Alternatives to March-In Rights

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ABSTRACT

The Bayh-Dole Act is an inspired piece of legislation. But its "march-in" provisions are too often a source of confusion and fear for private-sector companies that want to do business with the US government—despite the fact that the government has never exercised its march-in rights. Are there alternatives to march-in rights that would effectively serve the government's public policy needs while eliminating this perceived threat to private intellectual property rights? This Article describes march-in rights in theory and practice, and then weighs several alternatives to traditional Bayh-Dole march-in rights.

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I. INTRODUCTION: THE BAYH-DOLE ACT AND GOVERNMENT INTELLECTUAL PROPERTY POLICY

The Bayh-Dole Act, the "most inspired piece of legislation to be enacted in America over the past century,"[1] is a chapter of the Patent Act that controls the ownership and disposition of patents created with US government funds.[2] It grants certain private contractors patents in inventions created using US funds,[3] but restricts how those patents can be licensed[4] and under what circumstances they can be maintained in confidence.[5] It also controls how the US government can apply for patents[6] and how government-owned patents can be licensed to the private sector.[7] Aspects of the Bayh-Dole Act have been copied worldwide.[8]

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1. *Innovation's Golden Goose*, THE ECONOMIST, Dec. 12, 2002; *see also* John H. Raubitschek & Norman J. Latker, *Reasonable Pricing — A New Twist for March-In Rights Under The Bayh-Dole Act*, 22 SANTA CLARA COMP. & HIGH TECH. L.J. 149, 150 (2005) ("The Act has been enormously effective"); Abigail Amato Rives, *Reorienting Bayh-Dole's March-In: Looking to Purpose and Objectives in the Public's Interest*, 5 AMERICAN U. INTELL. PROP. BRIEF 77, 86 (2014) ("The Bayh-Dole Act . . . 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.").

2. *See* 35 U.S.C. §§ 200–12 (2012).

3. *See* 35 U.S.C. § 202 (2012).

4. *See* 35 U.S.C. § 204 (2012).

5. *See* 35 U.S.C. § 205 (2012).

6. *See* 35 U.S.C. § 207 (2012).

7. *See* 35 U.S.C. §§ 208–09 (2012).

8. *See* Manisha Singh Nair, *Indian Bayh-Dole on its Path*, IPFrontline (Oct. 8, 2007), http://ipfrontline.com/2007/10/indian-baye-dole-on-its-path/ [http://perma.cc/ZV29-8TA7] (discussing India's efforts to emulate Bayh-Dole in the context of university research); J. Steven Rutt & Stephen B. Maebius, *Technology Transfer Under Japan's Bayh-Dole: Boom or Bust Nanotechnology Opportunities?*, NANOTECHNOLOGY L. & BUS., Vol. 1, No. 3, Article 8 (2004) (discussing the Japanese government's efforts to emulate Bayh-Dole for nanotechnology); John Fraser and Ashley Stevens, *Understanding the Importance of Bayh-Dole*, Managing Intell. Prop. (Dec. 2005/Jan. 2006) ("Countries around the world are expressing their agreement by adopting laws similar to the Bayh-Dole Act. Germany, Korea and Taiwan are the most recent countries allowing academic institutions, as opposed to individual professors, to own inventions resulting from research in their labs. In Japan, the government is privatizing the entire university system in part because they want Japanese universities to become economic catalysts, like their US counterparts. The British and Canadian governments have established pools of funds to accelerate the commercialization of university research.").

March-in rights, which allow the government to forcibly license government-funded, privately-owned patents to third parties, are the most controversial feature of the Bayh-Dole Act.[9] In light of industry concerns over march-in rights, this Article analyzes whether there are any viable alternatives to march-in rights that would meet the government's objectives of ensuring effective commercialization. Part II addresses the evolution of the Bayh-Dole Act and the policies underlying it. Part III describes how march-in rights work in practice and prior efforts to trigger government march-in. Part IV discusses possible alternatives to march-in rights.

II. EVOLUTION OF THE BAYH-DOLE ACT

Prior to the 1980 enactment of the Bayh-Dole Act, under both Republican and Democratic administrations, the US government owned all patents to technology developed using government funds.[10] This *modus vivendi* reflected a government contracting ecosystem in which a small cadre of large, integrated, government-facing contractors supplied the government's technological needs. By the 1970s, however, deep concerns about the government's inability to disseminate the technologies it owned for the public benefit or to acquire superior technologies to serve its own needs led to a rethinking of how to encourage increased private sector participation in the government marketplace. This reconsideration also led to new ways of conveying government-developed technology to the private sector and, ultimately, consumers.[11] Along with the Stevenson-Wydler Technology Innovation Act, which jump-started agency technology-transfer efforts,[12] the Bayh-Dole Act was the first—and arguably most important—step in a process that has led to our current regime: a regime in which contractors own most intellectual property developed at public expense.

The Bayh-Dole Act itself applies narrowly to two classes of patents: patents on inventions developed by government contractors in the course of a funding agreement (so-called "subject inventions"[13]) and patents on inventions arising out of the work of federal employees.[14] The Bayh-Dole Act's rules concerning the disposition of

9. *See* 35 U.S.C. § 203 (2012).

