

# THE STATE GIVETH AND THE STATE TAKETH AWAY: PATENT RIGHTS UNDER THE BAYH-DOLE ACT

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## I. INTRODUCTION

A small business owner is considering applying for a government contract to produce a new type of solar panel. She has been working on solar cell technology for years and has patents on her previous designs. She could really use the funding, but has misgivings: Will the government get the patent to the new design, or even the previous designs? Such matters are controlled by the Bayh-Dole Act of 1980 (“Bayh-Dole”).<sup>1</sup> According to conventional wisdom, Bayh-Dole represents a major shift in patent rights to federally-funded inventions from the government to the contractor.<sup>2</sup> However, the rights Bayh-Dole gives contractors are limited and easily overridden. Conventional wisdom on Bayh-Dole ignores the numerous restrictions potentially placed on funding recipients, up to and including loss of the patent. This Note will discuss these limitations and how to best proceed with caution when entering into a government contract.

Bayh-Dole has been called “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.”<sup>3</sup> As the “technology transfer” movement shifted federal research and development from the private sector to the public sector, the allocation of patent rights to

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1. Bayh-Dole Act, 35 U.S.C. §§ 200–211 (2012).

2. See, e.g., Howard Markel, *Patents, Profits, and the American People—The Bayh-Dole Act of 1980*, NEW ENG. J. MED. (Aug. 29, 2013), <http://www.nejm.org/doi/full/10.1056/NEJMp1306553>; *Innovation’s Golden Goose*, ECONOMIST (Dec. 12, 2002), available at <http://www.economist.com/node/1476653>; *Bayh-Dole: 30 Years of Driven Innovation*, MY DESIRING-MACHINES (Jan. 16, 2013), <http://mydesiringmachines.wordpress.com/2013/01/16/bayh-dole-30-years-of-driven-innovation/>.

3. See, e.g., *Innovation’s Golden Goose*, *supra* note 2.

federally funded inventions became increasingly important.<sup>4</sup> Bayh-Dole allows a contractor receiving government funds to patent an invention conceived under a contract, whereas prior to Bayh-Dole, the funding agency generally obtained patent rights.<sup>5</sup>

Bayh-Dole has been much lauded and has been attributed to a major increase in technology licensing and innovation from universities and small businesses.<sup>6</sup> However, while some universities think Bayh-Dole is “the best thing since sliced bread,”<sup>7</sup> private companies disagree: three-fourths of the top U.S. information technology companies refuse to do government research out of fear of handing over valuable intellectual property rights.<sup>8</sup> Specifically, Bayh-Dole’s complexity and loopholes scare many private companies.<sup>9</sup>

Part II of this Note will describe the pre-Bayh-Dole landscape by discussing prior laws, and the economic and technological problems Bayh-Dole was enacted to address. Part III will provide the relevant statutory provisions of Bayh-Dole. In particular, Bayh-Dole provides several ways to shift control from the inventor to the government agency. Although contractors generally have the right to retain title to government-funded inventions, government agencies can eliminate or restrict this right in certain circumstances.<sup>10</sup> For example, the government automatically obtains a license for inventions arising from a funding contract, and can allow a third party to use an invention on the government’s behalf.<sup>11</sup> The government can also take title to an invention if disclosure procedures are not followed,<sup>12</sup> and the funding agency has the right to “march-in” and

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4. See *The Government's Patent Policy: The Bayh-Dole Act and "Authorization and Consent,"* MORRISON & FOERSTER (Oct. 6, 2002), [http://www.mfo.com/resources/news/2002/10/the-governments-patent-policy-the-bayhdole-act-a\\_\\_](http://www.mfo.com/resources/news/2002/10/the-governments-patent-policy-the-bayhdole-act-a__) [hereinafter MORRISON & FOERSTER].

5. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, FEDERAL RESEARCH: INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 9–10 (2009) [hereinafter *Federal Research*].

6. See, e.g., *Innovation's Golden Goose*, *supra* note 2.

7. COMM. ON GOV'T REFORM, 107TH CONG., TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT: HOW THE TREATMENT OF INTELLECTUAL PROPERTY RIGHTS IS MINIMIZING INNOVATION IN THE FEDERAL GOVERNMENT, H.R. DOC. NO. 107-90, at 98 (Comm. Print 2001) (statement of Christopher T. Hill, vice provost for research and professor of public policy and technology, George Mason University).

8. *Id.* at 106–07 (statement of Tom Davis, Cong. Rep., VA).

9. *Id.* at 74–75 (statement of Richard N. Kuyath, Counsel, 3M Corp.).

10. 35 U.S.C. § 202(a) (2012).

11. *Id.*

12. 35 U.S.C. § 202(c).

2015]

*The State Giveth and the State Taketh Away*

493

mandate licensing to a third party if the invention is not adequately commercialized.<sup>13</sup>

Part IV will explore Bayh-Dole's legislative history and how it has been applied through regulations. Part V will discuss how the government has used its rights to federally funded inventions under Bayh-Dole. Finally, Part VI will show how reality differs from conventional wisdom: Bayh-Dole is commonly interpreted to shift patent rights to a contractor, with failsafe provisions allowing the government to retain limited rights, mostly rarely and exceptionally.<sup>14</sup> However, this interpretation ignores the fact that the rapidly expanding "exceptional circumstances" exception, onerous disclosure requirements, broad licensing rights, and the threat of march-in rights give the government great latitude to control or even take contractors' patents.

## II. THE SCENE BEFORE BAYH-DOLE

### A. THE LAW

Patent rights grant a temporary monopoly to an inventor in exchange for public disclosure of an invention.<sup>15</sup> In the context of government-funded research, the best allocation of patent rights is a difficult question. Granting patent rights to inventors encourages and rewards innovation.<sup>16</sup> However, when the government funds an invention, granting patent rights to a private party can result in the taxpayer paying for the invention twice: once in funding research and development, and again in licensing fees required for use.<sup>17</sup>

Until 1980, there was no uniform policy for intellectual property tied to federally funded research.<sup>18</sup> Individual agencies were free to determine

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13. *Id.* § 203(a).

