause an access problem, the company was not misusing a Bayh-Dole invention. Genzyme simply failed in quality manufacturing. See *supra* Part II.B.; FABRAZYME, *supra* note 82, at 6-7 (describing Genzyme's production difficulties).

283. See *supra* note 130 and accompanying text.

284. See, e.g., Richard Lord, *Patients Suffering as Maker Rations Drug*, PITT. POST-GAZETTE, Jul. 10, 2011, at A-1; Matthew Perrone, *FDA Fines Genzyme \$175M for Manufacturing Problems*, ASSOC. PRESS, May 24, 2010.



march-in will not always be in the public interest. NIH must continue to consult the statutory text of the march-in provision, evaluate the circumstances in light of the Bayh-Dole's purpose, consider the likely outcomes, and weigh the public interest before proceeding with a march-in.

*B. Preserving the Strong Relationship Between Public and Private Sectors*

People often argue that even one instance of the government exercising march-in rights would have a far-reaching, chilling effect on the relationship between public funding and private industry.<sup>285</sup> However, this Article's proposed approach will not chill the strong relationship between universities and industry. For one, Bayh-Dole has successfully shifted the landscape of product development.<sup>286</sup> The collaborations between industry and academia are growing closer, and companies are increasingly relying on university investigators to generate new ideas.<sup>287</sup> Companies will not quickly abandon the opportunity to acquire cutting edge ideas from federal funding just because there has been a march-in.<sup>288</sup>

Even though this Article's proposed approach will shift and broaden the government's reasoning about march-in, it is not expected to drastically increase number of march-ins. March-in will continue to be the exception, not the rule.<sup>289</sup> There are economic reasons why misuse is unlikely—both companies and universities stand to benefit from successful product development.<sup>290</sup> Furthermore, companies can turn to the new march-in guidance for notice of what behavior is likely to constitute misuse.<sup>291</sup> This Article acknowledges that, for Bayh-Dole to work, contractors and licensees

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285. See, e.g., GOV'T ACCOUNTABILITY OFFICE, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 14 (2009) (describing the "chilling effect" as a disincentive to exercise march-in rights); 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, 665-66 (1998) (arguing that the government should not use march-in because companies would hesitate to enter into research agreements with federally funded researchers).

286. See generally MANAGING UNIVERSITY INTELLECTUAL PROPERTY, *supra* note 23, at 14-27 (describing the growing number of licenses for university technologies, and a U.S. innovation system that increasingly involves collaboration).

287. See *supra* note 188 and accompanying text.

288. Mary Eberle, Comment, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 177 (1999).

289. *Supra* Part III.A.

290. Eberle, *supra* note 288, at 177-78.

291. *Supra* Part III.B.

must enjoy a strong patent right in federally funded inventions.<sup>292</sup> The Article's proposal will combat misuse, but not open the door to numerous march-in proceedings.<sup>293</sup>

### *C. Improvement Over Other Proposed Solutions*

Many authors have suggested solutions to resolve perceived imperfections in the Bayh-Dole framework. Even the most recent Norvir march-in petition called for broader policy changes. This Article's proposal is a preferred policy option for several reasons. For one, this Article's approach is a practical solution, suggesting a minor modification with significant potential to deter misuse.<sup>294</sup>

Some authors have debated whether the government should use march-in as a mechanism to control the price of federally funded inventions.<sup>295</sup> This price control argument has been advanced in both academic and policy circles—it has specifically been raised in the context of the Norvir problem.<sup>296</sup> NIH has historically been reluctant to use march-in to control the market.<sup>297</sup> The agency's mission is focused on advancing knowledge and improving health.<sup>298</sup> NIH's view has been that Congress or the Federal Trade Commission is in a better position to address questions of drug pricing and market competition.<sup>299</sup> This Article's proposal allows NIH to prevent Abbott's exploitation of the Bayh-Dole privilege without requiring the research agency to exert control over the market.

Arguments that suggest march-in should be used to control price are flawed for many reasons. First, if a company knows that the

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292. *Supra* Part I.A.

293. *Supra* Part III.A.

294. Several authors have suggested more radical changes to the underlying federal research policy. *See de Larena, supra* note 35; *Sweeney, supra* note 35; *Rai & Eisenberg, supra* note 31.