10. *See*, *e.g.*, Memorandum and Statement of Government Patent Policy, 28 Fed. Reg. 10943 (Oct. 12, 1963) (Pres. Kennedy); 36 Fed. Reg. 16877 (Aug. 26, 1971) (Pres. Nixon).

11. *See generally* JAMES G. MCEWEN, DAVID S. BLOCH, RICHARD M. GRAY, & JOHN T. LUCAS, IP AND TECHNOLOGY IN GOVERNMENT CONTRACTS 6–9 (LexisNexis 2014).

12. Pub. L. 96-480, 94 Stat. 2311 (codified at 15 U.S.C. § 3701).

13. *See* 35 U.S.C. § 202 (2012).

14. *See* 35 U.S.C. § 209 (2012).

rights in subject inventions are likewise rather narrow. For the most part, they provide that a contractor can elect title to a subject invention first conceived or reduced to practice under a government contract, though in "exceptional circumstances," the government may retain title instead.[15]

There are three important limitations to the Bayh-Dole Act: 1) it is limited to patents, 2) it only applies to funding agreements, and 3) it only applies to small businesses and nonprofit organizations. I address each of these limitations in more depth below.

First, as noted, the Bayh-Dole Act is codified in Title 35 of the US Code and only applies to patents. The Act says nothing about the disposition of copyrights, trademarks, or trade secrets. Under the Federal Acquisition Regulation (FAR), however, similar rules apply to copyrights (in the form of computer software) and trade secrets (in the form of technical data)[16]—rules buttressed by the fact that the government cannot create copyrighted goods[17] and is statutorily barred from revealing contractor trade secrets.[18] Trademarks remain a special case, little understood by the government or the contracting community.[19]

Second, the Bayh-Dole Act only applies to patentable technology developed under "funding agreements"[20]—"contract[s], grant[s], or cooperative agreement[s] . . . funded in whole or in part by the Federal Government"[21]—in the United States. Other forms of government agreement may not trigger the Bayh-Dole Act at all,[22] and foreign contractors are not entitled to elect title to subject inventions.[23]

Third, the Bayh-Dole Act only applies to small businesses and nonprofit enterprises, including universities.[24] By its terms and as a question of its stated policy, the Bayh-Dole Act does not apply to large commercial concerns because the original statute wanted to encourage

15. FAR 27.302(b)(2), (d).

16. FAR Subpart 27.4, *Rights in Data and Copyrights,* applies to all executive agencies other than the Department of Defense. DFARS Subparts 227.71, *Rights in Technical Data,* and 227.72, *Rights in Computer Software and Computer Software Documentation*, apply to the Department of Defense.

17. *See* 17 U.S.C. § 105 (2012).

18. 5 U.S.C. § 552(b)(4) (2012).

19. *See generally* David S. Bloch & James G. McEwen, *Like Toddlers in Big Surf: Can the Government Control the Effects of Federal Trademark Liability?*, 33 PUB. CONT. L.J. 209 (2003).

20. 35 U.S.C. § 202(c) (2012).

21. 35 U.S.C. § 201(b) (2012).

22. *See*, *e.g.*, David S. Bloch & James G. McEwen, *"Other Transactions" With Uncle Sam: A Solution to the High-Tech Government Contracting Crisis*, 10 TEX. INTELL. PROP. L.J. 195 (2002).

23. FAR 27.302(b)(2)(i) (2014).

24. 35 U.S.C. §§ 201(h)–(i), 202(c) (2012).

"maximum participation of small business firms" and "collaboration between commercial concerns and nonprofit organizations, including universities, . . . nonprofit organizations and small business firms."[25] However, in 1987, President Reagan's Executive Order 12591 extended the Bayh-Dole Act's rule allowing private contractors to own government-funded patents to all organizations doing business with the government.[26] Similarly, the Bayh-Dole Act does not apply to the Department of Energy (DOE) or the National Aeronautics and Space Administration (NASA), whose organic statutes require that they own patents funded by certain of their efforts.[27] In contrast to the Bayh-Dole Act, the Atomic Energy Act states:

> Any invention or discovery, useful in the production or utilization of special nuclear material or atomic energy, made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the [Atomic Energy] Commission, regardless of whether the contract, subcontract, or arrangement involved the expenditure of funds by the Commission, shall be vested in, and be the property of, the Commission.[28]

The DOE's founding statute likewise indicates that "[w]henever any invention is made or conceived in the course of or under any contract of the [Energy] Department, other than nuclear energy research, development, and demonstration pursuant to the Atomic Energy Act of 1954 . . . title to such invention shall vest in the United States" unless the Secretary of Energy waives the Department's rights.[29]

As to NASA, and again unlike the Bayh-Dole Act, the Space Act states, "An invention shall be the exclusive property of the United States if it is made in the performance of any work under any contract of [NASA]."[30] But NASA and DOE are permitted to waive their default intellectual property rights in favor of a Bayh-Dole-like system and almost always use these waiver rules to grant contractors rights in subject inventions.[31]

Thus, by the end of the 1980s, a stated purpose of government procurement law was "to use the patent system to promote the utilization of inventions arising in federally supported research or

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25. *See, e.g.*, 35 U.S.C. § 200 (2012).