14. See, e.g., COMM. ON MGMT. OF UNIV. INTELLECTUAL PROP. ET AL., MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST 54 (STEPHEN A. MERRILL & ANNE-MARIE MAZZA EDS., 2010); MORRISON & FOERSTER, *supra* note 4.

15. See, e.g., Greg Blonder, *Cutting Through the Patent Thicket*, BLOOMBERG BUS. WK. (Dec. 20, 2005), available at <http://www.businessweek.com/stories/2005-12-19/cutting-through-the-patent-thicket/>.

16. See, e.g., 35 U.S.C. § 202.

17. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1996).

18. BAYHDOLE25, INC., THE BAYH-DOLE ACT AT 25, 2 (2006), available at [http://bayhdolecentral.com/BayhDole25\\_WhitePaper.pdf](http://bayhdolecentral.com/BayhDole25_WhitePaper.pdf).

how to allocate patent rights through agency-specific procedures and policies.<sup>19</sup> For some agencies, rights vested to the government by default; for others, the grantee could take title. Most agencies took the patent rights to federally funded inventions by default.<sup>20</sup> This system was favored because many believed that if the taxpayer funded an invention, then the invention should be available to the public.<sup>21</sup>

Many Bayh-Dole provisions previously existed in some form, mostly in informal recommendations and policies.<sup>22</sup> The government could use patents held by private parties under the Government Use Statute.<sup>23</sup> This statute authorized the federal government to use inventions arising from federally sponsored research without obtaining a license, and the Court of Claims to hear petitions and determine if fair compensation was in order.<sup>24</sup> In the 1940s, President Roosevelt called for a uniform patent policy and requested the Attorney General to investigate the matter.<sup>25</sup>

In 1947, the Department of Justice introduced an Attorney General's report outlining suggested changes to patent law.<sup>26</sup> The report suggested that the federal government should own all patents arising from federal funding to "assure free and equal availability of the inventions to American industry and science . . . [and] avoid undue concentration of economic power in the hands of a few large corporations . . ."<sup>27</sup> The report also suggested provisions that led to government licensing and march-in rights under Bayh-Dole.<sup>28</sup> The Non-Nuclear Act established a law with provisions

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19. *Id.*

20. *Federal Research*, *supra* note 5, at 9–10.

21. Jennifer A. Henderson & John. J. Smith, *Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize*, CTR. FOR INTEGRATION MED. & INNOVATIVE TECH., 2 (Oct. 2002), available at [http://www.cimit.org/news/regulatory/coi\\_part3.pdf](http://www.cimit.org/news/regulatory/coi_part3.pdf).

22. *Id.* at 3.

23. *Id.*; UNITED STATES STATUTES AT LARGE, 61 Cong. Ch. 423, June 25, 1910, 36 Stat. 851; SEAN O'CONNOR, Gregory Graff & David Winickoff, *Legal Context of University Intellectual Property and Technology Transfer*, NAT'L RES. COUNCIL 4 (Sept. 20, 2010), available at [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_058897.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_058897.pdf). The statute is also known as the "IP Takings Statute".

24. O'Connor, *supra* note 23, at 4.

25. *Id.* at 6.

26. *Id.* at 7; DEP'T OF JUSTICE, INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICIES 2 (1947).

27. O'Connor, *supra* note 23, at 8.

28. *Id.*

2015]

*The State Giveth and the State Taketh Away*

495

similar to march-in rights and was used at least once.<sup>29</sup> In 1965, the Department of Energy (“DoE”) established a patent regime enabling a contractor to retain title to an invention while the government received a right to its use.<sup>30</sup> Almost all of Bayh-Dole dates back to the 1960s or earlier.<sup>31</sup>

#### B. COMMERCIAL USE AND THE ECONOMY

Bayh-Dole was largely precipitated by the ill effects of the government’s underutilization of its inventions. A “debatable statistic” often used to extoll the virtues of Bayh-Dole<sup>32</sup> touts that, prior to 1980, 95 percent of federally sponsored inventions were not utilized.<sup>33</sup> The United States spent billions of dollars each year funding research, which was a number seen as wasteful given the low percentage of government-funded inventions actually achieving commercial use.<sup>34</sup>

These concerns were multiplied by the economic crisis of the 1970s. Immediately preceding Bayh-Dole’s inception, American industry was in serious decline. This industrial decline, along with oil embargoes, dragged down the stock market, devalued the dollar, and threatened America’s position as an economic superpower.<sup>35</sup> When the automotive and steel industries moved to Japan, there was speculation that Japan and Germany would take the lead in the global economy.<sup>36</sup> Bayh-Dole’s enactors needed to rescue the United States from “industrial irrelevance.”<sup>37</sup>

The Bayh-Dole Act was developed hand-in-hand with the technology transfer movement. As industry floundered and deep budget cuts were

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29. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT, *supra* note 7, at 99 (this part of the Non-Nuclear Act was repealed in 1980 upon the adoption of the Bayh-Dole Act).

30. JAMES MCEWEN ET AL., INTELLECTUAL PROPERTY IN GOVERNMENT CONTRACTS 35 (2d ed. 2012).

31. See O’Connor, *supra* note 23.

32. Robert M. Yeh, *The Public Paid for the Invention: Who Owns It?*, 27 BERKELEY TECH. L.J. 453, 471 (2012).

33. *Innovation’s Golden Goose*, *supra* note 2, at 1.