295. *Compare* Arno & Davis, *supra* note 30 (arguing that march-in authorizes the government to review drug prices, and exercise march-in rights when prices exceed what is reasonable), *with* Raubitschek & Latker, *supra* note 30 (arguing that there is no reasonable pricing requirement under the Bayh-Dole Act).

296. *See* Arno & Davis, *supra* note 30; Raubitschek & Latker, *supra* note 30; NORVIR PETITION 2012, *supra* note 5. Numerous people and organizations submitted comments to NIH in the context of the 2004 Norvir march-in request, regarding pricing considerations. *See* OFFICE OF TECHNOLOGY TRANSFER, PUBLIC MEETING: NATIONAL INSTITUTES OF HEALTH – BUILDING 50 (May 25, 2004), *available at* <http://www.ott.nih.gov/policy/meeting/List-of-Speakers.pdf> (providing a list of speakers at the public meeting).

297. CASE OF NORVIR, *supra* note 79, at 5-6 (in NIH's view, concerns over drug pricing should be dealt with through legislation and the FTC is the appropriate agency to address questions about Abbott's anticompetitive behavior).

298. *About NIH: Mission*, NATIONAL INSTITUTES OF HEALTH (Mar. 15, 2013), <http://www.nih.gov/about/mission.htm>.

299. *See* CASE OF NORVIR, *supra* note 79, at 6.

government will limit pricing decisions, then it is less likely to pursue a project with high R&D costs.<sup>300</sup> Companies consider R&D costs along with predicted profits when deciding whether to invest in future projects.<sup>301</sup> They assume they will be able to set prices based on the value of a product on the market, and can estimate profits based on this predicted value.<sup>302</sup> If the government dictates prices, the company will not be able to predict profits. A company may not pursue projects that are subject to significant pricing oversight. Adopting a policy to control prices could have the effect of making Bayh-Dole inventions unattractive to the private sector.

In October 2012, march-in petitioners specifically requested that NIH set a ceiling on domestic drug prices when the drug is based on a federally funded invention.<sup>303</sup> The proposed policy would require a march-in when the price of a drug in the U.S. is higher than the price in other high-income countries.<sup>304</sup> Under this proposed policy, a contractor or licensee could avoid march-in by proving that the high U.S. cost is necessary to recover actual R&D expenditures.<sup>305</sup> This proposal reflects a misunderstanding of how companies set prices. For one, companies do not consider sunk costs—R&D costs—when setting price.<sup>306</sup>

Furthermore, U.S. healthcare prices are higher than prices in other high-income countries for many reasons.<sup>307</sup> Because of the structure of the healthcare market and our strong IP protection, the

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300. David R. Francis, *The Effect of Price Controls on Pharmaceutical Research*, NAT'L BUREAU ECON. RESEARCH, <http://www.nber.org/digest/may05/w11114.html> (last visited Aug. 7, 2013) (describing a study showing that cutting pharmaceutical prices in the U.S. would lead to fewer R&D projects being undertaken).

301. Thursday, *supra* note 177, at 14-15.

302. See, e.g., Jessica Wapner, *A Secret Revealed: Why Drugs Cost What They Do*, PLOS BLOGS (Apr. 20, 2011), <http://blogs.plos.org/workinprogress/2011/04/20/a-secret-revealed-why-drugs-cost-what-they-do/> (factors in price calculations include: how many people will buy a drug, how many of them have insurance, how many are likely to have Medicare or Medicaid, for how long a patient will take the drug, how much it costs to manufacture, and what the drug treats).

303. NORVIR PETITION 2012, *supra* note 5, at 16-17.

304. *Id.* at 17.

305. *Id.* (quoting the suggested policy provision that “a licensee may rebut the presumption of unreasonable pricing by providing evidence that its actual risk adjusted R&D costs would not be recovered, but for the charging of higher prices in the U.S. market, or other evidence specific to the risk adjusted costs for the licensed invention”).

306. Thursday, *supra* note 177, at 16-17 (observing that to maximize profits, a firm balances marginal costs and marginal revenues. Firms do not consider fixed costs when setting prices and determining level of output.).

307. Donald L. Barlett & James B. Steele, *Why Drugs Cost So Much*, TIME MAGAZINE (Feb. 2, 2004), <http://www.time.com/time/magazine/article/0,9171,993223,00.html>.