26. Exec. Order No. 12591 was implemented primarily by FAR part 27,52.227-11 and 52.227-13, along with (at the Department of Defense) DFARS 252.227-7038 in supplement X27 and X27.5227. It has since been codified at 35 U.S.C. § 210(c).

27. *See*, *e.g.*, 42 U.S.C. §§ 2182, 5908 (2012); 51 U.S.C. § 20135 (2012); US Dep't of Energy v. White, 210 U.S.P.Q. 425 (C.C.P.A. 1981).

28. 42 U.S.C. § 2182 (2012).

29. 42 U.S.C. § 5908(a) (2012).

30. 51 U.S.C. § 20135(b)(1) (2012).

31. *See* 10 C.F.R. 784 (2014).

development."[32] This policy aim superseded other possible incentives for acquiring intellectual property. Unlike in the private sector, the government views patents not as economic assets or defensive weapons in IP litigation, but rather as vehicles for technology transfer.[33] But technology transfer is not the only policy objective enshrined in the Bayh-Dole Act. Rather, 35 U.S.C. § 200 identifies several different government goals, which include:

> "[P]romot[ing] the utilization of inventions arising from federally supported research or development."
>
> "[E]ncourag[ing] maximum participation of small business firms in federally supported research and development efforts."
>
> "[P]romot[ing] collaboration between commercial concerns and nonprofit organizations, including universities."
>
> "[E]nsur[ing] that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery."
>
> "[P]romot[ing] the commercialization and public availability of inventions made in the United States by United States industry and labor."
>
> "[E]nsur[ing] that the Government obtain sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against the non-use or unreasonable use of inventions."[34]

As discussed below, march-in rights are one of the several ways that the government seeks to satisfy these sometimes inconsistent goals.

III. MARCH-IN RIGHTS

A. Definition of March-In Rights

March-in rights are the government's only real vehicle for enforcing the limitations contained in the Bayh-Dole Act. The government's march-in rights are set forth in 35 U.S.C. § 203, which states that "the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor . . . to grant a nonexclusive, partly exclusive, or exclusive license in any field of use to responsible applicant or applicants, upon terms that are reasonable under the circumstances" in four specific situations:

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32. 37 C.F.R. § 404.2 (2014).

33. 35 U.S.C. § 200 (2012) ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development.").

34. *Id*.

1. "[T]he contractor . . . has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."
2. March-in rights are "necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor."
3. "[T]o meet requirements for public use specified by Federal regulations" if "said requirements are not reasonably satisfied by the contractor."
4. The contractor fails to honor its US manufacturing commitments as required by 35 U.S.C. § 204.[35]

The government's march-in rights are intended to "protect the public against nonuse or unreasonable use of inventions."[36] Under § 203(b), march-in determinations are not subject to the Administrative Procedures Act but rather are governed by agency-specific rules.[37] March-in determinations can be appealed within sixty days of the determination in the US Court of Federal Claims. The government can exercise march-in rights *sua sponte* or may act in response to a third-party petition.[38]

The march-in mechanism thus lets the government force the patentee to grant royalty-bearing sublicenses in the event that the patentee is not commercializing a subject invention and public policy concerns require another manufacturing source. In this sense, march-in rights are similar to a "best efforts" clause in a commercial contract (that is, a clause requiring a licensee to use its best efforts to commercialize a patented invention). As Senator Birch Bayh explained:

> 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.[39]

As a result, march-in rights were originally created to ensure that patent owners would commercialize—rather than suppress—subject inventions. Of course, march-in rights can be justified by the proposition that the public, which arguably funded the most critical parts of the inventive process—conception and prototyping, should not have to pay twice for the technology embodied in a subject invention.

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35. 35 U.S.C. § 203 (2012).
36. 35 U.S.C. § 200 (2012).
37. 35 U.S.C. § 203(b) (2012).
38. 37 C.F.R. § 401.6(b).
39. Statement of Sen. Birch Bayh to the Nat'l Inst. of Health (May 24, 2004), https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf [https://perma.cc/P8VC-7G9Q].

B. Other Restrictions on Subject Inventions

Patents on subject inventions are subject to a series of regulations and rules. In theory, a contractor must follow these rules in order to elect title to an invention developed at government expense. Some of these rules apply before the contractor is permitted to take title to a subject invention, while others govern what the contractor can (or must) do once it owns the resulting patent. Before the contractor can elect title, it must notify the government that it has developed a subject invention in a format provided by the government.[40] After the contractor has elected title, it must make reasonable and good faith efforts to commercialize the subject invention in the United States.[41] For example, the contractor must manufacture substantially in the United States and preferentially issue licenses to subcontractors and manufacturers in the United States.[42] To ensure its compliance with these rules, the patentee must list the government as a funder on the face of its patent[43] and provide periodic utilization reports on its efforts to comply with the Bayh-Dole Act's policies.[44] The government retains a royalty-free, nonexclusive, fully paid-up government-purpose license, along with the right to approve sublicenses to ensure that "the right to obtain by the government" is expressly conveyed in any sublicense.[45]

C. The Government's Refusal to Exercise March-In Rights

Though march-in rights have been a feature of the statutory landscape since 1980, they have never been exercised. There have been a total of five march-in petitions decided by a government agency—all, as it happens, by the National Institutes of Health (NIH). In each instance, the government has declined to march in and force the licensee to grant additional licenses.