34. Markel, *supra* note 2.

35. *Id.*

36. *Id.*

37. *Id.*

made to the defense industry, Congress developed legislation to encourage the transfer of technology from the government to the private sector.<sup>38</sup>

### III. STATUTORY PROVISIONS

Bayh-Dole applies to funding agreements with the government, including procurement contracts, grants, and cooperative agreements.<sup>39</sup> It is enacted as 35 U.S.C. §§ 200–211.<sup>40</sup>

#### A. POLICY AND OBJECTIVE

Bayh-Dole begins by laying out its motivating policies and objectives.<sup>41</sup> The intent of the Act is “to promote the utilization of inventions arising from federally supported research or development, to ensure that inventions . . . are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery,” to encourage “the commercialization and public availability of inventions,” and “to ensure that the Government obtains sufficient rights in federally supported inventions to meet [its] needs and protect the public against nonuse or unreasonable use of inventions.”<sup>42</sup>

#### B. DEFINITIONS

The definitions of certain terms within Bayh-Dole are crucial to determining the scope of the government’s rights to inventions, and are provided in § 201.<sup>43</sup> A “contractor” is “any person, small business firm, or nonprofit organization that is a party to a funding agreement.”<sup>44</sup> A “funding agreement” is “any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of

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38. *Id.* at 1, 15; Carl L. Vacketta et al., *Technology Transfer*, 94–12 BRIEFING PAPERS 1, 1 (1994). In addition to the Bayh-Dole Act, Congress passed several acts in the 1980s aimed directly at encouraging technology transfer, such as the Stevenson-Wydler Technology Innovation Act and Technology Transfer Act of 1986 for cooperative research agreements, and the 1988 Advanced Technology Program designed to aid in the commercialization of new technologies. *Id.*

39. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 70.

40. 35 U.S.C. §§ 200–211 (2012).

41. *Id.* § 200.

42. *Id.*

43. *Id.* § 201.

44. *Id.* § 201(c).

2015]

*The State Giveth and the State Taketh Away*

497

experimental, developmental, or research work funded in whole or in part by the Federal Government.”<sup>45</sup>

An “invention” is broadly defined as “any invention or discovery which is or may be patentable or otherwise protectable” under the statute.<sup>46</sup> Bayh-Dole applies to any “subject invention,” which is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.”<sup>47</sup> The definition covers a broad range of situations that can take unwary contractors by surprise.<sup>48</sup> For example, Bayh-Dole might include technology conceived under government funding but later reduced to practice at the inventor’s personal expense.<sup>49</sup> At the other end of the spectrum, Bayh-Dole could also include inventions conceived long before a government contract if reduction to practice occurred during the course of the contract.<sup>50</sup>

### C. DISPOSITION OF RIGHTS

Section 202 establishes the basic allocation of patent rights. As written, § 202(a) applies to “[e]ach nonprofit organization or small business firm,”<sup>51</sup> but for most agencies this has been extended to both large and small businesses.<sup>52</sup> Each organization or business “may, within a reasonable time after disclosure . . . elect to retain title to any subject invention.”<sup>53</sup> The contractor can elect to retain title by following the appropriate procedures, but does not automatically receive it.<sup>54</sup>

In certain circumstances, a contract can “provide otherwise” and not allow a contractor to take title.<sup>55</sup> Section 202(a) enumerates four situations in which this can occur:

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45. *Id.* § 201(b).

46. *Id.* § 201(d).

47. *Id.* § 201(e).

48. See MORRISON & FOERSTER, *supra* note 4.

49. *Id.*

50. *Id.*; Pilley v. United States, 74 Fed. Cl. 489 (2006).

51. 35 U.S.C. § 202(a) (2012).

52. William F. Ferreira, *Academic-Industry Collaboration Under Federal Grants and Cooperative Agreements: Financial, Administrative, and Regulatory Compliance*. 18 RESEARCH MANAGEMENT REVIEW 1, 2 (Spring/Summer 2011).

53. 35 U.S.C. § 202(a) (emphasis added).

54. *Id.*

55. *Id.*

- (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government,
- (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter,
- (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or,
- (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs . . .<sup>56</sup>

The most widely applicable exception is § 202(a)(ii), the “exceptional circumstances” exception.

#### D. DISCLOSURE REQUIREMENTS

Contractors must disclose inventions to the funding agency “within a reasonable time” at the risk of losing title to the invention.<sup>57</sup> Under § 202(c)(1), disclosure is required “within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters,” and the federal government may receive title to “any subject invention not disclosed to it within such time.”<sup>58</sup> The contractor must then disclose whether it will retain title to the invention within two years of the initial disclosure and file a patent application within one year.<sup>59</sup> The funding agency may further require periodic reports on the utilization of the invention.<sup>60</sup> If any of the disclosure requirements are not met, the federal government “may receive title” to the invention.<sup>61</sup>

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56. *Id.*

57. *Id.* § 202(c)(4).

58. *Id.*

59. *Id.*

60. *Id.* § 202(c)(5).

61. *Id.* § 202(c)(4).

2015]

*The State Giveth and the State Taketh Away*

499

#### E. GOVERNMENT LICENSE

Under § 202(c)(4), the funding agency obtains “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world” for all subject inventions to which a contractor takes title.<sup>62</sup> A paid-up license, also known as a royalty-free license, entitles the funding agency to freely use an invention without compensating the inventor.<sup>63</sup> There are two prongs of the licensing grant: First, the agency itself may use the subject invention. Second, the agency may allow another company or research institution to use the invention.<sup>64</sup> Section 202(c)(4) also allows the funding agreement to provide for “additional rights, including the right to assign or have assigned foreign patent rights in the subject invention.”<sup>65</sup>

#### F. MARCH-IN RIGHTS

March-in rights allow the funding agency to force the contractor “to grant a nonexclusive, partially exclusive, or exclusive license” to a third party or “to grant such a license itself” if the agency determines that action is necessary (1) “because the contractor has not taken . . . effective steps to achieve practical application of the subject invention;” (2) “to alleviate health or safety needs . . . not reasonably satisfied by the contractor;” (3) “to meet requirements for public use specified by Federal regulations;” or (4) because the goods were substantially manufactured overseas without the proper approvals.<sup>66</sup> Essentially, if the contractor does not properly make use of a subject invention, march-in rights allow the government to find someone who will.