U.S. “subsidizes” the costs of pharmaceutical R&D for the whole world.<sup>308</sup> Other countries allow the national government to negotiate drug prices, which does not occur at the same level in the U.S.<sup>309</sup> Trying to control the price of some drugs through march-in is a narrow and unsatisfactory suggestion within a larger ecosystem where the U.S. must find a way to address escalating health spending.

Finally, price discrimination on the global pharmaceutical market is generally a positive thing.<sup>310</sup> Companies will sell the same product at different prices based on demand in different markets.<sup>311</sup> Consumers in poorer markets will not be able to pay for expensive drugs, so companies will drop prices to reach those markets.<sup>312</sup> Price discrimination can increase access to medicine, and benefits communities that need it most.<sup>313</sup> Blocking companies from price discrimination at the higher-income level could reduce this beneficial price discrimination at lower-income levels.

This Article’s proposed approach to march-in would solve the problem of “excessive or unreasonable” U.S. prices without the adverse consequences.<sup>314</sup> If a company sets an excessive or unreasonable price, the government would be able to march-in under the new approach. Charging excessive prices is inconsistent with the purpose of the Bayh-Dole Act. It limits utilization and availability of the product. By definition, if it is excessive or unreasonable, then the price is higher than what the company could achieve under normal market forces—and higher than what should be necessary to encourage commercialization. Excessive drug prices are also not in the public interest. Under this Article’s approach, it is appropriate to march-in when there are excessive prices. However, there may be circumstances where a company legitimately charges

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308. *E.g., id.*

309. GOV’T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: AN OVERVIEW OF APPROACHES TO NEGOTIATE DRUG PRICES USED BY OTHER COUNTRIES AND U.S. PRIVATE PAYERS AND FEDERAL PROGRAMS 1 (2007), available at <http://www.gao.gov/new.items/d07358t.pdf>.

310. WORLD HEALTH ORG., WORLD INTELLECTUAL PROP. ORG. & WORLD TRADE ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 159-60 (2013); Frank R. Lichtenberg, *Pharmaceutical Companies’ Variation of Drug Prices Within and Among Countries Can Improve Long-Term Social Well-Being*, 30 HEALTH AFFAIRS 1539, 1539-40 (2011).

311. William W. Fisher III, *When Should we Permit Differential Pricing of Information?*, 55 UCLA L. REV. 1, 7 (2007).

312. *Id.* at 7-8.

313. See *e.g.*, WORLD HEALTH ORG., WORLD INTELLECTUAL PROP. ORG. & WORLD TRADE ORG., *supra* note 310, at 159 (Box 4.5 describes an example of Novartis making a lower cost malaria treatment available for public sector use).

314. NORVIR PETITION 2012, *supra* note 5, at 17.

high prices or charges more in the U.S. This Article's approach would limit unreasonable prices without the government exercising undue control over price decisions.

#### CONCLUSION

The Bayh-Dole Act has been successful in bringing federally funded inventions to market, and to the consumer. In passing the Act, Congress took a calculated risk; sometimes inventors, universities, small businesses, and large companies will not live up to their end of the bargain. March-in is the safety valve in the Act that gives the government and the public recourse if private parties misuse the Bayh-Dole privilege. Based on the current narrow drafting and interpretation of the march-in provision, it has not been an effective tool to correct misuse.

A minor modification and reorientation of the march-in decision process will go a long way in creating an effective safety valve. If federal research agencies consider the purpose and objectives of the Act and weigh the public's interest when considering a march-in, they will be able to prevent the full range of Bayh-Dole misuses.

NIH can, and should, start marching-in now. Congress should also act to formally establish this new approach to march-in. The government can stop Abbott from continuing to manipulate the HIV/AIDS treatment market. Abbott is restricting access to a federally funded invention and impeding the development of new, better treatments. Marching-in would block these actions that are antithetical to the purpose and objectives of Bayh-Dole and promote the public's interest. In doing this, the government will also send a signal that misuse of inventions will not be tolerated. Bayh-Dole affords great opportunities, but those opportunities come with responsibilities—march-in can be the safety valve to ensure contractors and licensees live up to their responsibility.