1. *In re CellPro* (1997)

In re CellPro was the first formal march-in petition to reach the federal courts.[46] The US government's refusal to march in on a Johns

40. FAR 27.302(b)(1), (d)(1)(i).
41. FAR 27.302(g).
42. *Id*.
43. FAR 52.227-11(e)(4).
44. FAR 27.302(e).
45. 37 C.F.R. § 401.14(a).
46. *In re Petition of CellPro, Inc.* (Nat'l Inst. of Health, 1997) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf

Hopkins pharmaceutical patent sparked immediate controversy both because it was the first time the concept of march-in was introduced to a wider audience of activists and IP lawyers and because it seemed to favor strong patents rights even at the expense of more rapid commercialization.[47] In the *CellPro* decision, Johns Hopkins University owned a government-funded patent on a particular stem cell antibody. CellPro, Inc. obtained Food and Drug Administration (FDA) approval for a drug product involving an antibody, and the university sued CellPro for patent infringement.[48] In response, CellPro first asked the court for a compulsory license and then petitioned the NIH to march in on the theory that Johns Hopkins had failed to effectively commercialize the subject invention because it had not yet obtained FDA approval to market the patented antibody. The NIH refused to exercise its march-in rights, reasoning that John Hopkins University (which was seeking its own FDA approval, albeit at a slower pace) was taking reasonable efforts to commercialize its patent and that CellPro had failed to even ask for a license from the university.[49] By favoring the patentee over a proposed entrant that promised to reach the market faster, *CellPro* set the template for later march-in petitions and also triggered the first stirrings of proposals to reform (or at least reinterpret) the Bayh-Dole Act.[50]

2. *In re Norvir I* (2004)

Seven years later, the NIH was required to address a second march-in petition—this time triggered by citizen-activists rather than a drug company seeking early market entry. In the first *Norvir* march-in petition,[51] an activist group named Essential Inventions

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[http://perma.cc/V3QY-HZQD] [hereinafter CellPro NIH]; *see also* John Hopkins Univ. v. CellPro, Inc., 931 F. Supp. 303 (D. Del. 1996).

47. *Compare* Kevin W. McCabe, *Implications of the CellPro Determination on Inventions Made With Federal Assistance: Will the Government Ever Exercise Its March-In Rights?*, 27 PUB. CONT. L.J. 645, 649 (1998) (defending the refusal to exercise march-in rights) *with* Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 171 (1999) (arguing, *contra* McCabe, "that a march-in under one of the four circumstances enumerated in the Act would not harm technology transfer"); *see also* Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the* Hopkins v. CellPro *March-in Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211 (2000).

48. *CellPro*, 931 F.Supp. at 306.

49. CellPro NIH, *supra* note 46.

50. *See, e.g.*, Eberle, *supra* note 47, at 171; Valoir, *supra* note 47.

51. *In the Case of Norvir® Manufactured by Abbott Laboratories, Inc (Norvir I)* (Nat'l Inst. of Health, 2004) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf [http://perma.cc/ST6Z-8C5L]. Winston & Strawn represents Abbott Laboratories, including in connection with Norvir, but I have no role in the Abbott relationship and am speaking here solely in my personal capacity.

complained to the NIH that patentee Abbott Laboratories had unreasonably raised the price of the antiretroviral Norvir, a drug of only modest efficacy on its own but synergistic in combination with certain other drugs. In this instance, unlike *In re CellPro*, there was no dispute that Abbott had successfully commercialized its subject invention; rather, the petitioners urged the NIH to march in because the high price of Norvir allegedly put the health and safety of the public at risk. The NIH refused to exercise its march-in rights, reasoning that the Bayh-Dole Act does not reach pricing decisions so long as the patentee has taken reasonable steps to achieve practical commercialization:

> Norvir® has been available for use by patients with HIV/AIDS since 1996 and is being actively marketed by Abbott and prescribed by physicians primarily as a booster drug. Accordingly, this drug has reached practical application and met health or safety needs as required by the Bayh-Dole Act. The NIH believes that the issue of drug pricing is one that would be more appropriately addressed by Congress, as it considers these matters in a larger context. The NIH also maintains that the FTC is the appropriate agency to address the question of whether Abbott has engaged in anti-competitive behavior.[52]

Norvir I reached the same result as *CellPro* (a refusal to march in) for similar reasons (Abbott is making reasonable efforts to commercialize its patented invention), but it adds an activist's dimension to the debate; for the first time, private pressure groups tried to use the Bayh-Dole Act in an effort to influence corporate decisions (specifically, pricing).

3. *In re Xalatan* (2004)

In a companion case to *In re Norvir I*, Essential Inventions challenged the price in the United States of Pfizer's anti-glaucoma medicine Xalatan as unreasonably high compared with its price in other countries.[53] *Xalatan* followed the same pattern as *Norvir I*: NIH concluded that Pfizer had effectively commercialized the subject invention "because it [was] being utilized and [had] been made widely available for use by glaucoma patients for at least eight years."[54] The NIH declined to second-guess Pfizer's pricing decisions:

> [T]he NIH believes that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of whether drugs should be sold in the United States for the same price as they are sold in Canada and Europe has global implications and, thus, is appropriately left for Congress to address legislatively.[55]

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52. *Id*.