#### G. PREFERENCE FOR UNITED STATES INDUSTRY

Section 204 requires that a business or organization taking title to an invention under Bayh-Dole cannot grant an exclusive right to any organization unless “any products embodying the subject invention or produced through the use of the subject invention will be manufactured

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62. *Id.*

63. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-03-536, TECHNOLOGY TRANSFER: AGENCIES’ RIGHTS TO FEDERALLY SPONSORED BIOMEDICAL INVENTIONS, at 7 (July 2003) [*hereinafter Agencies’ Rights*].

64. 35 U.S.C. § 202(c)(4).

65. *Id.*

66. *Id.* § 203(a).

substantially in the United States.”<sup>67</sup> However, this requirement may be waived on a case-by-case basis if reasonable and unsuccessful efforts have been made to comply or domestic manufacture is not “commercially feasible.”<sup>68</sup>

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67. *Id.* § 204.

68. *Id.*

2015]

*The State Giveth and the State Taketh Away*

501

SUMMARY: STATUTORY LIMITATIONS ON CONTRACTOR RIGHTS			
Exceptional Circumstances	§ 202(a)(1)	In “exceptional circumstances” where the agency determines it would better promote Bayh-Dole’s policy and objectives	A contract may provide that the government, not the contractor, obtains title to an invention
Disclosure	§ 202(c)(1)	If the contractor does not disclose an invention within “reasonable time” and give periodic reports on utilization	The contracting agency may receive full title if the contractor fails to comply
Licensing / “Subject Invention”	§ 202(c)(4) § 201	The funding agency automatically obtains a license to practice or have practiced on its behalf any “subject invention”. A “subject invention” is any invention conceived or first reduced to practice in performance of a funding agreement	The government has a license to practice or have a third party practice any invention that the contractor either conceived or reduced to practice under the contract
March-in Rights	§ 203(a)	If action is needed due to ineffective use of an invention, a health or safety concern, or goods are substantially manufactured outside of the United States	The funding agency can require the contractor to grant a license to a third party or grant such a license itself

#### IV. ENACTING BAYH-DOLE

##### A. LEGISLATIVE HISTORY

Bayh-Dole was signed into law as part of House Bill 6933 of the 96th Congress. Sections 1–5 relate to patent and trademark office procedures. Section 6, which would become Bayh-Dole, relates to government-funded inventions.<sup>69</sup> Prior to enacting Bayh-Dole, all relevant parts of House Bill 6933 were replaced by the text of S. 414 in an amendment-by-substitution procedure.<sup>70</sup> Senate Bill 414, The University and Small Business Patent Procedures Act, was introduced by Senators Birch Bayh and Bob Dole on February 9, 1979.<sup>71</sup>

The original version of House Bill 6933 had some meaningful differences from the final version:<sup>72</sup> Originally, House Bill 6933 gave small businesses and nonprofits the right to take title to “contract inventions” upon filing a patent application within a reasonable time.<sup>73</sup> It also gave more limited rights to “other contractors,” who could file a patent application and receive an exclusive license with the exclusive right to grant sublicenses.<sup>74</sup>

Senate Bill 414 proposed a law similar in structure, but was limited to cover only nonprofits, universities, and small businesses.<sup>75</sup> In addition to including “[e]ach nonprofit organization or small business firm” within this limitation,<sup>76</sup> it ended with the disclaimer that “[n]othing in this chapter is intended to alter the effect of the laws . . . with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.”<sup>77</sup>

This narrowing of the scope of the law was made in response to “serious opposition from consumer advocates and antitrust lawyers.”<sup>78</sup> Lobbying parties expressed concerns about giving monopolies to big

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69. O’Connor, *supra* note 23, at 16.

70. *Id.*

71. *Id.* at 17.

72. See H.R. 6933 96th Cong. (1980), *cf.* Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980).

73. *Id.* § 382.

74. *Id.* § 383–84.

75. *Id.*

76. S. 414, 96th Cong. § II (1979). *See also* 35 U.S.C. § 202(a).

77. S. 414 § II. *See also* 35 U.S.C. § 210(b).

78. Henderson, *supra* note 21, at 3.

2015]

*The State Giveth and the State Taketh Away*

503

federal contractors.<sup>79</sup> Although the House wanted to enact a completely uniform patent policy covering all businesses large and small, they allowed the Senate to replace the final section of House Bill 6933 with that of Senate Bill 414 in order to get the first five parts of the bill passed in a timely fashion.<sup>80</sup> However, Bayh-Dole was extended to large and for-profit businesses only a few years later.

The primary driving force for the new legislation was the decline of the American economy in the global marketplace:

[E]conomic malaise . . . arises out of a failure of American industry to keep pace with the increased productivity of foreign competitors . . . . The rate of investment as a proportion of GNP has averaged about one half the rate for France and Germany . . . . [T]he decline in expenditures for research and development is especially significant to the health of the overall economy.<sup>81</sup>

By encouraging innovation and the commercialization of inventions, Congress sought to prevent the United States from falling any further behind global competitors in the development of new products.<sup>82</sup>

An additional goal was to assuage business' fears that entering into government contracts would mean losing control of their intellectual property. Small businesses, in particular, avoided government contracts or even using university research facilities for fear of losing their patent rights.<sup>83</sup> Potential grantees were alarmed at the thought of the government taking title to their patents, as well as "background rights," wherein the government would obtain a license to inventions conceived prior to a contract.<sup>84</sup>

Congress could not, however, give contractors too much control, due to fears of giving unfair monopolies to large businesses.<sup>85</sup> As a result, several safeguards were used, including limiting Bayh-Dole to small businesses as well as granting the government march-in rights and the right

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79. *Id.*

80. O'Connor, *supra* note 23, at 18. The original version also contained two parts that were removed. Section 404 would have allowed the government to recoup funding dollars if an invention proved to be lucrative. Section 210 would have allowed the Department of Commerce to coordinate licensing. *Id.*

81. H.R. REP. NO. 96-1307, at 1 (1980), reprinted in 1980 U.S.C.C.A.N. 6460, 6460-61.

82. S. REP. NO. 96-480, at 1 (1979).

83. S. REP. NO. 96-480, at 21-22.

84. *Id.* at 22-23.

85. *Id.* at 28; O'Connor, *supra* note 23, at 17.

to have an invention practiced on its behalf.<sup>86</sup> The inclusion of these rights, reasoned the Senate, “should be a sufficient safeguard to protect public welfare requirements and prevent any undesirable economic concentration.”<sup>87</sup>

## B. AMENDMENTS

The Bayh-Dole Act has been amended several times. The most significant overhaul was a 1983 presidential memorandum and a 1987 executive order that extended Bayh-Dole to cover organizations other than non-profits and small businesses.<sup>88</sup>

Originally, § 202(a) provided three situations in which a funding agreement could “provide otherwise,” that is not allow a contractor to take title.<sup>89</sup> This was revised in 1984. The first situation was changed to include contractors located outside of the United States or subject to the control of a foreign government.<sup>90</sup> A fourth scenario was added, allowing the contracting agency to contract around the default title allocation for DoE naval nuclear propulsion or weapons-related programs.<sup>91</sup>

In 1983 President Ronald Reagan released the “Memorandum of the Government Patent Policy,” providing that Bayh-Dole should be applied the same to all organizations as a matter of policy.<sup>92</sup> Under a 1987 executive order, any rights under Bayh-Dole may be waived if one of two requirements is met:

- (1) . . . the interests of the United States and the general public will be better served thereby . . . or (2) . . . the award involves co-sponsored, cost sharing, or joint venture research and development, and the performer, cosponsor or joint venturer is making substantial contribution of funds, facilities or equipment to the work performed under the award.<sup>93</sup>

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86. S. REP. NO. 96-480, at 28.

87. *Id.*

88. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT, *supra* note 7, at 9–10.

89. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 § 202(a) (1980).

90. Trademark Clarification Act of 1984, Pub. L. No. 98-620, 98 Stat. 3335 § 501 (1984).

91. *Id.*

92. MEMORANDUM ON GOVERNMENT PATENT POLICY, AMERICAN PRESIDENCY PROJECT (Feb. 18, 1983), available at <http://www.presidency.ucsb.edu/ws/?pid=40945>.

93. *Id.*

2015]

*The State Giveth and the State Taketh Away*

505

Further, the order made two provisions mandatory for large businesses: the stated purpose and march-in rights. The order also suggests applying other provisions to large businesses in appropriate circumstances.<sup>94</sup>

### C. REGULATIONS

Several regulations establish procedures for agencies to follow in complying with Bayh-Dole. The Federal Acquisition Regulation controls procedures for procurement contracts.<sup>95</sup> The primary procedural regulation, established by the Department of Commerce (“DoC”), is followed by most agencies. The Department of Defense (“DoD”), Department of Energy, and National Aeronautics and Space Administration (“NASA”) have established their own regulations.

#### *1. Federal Acquisition Regulation*

The Federal Acquisition Regulation (“FAR”) controls federal acquisition procedures and contracts.<sup>96</sup> It begins with general regulations, which many agencies defer to in the area of patent rights.<sup>97</sup> Individual agencies also have supplementary regulations that may vary from the general ones.<sup>98</sup> Procurement contracts generally incorporate parts of FAR by reference.<sup>99</sup>

Although many aspects of the FAR can be contracted out of, this does not apply to the government license—under no circumstances may the government license of § 202(a) be eliminated by a funding contract.<sup>100</sup> The terms of the government license can, however, be limited in appropriate circumstances.<sup>101</sup> March-in rights are also mandatory, but the parties are largely free to contract around all other sections of FAR.<sup>102</sup> In applying

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94. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT, *supra* note 7, at 98–99.

95. 48 C.F.R. §§ 1–9999 (2013).

96. *Id.*

97. *Id.* §§ 1–99.

98. *Id.* §§ 100–9999.

99. Margarete M. Gatti & Louis K. Rothberg, *US Government Contracts and Rights in Patent and Tech Data*, MORGAN LEWIS 9 (March 2012), available at [https://www.morganlewis.com/pubs/IntTrade\\_GvtContracts-RightsinPatents\\_29march12.pdf](https://www.morganlewis.com/pubs/IntTrade_GvtContracts-RightsinPatents_29march12.pdf).

100. DEP’T OF DEF., INTELLECTUAL PROPERTY: NAVIGATING THROUGH COMMERCIAL WATERS: ISSUES AND SOLUTIONS WHEN NEGOTIATING INTELLECTUAL PROPERTY WITH COMMERCIAL COMPANIES 2–3 (Oct. 15, 2001).

101. *Id.*

102. *Id.* at 4–6.