53. *In the Case of Xalatan® Manufactured by Pfizer, Inc.* (Nat'l Inst. of Health, 2004) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf [http://perma.cc/XN47-695K].

54. *Id.*

55. *Id*.

Xalatan and *Norvir I* reached the same result for the same reason: it is for Congress, not the NIH, to decide whether high prices are a sufficient reason to exercise march-in rights (and hence undermine patent rights in government-funded inventions).[56]

4. *In re Fabrazyme* (2010)

Unlike the *CellPro*, *Xalatan*, and *Norvir* petitions, the *Fabrazyme* petition involved an actual, acute shortage of a patented drug.[57] Fabrazyme is the brand name of a subject invention developed by the Mount Sinai School of Medicine to treat Fabry's disease, a genetic disorder. Mount Sinai licensed the patent to Genzyme, which obtained FDA approval and marketed Fabrazyme for several years. After FDA approval, however, Genzyme experienced significant manufacturing problems that resulted in at least one contaminated batch of Fabrazyme. In response, FDA fined Genzyme $175 million, temporarily suspended Genzyme's manufacturing rights, and imposed additional oversight. This led to a significant short-term drop in the supply of Fabrazyme and prompted physician C. Allen Black, Jr. to petition the NIH to march in.[58] However, because no third parties were close to being able to manufacture FDA-approved Fabrazyme and Genzyme expected to resume full manufacturing shortly, the NIH declined to exercise its march-in rights, reasoning that the fact that Genzyme suffered unrelated regulatory problems after achieving practical commercialization was an insufficient basis to march in.[59]

5. *In re Norvir II* (2012)

In 2012, a coalition of activist groups (Knowledge Ecology International, the American Medical Students Association, the US Public Interest Research Group, and Universities Allied for Essential Medicines) asked the NIH to reconsider *In re Norvir I* based on continued pricing disparities between countries and in connection with

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56. *See generally* John H. Rabitschek & 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, 160 (2005).

57. I*n the Case of Fabrazyme® Manufactured by Genzyme Corporation* (Nat'l Inst. of Health, 2010) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf [http://perma.cc/EGJ4-SC63] [hereinafter *Fabrazyme*].

58. *See generally* William O'Brien, *March-in Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?*, 43 SETON HALL L. REV. 1403, 1419–23 (2013).

59. *Fabrazyme*, *supra* note 57.

different health insurance regimes.[60] However, "[t]he NIH continue[d] to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients."[61]

6. Other March-In Petitions

In addition to these five full-blown petitions, there have been several other march-in efforts that fizzled short of decision.[62] There were discussions concerning march-in for anti-anthrax vaccines during the height of the anthrax crisis post-9/11,[63] and there have been occasional petitions to the Department of Energy[64] and the Department of Defense[65] in which march-in-type rights were raised.[66] Most recently, Senator Patrick Leahy sent a July 2013 letter to NIH urging it to force Myriad Genetics to license its patents relating to breast cancer testing methods.[67] At least since the Bayh-Dole Act was enacted, none of these petitions has ever reached the point of decision.

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60. *In the Case of Norvir® Manufactured by AbbVie* (Nat'l Inst. of Health, 2013) (determination), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf [http://perma.cc/V8E3-D8RG].

61. *Id.* at 7. Winston & Strawn represents AbbVie, including in connection with Norvir, but I have no role in the Abbott relationship and am speaking here solely in my personal capacity.

62. *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS, at 9–14 (2009).

63. *See*, *e.g.*, Raymond A. Kurz & Celine Jimenez Crowson, *Patents 'R' Us?,* 24 L. TIMES 44 (Nov. 5, 2001).

64. *E.g.*, Diane M. Sidebottom, *Intellectual Property in Federal Government Contracts: The Past, The Present, and One Possible Future*, 33 PUB. CONT. L.J. 63, 95 n.245 (2003) (identifying two possible march-in events by DOE's predecessor, the Atomic Energy Commission, in 1974).

65. *E.g.*, *Patent Policy*: *Hearings Before the S. Comm. on Sci., Tech., and Space of the Comm. on Commerce, Sci. and Transp.,* 96th Cong., 366 (2004) (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy) ("Only once can I recall there was a case where we exercised march-in rights. It was a case involving two patents held by MIT. There was a complainant who felt as though the patents were not being utilized. As to one of the patents, it was found that MIT was using it and was allowed to retain exclusive title. In the case of the other, we found that MIT was not effectively using it, and they did provide for the complainant to use the patent."); *see also* Campbell Plastics Eng'g & Mfg. Co. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004) (explaining that the DOD took title to the subject invention for failure to follow Bayh-Dole Act invention disclosure rules).