FAR, “agencies shall strike a balance between the Government’s need and the contractor’s legitimate proprietary interest.”<sup>103</sup>

General FAR reporting requirements are followed by most agencies. Once an inventor has disclosed an invention in writing to a contractor responsible for patent matters, the contractor must, within two months, disclose the invention in writing to the Contracting Officer.<sup>104</sup> The contractor then has two years to elect in writing whether to take title to the invention, and generally must file a patent application within one year of this election.<sup>105</sup> The patent application must be accompanied by a “government interest statement” disclosing the government’s rights to the invention.<sup>106</sup> If the contractor fails to retain title, the contracting agency may request title within sixty days of the omission.<sup>107</sup> FAR does not detail the steps the agency must take to take title upon failure to disclose.<sup>108</sup>

The general section of FAR does *not* incorporate the § 202(a) exceptions in which a contract may restrict a contractor’s right to retain title.<sup>109</sup> In the absence of a supplementary FAR clause to the contrary, agencies have to obtain a determination of exceptional circumstances from the head of the agency, which requires “significant justification.”<sup>110</sup> The Department of Health and Human Services (“HHS”) is in the process of amending its supplementary regulation to circumvent this requirement entirely.<sup>111</sup> However, with one narrow exception, no agency can completely

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103. 48 C.F.R. § 27.402 (2007); TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 40.

104. 48 C.F.R. § 52.227-11.

105. *Id.*

106. *Id.*; U.S. GOV’T ACCOUNTABILITY OFFICE, GAO/RCED-99-242, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION, at 4 (1999).

107. GAO/RCED-99-242, *supra* note 106, at 4.

108. See GAO/RCED-99-242, *supra* note 106, at 4.

109. See 48 C.F.R. § 52.227-11; Natalie Derzko, Jennifer Plitsch & Saurabh Anand, *HHS Proposes to Amend Acquisition Regulations Regarding Application of Bayh-Dole Act and Data Rights*, COVINGTON & BURLING E-ALERT (Jan. 18, 2013), [http://www.cov.com/files/Publication/49aa529f-4999-4a9b-a59b-71c12a595665/Presentation/PublicationAttachment/01a640e8-26fb-4775-a952-7ac7f4728944/HHS\\_Proposes\\_to\\_Amend\\_Regulations\\_Regarding\\_Application\\_of\\_Bayh-Dole\\_Act\\_and\\_Data\\_Rights.pdf](http://www.cov.com/files/Publication/49aa529f-4999-4a9b-a59b-71c12a595665/Presentation/PublicationAttachment/01a640e8-26fb-4775-a952-7ac7f4728944/HHS_Proposes_to_Amend_Regulations_Regarding_Application_of_Bayh-Dole_Act_and_Data_Rights.pdf).

110. Derzko, *supra* note 109, at 1.

111. *Id.*

2015]

*The State Giveth and the State Taketh Away*

507

take away a contractor's right to retain title.<sup>112</sup> At most, the right to take title may be restricted.<sup>113</sup>

## 2. Department of Commerce

The DoC developed regulations codified in 37 C.F.R. § 401.<sup>114</sup> Although compliance is elective, the DoC regulations are followed by almost all government agencies. Some agencies implement their own regulations, which deviate from the DoC in certain areas.<sup>115</sup> In practice, regulation is decentralized; the DoC does not ensure compliance with Bayh-Dole, but rather sees its role as "facilitating its operation."<sup>116</sup> Agencies see Commerce as a "coordinator," and it is up to the individual agencies to apply Bayh-Dole and determine whether contractors are complying.<sup>117</sup>

37 C.F.R. § 401.3 provides the procedure for using the exceptions outlined in § 202(a) to restrict a contractor's patent rights at the time of contract.<sup>118</sup> When using these exceptions, the agency shall only make "such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception."<sup>119</sup> Contracts related to DoE's naval nuclear propulsion program are exempted from this limitation.<sup>120</sup> To utilize a § 202(a) exception, the agency must "prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist."<sup>121</sup> In the case of the "exceptional circumstances" exception under § 202(a)(ii), this should include an analysis addressing "with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200."<sup>122</sup> These materials shall be promptly provided to the contractor with a

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112. See John Gladstone Mills III, Donald Cress Reiley III & Robert Clare Highley, 5 PAT. L. FUNDAMENTALS § 18:7.30 (2d ed. 2014). The right to take title can only be completely eradicated for DoE naval nuclear propulsion or weapons programs. *Id.*

113. *See id.*

114. 37 C.F.R. § 401 (2013).

115. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/RCED-98-126, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 1, at 1–2 (1998).

116. *Id.* at 6.

117. *Id.*

118. 37 C.F.R. § 401.3.

119. *Id.*

120. *Id.*

121. *Id.* § 401.3(e).

122. *Id.*

notification of its rights to appeal the determination of whether an exception applies.<sup>123</sup>

The DoC regulations outline the same timing requirements for disclosure of an invention to the funding agency as outlined in the FAR, with one additional procedural detail:<sup>124</sup> if a contractor fails to comply with the disclosure requirements, “the contractor will convey to the Federal agency, upon written request, title to any subject invention.”<sup>125</sup>

All agencies follow the DoC regulations regarding march-in rights, which outline the very particular course of action the government must take when evaluating a march-in.<sup>126</sup> First, if an agency receives information indicating march-in rights may be necessary, it must first “notify the contractor in writing of the information and request informal written or oral comments from the contractor.”<sup>127</sup> The contractor then has thirty days to respond. If a timely response is received, the agency can choose to initiate march-in proceedings or notify the contractor that it will not do so.<sup>128</sup> This must be done within 60 days of receiving comments.<sup>129</sup> If the agency decides to march in, written notice must be sent to the contractor detailing the reason for marching in with sufficient specificity “to put the contractor on notice of the facts upon which the action would be based” and the fields of use in which licensing will be requested.<sup>130</sup> This initiates march-in proceedings, and must be done by the head of the agency or her designee.<sup>131</sup> The contractor then has thirty days to respond.<sup>132</sup> If the response raises a material issue of fact, the agency must initiate fact-finding.<sup>133</sup>

Fact-finding should be “as informal as practicable,” but the contractor should be given the chance to appear with counsel and submit evidence, and there should be a transcribed record absence waiver thereof.<sup>134</sup> After

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123. *Id.*

124. See 37 C.F.R. §§ 401.14(c)–(d); 48 C.F.R. § 52.227-11.

125. 37 C.F.R. § 401.14(d) (emphasis added).

126. See 45 C.F.R. § 650.13 (2013).

127. See 37 C.F.R. § 401.6.

128. 37 C.F.R. § 401.6(b).

129. *Id.*

130. 37 C.F.R. § 401.6(c).

131. *Id.*

132. *Id.* § 401.6(d).

133. *Id.*

134. *Id.* § 401.6(e).

fact-finding, the official must submit a report to the head of the agency summarizing their finding of facts.<sup>135</sup> The agency representative and the contractor then have thirty days to respond with written arguments, and the agency head may request oral arguments.<sup>136</sup> The head of the agency must then consider the fact-finding, the arguments, and the policies of the Bayh-Dole Act in § 200, and make a determination within ninety days of fact-finding or oral arguments.<sup>137</sup> If the agency head decides not to march-in, proceedings can be terminated at any point.<sup>138</sup> These march-in procedures are the most complex ones in Bayh-Dole, making it more difficult for a contracting agency to march-in than to assert other rights.

### 3. *The Department of Energy and NASA*

The DoE and NASA do not strictly adhere to the Bayh-Dole Act as established in the DoC regulations.<sup>139</sup> These agencies treat large and small entities differently.<sup>140</sup> The DoE has its own patent regulations: DEAR.<sup>141</sup> In DEAR, small entities are treated much as they are in the DoC regulations and FAR.<sup>142</sup> The DoE, however, can obtain broader rights in some circumstances.<sup>143</sup> Specifically, the DoE can take rights to “background inventions” that are not subject inventions under Bayh-Dole.<sup>144</sup> Background patents are those already owned by the contractor that necessarily infringed “upon the practice . . . of any specific process . . . which is a subject of the research, development, or demonstration work performed under the contract.”<sup>145</sup> For large entities, the DoE generally takes title to the invention, although this allocation can be waived.<sup>146</sup> Further, if a contract implicates national security, as for DoE nuclear programs, the rights must always vest to the funding agency.<sup>147</sup>

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135. *Id.* § 401.6(f).

136. *Id.*

137. *Id.* § 401.6(g).

138. *Id.* § 401.6(h).

139. MC EWEN, *supra* note 30, at 52.

140. *Id.* at 52.

141. *Id.* at 68.

142. 48 C.F.R. § 952.227-11 (2013); MC EWEN, *supra* note 30, at 68.

143. MC EWEN, *supra* note 30 at 69. See *infra* Part V.B.

144. 48 C.F.R. § 952.227-13(k); MC EWEN, *supra* note 30, at 70.

145. 48 C.F.R. § 952.227-13(k)(i)(ii); MC EWEN, *supra* note 30, at 70.

146. 48 C.F.R. § 927.302(a) (2013); MC EWEN, *supra* note 30, at 70.

147. MC EWEN, *supra* note 30, at 71.

NASA uses a regime similar to the DoE's. Generally, small businesses may take title to subject inventions and large businesses may not.<sup>148</sup> NASA also requires heightened reporting procedures, and has latitude to obtain rights to background inventions.<sup>149</sup> For large entities, waivers may be used to take title to inventions in limited circumstances.<sup>150</sup>

## V. THE ACT IN PRACTICE: WHAT RIGHTS THE GOVERNMENT HAS ASSERTED

The above-described statutes and regulations give government agencies a great deal of flexibility in how much control to exert over a contractor's patent rights. The true amount of concern a contractor should have is therefore dependent on how much control these agencies actually care to take. A few "Government personnel assume that it is in the Government's interests to take every last right that can be obtained . . . and to do less would fail to protect the Government's interest."<sup>151</sup> On the other hand, it is "the Government's written policy to obtain only the minimum rights necessary for any acquisition."<sup>152</sup>

### A. THE RIGHT TO TAKE TITLE

Bayh-Dole allows a contractor to "elect to retain title to any subject invention."<sup>153</sup> Patent rights do not automatically transfer to a contractor. The contractor must go through the appropriate steps. Further, Bayh-Dole does not circumvent the traditional rule that patent rights vest in the inventor, not his employer. In *Stanford v. Roche*, the Supreme Court held that Bayh-Dole does not "automatically vest[] title to federally-funded inventions in federal contractors," but rather initial ownership belongs to the inventor.<sup>154</sup> Contractors must explicitly contract for a different arrangement.<sup>155</sup>

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148. *Id.* at 71.

149. *Id.* at 71.

150. *Id.* at 70–73.

151. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 41.

152. *Id.*

153. 35 U.S.C. § 202(a) (emphasis added).

154. Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2198 (2011).

155. *Id.*

### B. EXCEPTIONAL CIRCUMSTANCES

Section 202(a) provides four circumstances in which a contracting agency may eliminate or restrict a contractor's right to take title. Of the four, the "exceptional circumstances" exception under § 202(a)ii is the most commonly used. Although the exception should only be used in rare and drastic circumstances and requires a lengthy approval process, including obtaining a determination of exceptional circumstances,<sup>156</sup> it has been used many times.

For instance, the National Institutes of Health ("NIH") has used the exceptional circumstances exception to enter into contracts with limited restrictions on contractors' rights to retain title, despite NIH policy making this difficult.<sup>157</sup> Because of the level of oversight needed to obtain a determination of exceptional circumstances, NIH provisions should only restrict a contractor's rights in a narrowly-tailored fashion.<sup>158</sup>

In a few cases, the NIH has issued determinations of exceptional circumstances to allow the sharing of research resources and data.<sup>159</sup> In one case, the patent rights to cDNA libraries, clones, and sequences arising from the Full-length cDNA Initiative were essentially eliminated.<sup>160</sup> The rights were exclusively licensed to the National Cancer Society, preventing researchers from patenting their findings.<sup>161</sup> The NIH director issued a determination of exceptional circumstances, reasoning that "the NIH Full-Length cDNA Initiative will most effectively contribute to a resource for the research community if they are made publicly available without restriction and in a timely manner. The sharing of materials and data in a timely manner has been an essential element in the rapid progress that has been made in biomedical research."<sup>162</sup>

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156. 37 C.F.R. § 401.3(b).