66. Rabitschek & Latker, *supra* note 1, at 154–55.

67. Letter from Sen. Patrick Leahy, to Dr. Francis S. Collins, Dir., Nat'l Inst. of Health, http://patentdocs.typepad.com/files/leahy-letter.pdf [http://perma.cc/VN27-XPH4]. A decision on Sen. Leahy's letter likely was forestalled by the Supreme Court's decision to invalidate at least some of the patents on the involved subject inventions. *See* Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

IV. ALTERNATIVES TO MARCH-IN RIGHTS

Academics and activist groups point to the five NIH decisions and other failed efforts to exercise march-in rights as proof that the current structure is fundamentally flawed. According to some, march-in is a "paper tiger," ineffective in achieving Bayh-Dole's public policy goals.[68] Indeed, the academic literature surrounding the Bayh-Dole Act's march-in clause almost uniformly calls for enhanced government march-in rights.[69]

Even without changes to the Bayh-Dole Act, the US government has two ways to enable a third party to practice a government-funded, privately-held patent. First, the government could use its own government-purpose license under 35 U.S.C. § 202(c)(4). Second, the government could use its authorization-and-consent authority under 28 U.S.C. § 1498 in order to immunize a third party from infringement liability. In both instances, however, the scope of the resulting license or authorization (as it relates to commercial uses) is unclear.[70] At a further extreme, some commentators advocate for an express compulsory license regime.[71] Compulsory license regimes exist in other forms of intellectual property—for example, music performance and reproduction copyrights are subject to a complicated web of compulsory licenses.[72] But in the context of high-technology patents, a compulsory license could dramatically reduce the value of the government-sponsored patents and consequently the incentive to invest in commercialization.[73] Indeed, a compulsory-license regime would yield almost the same situation that existed prior to the enactment of the Bayh-Dole Act.

Other commentators—like the petitioners in the *Xalatan* and *Norvir II* petitions—suggest a form of price control, in which drug prices deemed "too high" (generally in comparison to prices in other

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68. O'Brien, *supra* note 58, at 1405, 1429.

69. *E.g.*, *id.* at 1429–30; Eberle, *supra* note 47, at 179; 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 (1999); Rives, *supra* note 1, at 77; Valoir, *supra* note 47, at 239.

70. McGarey & Levey, *supra* note 69, at 1113–15.

71. Kimberly M. Thomas, Comment, *Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in the Absence of an Experimental Use Exception*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347, 349 (2006) (footnote omitted) ("[T]his comment suggests reformation of the Bayh-Dole Act, a federal technology transfer policy, as the conduit to enact a compulsory licensing provision.").

72. 17 U.S.C. § 115 (2012).

73. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37(2) J.L. MED. & ETHICS 247 (2010) (discussing the literature).

jurisdictions) would be per se justification for march-in.[74] But the government is a poor judge of how private companies should price their products and hence has wisely refrained from using march-in rights to dictate how much companies should charge for patented goods and services.[75]

Both the relative paucity of march-in cases and the fact that all of the march-in petitions for granting third-party licenses that have gone to decision have been refused suggest that the march-in provisions of the Bayh-Dole Act set roughly the correct balance. If government-funded patents were being serially suppressed, it is reasonable to expect that more march-in petitions would be filed. Also notable is the fact that only one march-in petition (*CellPro*) involved a petition by a company that actually wanted—and could use—a compulsory license. In the other four march-in petitions to the NIH, the petitioner wanted the US government to march in but was not in a position to actually make the product covered by the government-funded patent. Perhaps the paucity of further activist petitions reflects private-actor expectations that their efforts will be in vain. But the paucity of further pharmaceutical company petitions (compared to, say, citizen petitions to the FDA or challenges to the Hatch-Waxman Act) and the absence of any petitions from non-pharmaceutical businesses suggest a relatively high level of comfort with the existing Bayh-Dole Act architecture. This is not altogether surprising. After all, the Bayh-Dole Act is viewed as an unrivaled success in encouraging and effectuating technology transfer, so it is hard to see why march-in should be made easier.[76]

Indeed, if there is a problem with the march-in right, it may be that its chilling effects are too extreme. Despite the fact that they have never been exercised and have only even been requested in the pharmaceutical context, march-in rights remain a very significant concern for private companies—particularly the kind of high-tech companies that the Bayh-Dole Act was intended to bring in to the

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74. Peter Arno & Michael 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); *see also* Rives, *supra* note 1, at 119 ("NIH can, and should, start marching-in now."); O'Brien, *supra* note 58, at 1431 ("[T]he Fabrazyme case demonstrates [the NIH's] failure in effectuating another primary goal: protecting the public health and safety from the nonuse or unreasonable use of inventions funded by taxpayer dollars.").

75. *See* Raubitschek & Latker, *supra* note 1, at 150, 165–67 ("The Act has been enormously effective.").

76. *See* Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, *in* 3 INNOVATION POLICY AND THE ECONOMY 91, 103 (Adam B. Jaffe, Josh Lerner, & Scott Stern eds., 2003) ("The Bayh-Dole Act and related legislation appear to have had their desired effect.").

government contracting ecosystem. It is difficult to quantify the deterrent effects of 35 U.S.C. § 203 or 28 U.S.C. § 1498. But anecdotally—and this is wholly consistent with the author's own experience—the reluctance of such companies to do business with the government is almost invariably tied up in concerns over the government's right to appropriate private sector intellectual property.[77] This result runs directly counter to the US government's desire for maximum competition[78] and is contrary to the stated goal of the Bayh-Dole Act.[79]

In part, this concern springs from misconception concerning the nature of patent rights in general. As it stands, the government has the absolute right to practice any US patent. This is not a function of the Bayh-Dole Act at all, but rather it is an attribute of US sovereignty as reflected in 28 U.S.C. § 1498.[80] But even with that attribute understood, coupled with the fact that in more than thirty-five years the government has never exercised its march-in rights, the anxiety remains. The anxiety is not altogether ill-founded. Since 1997, the NIH has averaged more than one march-in petition every five years—and each march-in petition potentially puts at risk the staggeringly massive investment that branded pharmaceutical companies make in developing new drug therapies[81]—$2.6 billion per new drug in 2014, according to the Tufts Center for the Study of Drug Development.[82]

Instead of looking for ways to strengthen march-in rights, perhaps the better solution would be to look at ways to eliminate the march-in provisions of the Bayh-Dole Act and Executive Order 12591, while still ensuring that the government's policy in favor of effective

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77. *See generally* Nancy O. Dix, Fernand A. Lavallee, & Kimberly C. Welch, *Fear and Loathing of Federal Contracting: Are Commercial Companies* Really *Afraid to Do Business with the Federal Government? Should They Be?,* 33 PUB. CONT. L.J. 5 (2003).

78. *E.g.*, GUIDELINES FOR CREATING AND MAINTAINING A COMPETITIVE ENV'T FOR SUPPLIES AND SERVS. IN THE DEP'T OF DEF. (OFFICE OF THE UNDERSEC'Y OF DEF. FOR ACQUISITION, TECH., AND LOGISTICS, 2014).

79. *See* 35 U.S.C. § 2000 (2012).

80. "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498(a) (2012).

81. *See, e.g.*, Joseph Allen, *High Noon for Bayh-Dole*, IP WATCHDOG (Jul. 17, 2013), http://www.ipwatchdog.com/2013/07/17/high-noon-for-bayh-dole/id=43371/ [http://perma.cc/BL6F-WKMW] ("[T]his march-in could only happen after companies have invested years of effort and hundreds of millions—or billions—of dollars to develop a new product.").

82. Press Release, Tuft's Center for the Study of Drug Development (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study [http://perma.cc/6NVT-2BPH].

commercialization is met. There are at least three logical options for avoiding or replacing march-in rights: alternative contractual vehicles, economic penalties, or litigation remedies.

A. Alternative Contractual Vehicles

The Bayh-Dole Act only applies to funding agreements. The government has a wide variety of other contractual vehicles at its disposal. For example, Other Transactions Authority allows businesses to contract around the restrictions imposed by the Bayh-Dole Act.[83] Other Transactions (OTs) are available by statute to NASA and the Department of Energy[84] and have been used by other agencies based on regulatory enactments.[85] The use of alternative contract types does not require any new legislation—these vehicles already exist, and based on recent Supreme Court precedents, there is good reason to think that parties are allowed to contract around the Bayh-Dole Act, even with respect to funding agreements.[86] But while OTs and other new contract types may be an effective solution, the widespread adoption of OTs as an alternative to funding vehicles would require a broad-based change in government contracting practice that seems unlikely—especially in response to continued concerns about march-in rights.

B. Economic Penalties

At present, the government's only remedy for a contractor's failure to effectively commercialize a subject invention is the exercise of march-in rights—a nuclear option. It might be possible instead to impose a number of different systems of fines or payments. For example, the government might impose fines on companies that fail to follow agreed upon commercialization plans or achieve specific contractual milestones. Such a system would be akin in structure to a contractual penalty clause. Another option would be a maintenance fee specific to subject inventions. Patents already require maintenance fees that increase over time.[87] The law could be changed

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83. *See, e.g.*, David S. Bloch & James G. McEwen, *"Other Transactions" With Uncle Sam: A Solution to the High-Tech Government Contracting Crisis*, 10 TEX. INTELL. PROP. L.J. 195 (2002).

84. *See* 10 U.S.C. § 2371 (2014); 51 U.S.C. § 20113(e) (2010).

85. *See, e.g.*, MCEWEN, *supra* note 11, at § 3.11; *see also* L. ELAINE HALCHIN, CONG. RESEARCH SERV., RL34760, OTHER TRANSACTIONS (OT) AUTHORITY 5–6 (2011).

86. *See* Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 563 U.S. 776 (2011).

87. 35 U.S.C. § 41(b) (2013); Post Issuance Fees, 37 C.F.R. § 1.20 (2013).

to impose additional fees on some or all subject invention patents in order to create additional incentives to monetize them. Contracts subject to the Bayh-Dole Act could also include buyout clauses: if a government contractor wants to avoid the risk of march-in, it can repay some or all of the government's expenditures relating to the subject invention. By reimbursing the public for the cost of invention, the contractor would eliminate the concern that the public good is not being served or that innovations paid for with public money are being used for private benefit. Considering the value of pharmaceutical patents, it is conceivable that a Pfizer or a Genzyme would have been inclined to buy out the risk of a march-in challenge to a blockbuster drug, while less-promising patented drugs presumably would remain subject to the march-in risk (and hence spur additional research or, alternatively, voluntary relinquishment of the patent). Such economic remedies would require only minor tweaks to the existing structure of the Bayh-Dole Act. Recoupment was considered and rejected in the months leading up to the enactment of the Bayh-Dole Act.[88] It has been consistently rejected since.[89] But in light of current realities, it might be worth revisiting those debates.

C. Litigation Remedies

Another alternative to traditional march-in would be to shift the process from agencies (which are loath to involve themselves in fact-finding) to the court system. At present, defendants cannot assert a Bayh-Dole Act defense.[90] They cannot rely on the government's right to assert ownership because whether the government chooses to exercise that right is purely discretionary.[91]

It would not be difficult, however, to reframe the law to allow a Bayh-Dole Act defense. In a case involving a Bayh-Dole Act affirmative defense, the courts (as opposed to a government agency) would determine when the patentee has complied with the Act. This is the kind of analysis courts undertake routinely. Courts are inherently better suited to make factual determinations and develop rules of general applicability, because that is the heart of the

88. *See* John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist for March-In Rights Under The Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 163 (2005).

89. *See* Rebecca S. Eiseinberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1716 (1996).

90. *See* Platzer v. Sloan-Kettering Inst. for Cancer Res., 787 F.Supp. 360, 364 (S.D.N.Y. 1992).

91. *See* Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1352–53 (Fed. Cir. 2007).

common-law adversarial decision-making process; courts *exist* to resolve contested issues. By contrast, the NIH has repeatedly—in each of its five march-in decisions—disclaimed any competency to make such contested factual determinations. Making the Bayh-Dole Act an explicit part of the litigation process also would ensure march-in-type remedies are only in play with respect to patents with significant economic value.

There are a number of ways a litigation-based remedy could be structured. For one, the courts could simply conclude that the failure to comply fully with the Bayh-Dole Act is a form of patent misuse. Similarly, the False Claims Act prohibits the submission of a material "false record or statement" to the government.[92] In theory, an inaccurate commercialization report submitted to the government could be viewed as a species of false claim. Under 35 U.S.C. § 211, "[n]othing in [the Bayh-Dole Act] shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law," so there is no legal barrier to letting courts consider a patentee's compliance with the Bayh-Dole Act as a defense.[93]

Another alternative would be to change pleading requirements for subject inventions. The Federal Judicial Council could promulgate a rule that any patentee asserting a subject invention in litigation would need to affirmatively state that it has complied with the Bayh-Dole Act and applicable regulations. If that affirmative allegation were later proved false, the defendant could seek sanctions against the patentee under Federal Rule of Civil Procedure 11.[94]

The idea of a private right of action for Bayh-Dole Act violations was considered and rejected when the law was enacted.[95] Again, though, that decision need not stand for all time. These litigation remedies could largely be enacted by administrative regulations, though it is possible that certain minor amendments to Title 35 also would be required.

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92. 31 U.S.C. § 3729(a)(1)(B) (1982).

93. 35 U.S.C. § 211 (2012).

94. "By presenting to the court a pleading, written motion, or other paper—whether by signing, filing, submitting, or later advocating it—an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances . . . (2) the claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law; [and] (3) the factual contentions have evidentiary support . . . ." FED. R. CIV. P 11(b).

95. *See* John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist for March-In Rights Under The Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 156 (2005), *quoting* S. Rep. No. 96-480 at 33–34 (1979).

D. Assessment of Alternatives

Of these options, the author tends to favor a form of litigation remedy. There is no reason that a patentee holding a US government-funded patent should not need to affirmatively plead compliance with applicable laws and regulations. However, the author remains skeptical that widespread adoption of alternative contractual vehicles will occur, though they could solve several other issues in government contracting.[96] And the author is affirmatively opposed to economic penalties or compulsory licenses, which would do far more harm than good because each option would, in its own way, significantly reduce the incentive of technology companies to invest in commercializing government-financed technology.

V. CONCLUSION: INCREMENTAL CHANGES ARE BEST

By any measure, the Bayh-Dole Act has been a smashing success. And as discussed above, the Act's march-in provision is an important part of the overall statutory architecture. But it also has the unintended effect of suppressing some amount of private-sector participation in US government contracting efforts. Because that is so, it is reasonable to consider modest, calibrated changes to the march-in right. But those changes should not make it easier for the government to exercise those rights—encouraging march-in petitions would further reduce private-sector incentives to seek out government funding. At best, of the options above, the author would support strengthening the Bayh-Dole Act's other provisions, perhaps by creating an affirmative defense of failure to comply with the law and applicable regulations.

Of course, one size need not fit all. Perhaps the mandatory rules set forth in the Bayh-Dole Act, complete with march-in rights, could continue to apply to small businesses, nonprofits, and universities, while agencies could relax the rules for large contractors—the way the Department of Defense has exercised the right to specially negotiate intellectual property license rights.[97] On balance, the Bayh-Dole Act's success is probably reason enough to avoid any radical changes. But to the extent that industry remains afraid or unwilling to do business with the government, some of the more industry-friendly modifications discussed herein should be considered.

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96. *See* Bloch & McEwen, *supra* note 83.

97. *See* 48 C.F.R. 252.227-7013(b)(4) (2014); 48 C.F.R. 252.227-7014(b)(4) (2015).