157. See Jeffrey W. Thomas, *Exceptional Circumstances to the Bayh-Dole Act: An NIH Perspective*, Address at the Federal Laboratory Consortium National Meeting (May 8, 2008), [http://globals.federallabs.org/pdf/2008/Contractors\\_Thomas.pdf](http://globals.federallabs.org/pdf/2008/Contractors_Thomas.pdf).

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. Harold Varmus, *Determination of Exceptional Circumstances (DEC) under 35 USC 202(a)(ii) and 37 CFR 401.3(a)(2) and (e) for the NIH Full-Length cDNA Initiative Contract and its Subcontracts, Statement of Policy*, HUMAN GENOME PROJECT (Nov. 16, 1999), excerpt available at <http://www.genome.gov/10001801>.

The NIH also used the exceptional circumstances exception to allow free sharing of research at the NCI-Frederick, a federally funded research center where contractors work alongside government employees.<sup>163</sup> Additional initiatives where a § 202(a) exception was granted using a declaration of exceptional circumstances include the Mammalian Gene Collection Initiative<sup>164</sup> and Initiative for Chemical Genetics.<sup>165</sup>

The NIH has also informally used the exception without obtaining a declaration of exceptional circumstances.<sup>166</sup> It has added an “Intellectual Property Option to the Collaborator” clause to a variety of funding agreements.<sup>167</sup> This clause gives a “collaborator” a paid-up, nonexclusive license to a contractor’s patents.<sup>168</sup> Although this provision was originally drafted to narrowly allow pharmaceutical companies to use patented drugs in clinical trials, its broad language has led to its broad application, and the NIH has begun to use this clause for a wide range of agreements.<sup>169</sup> Although the NIH sometimes obtains a determination of exceptional circumstances through the collaborator clause, in many instances it has not.<sup>170</sup>

Another agency, the DoE, has the most latitude in using the exceptional circumstances exception, and it uses the exception frequently.<sup>171</sup> For example, in 2009 the DoE determined there were exceptional circumstances for technologies related to energy efficiency.<sup>172</sup> The determination applies to renewable energy technologies such as wind

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163. Varmus, *supra* note 162. For government employees, Bayh-Dole does not apply and rights vest in the government. MC EWEN, *supra* note 30.

164. Merrill & Mazza, *supra* note 14, at 54.

165. Robert Mullan Cook-Deegan & Stephen J. McCormack, *Patents, Secrecy, and DNA*, 293 SCI. 217 (July 13, 2001).

166. Robert Hardy, *DECs, Near-DECs, and Other Bayh-Dole Deviations*, Address at the Federal Laboratory Consortium Mid-Atlantic Regional Meeting (Oct. 23, 2007), [http://www.flcmidatlantic.org/archive/2007\\_annual\\_meeting/2007\\_annual\\_meeting\\_agenda.html](http://www.flcmidatlantic.org/archive/2007_annual_meeting/2007_annual_meeting_agenda.html).

167. *Id.*

168. *Id.*; NAT'L INST. OF HEALTH, INTELLECTUAL PROPERTY OPTION TO THE COLLABORATOR (2008), [http://bayhdolecentral.com/3\\_DIV\\_SCAN/2564\\_001\\_OCR\\_NEXT\\_4.pdf](http://bayhdolecentral.com/3_DIV_SCAN/2564_001_OCR_NEXT_4.pdf).

169. NAT'L INST. OF HEALTH, INTELLECTUAL PROPERTY OPTION TO THE COLLABORATOR, *supra* note 168. The provision has been used in CRADAs, MTAs, and in the middle of multi-year awards.

170. Varmus, *supra* note 162.

171. DEPT OF ENERGY, DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT FOR ENERGY EFFICIENCY, RENEWABLE ENERGY, AND ADVANCED ENERGY TECHNOLOGIES 1–2 (2013), <http://energy.gov/sites/prod/files/2014/01/f6/DEC%20for%20Energy%20Efficiency%20Renewable%20Energy%20%26%20Advanced%20Energy.pdf>.

172. *Id.*

2015]

*The State Giveth and the State Taketh Away*

513

and solar power and advanced energy technologies, such as “projects for advanced components and materials.”<sup>173</sup> It also applies to “energy efficiency, storage, integration, and related technologies, including . . . for buildings [and] transportation.”<sup>174</sup> For such technologies, the DoE can use a “U.S. Manufacturing Plan” clause.<sup>175</sup> These plans can vary in detail and are assessed on a case-by-case basis, but can go as far as to grant title to the DoE.<sup>176</sup>

Like NIH, the DoE has implemented a policy that restricts contractors’ rights without following the determination of the exceptional circumstances procedure.<sup>177</sup> For example, the Principles to Guide Bioenergy Research Center (“BRC”) Intellectual Property Negotiations requires that “60% of [royalties and equity] after expenses from the licensing of IP in the field of the core technologies shall remain under the control of the BRC.”<sup>178</sup>

### C. LICENSING AND THE DEFINITION OF “SUBJECT INVENTION”

Government licensing rights are broader than they appear at first blush—the government automatically obtains a license to any invention first “conceived” or “reduced to practice” during the contract term.<sup>179</sup> Thus, with the appropriate timing, the government can freely license “subject inventions” first conceived long before the start of a contract, or first reduced to practice long after a contract ends.

Bayh-Dole gives the government a nonexclusive, paid-up license to any “subject invention”: an invention “conceived” or “reduced to practice” “in performance of” a contract.<sup>180</sup> The terms “conception” and “reduction to practice” are commonly used in patent law to determine who invented something first.<sup>181</sup> Conception is a definite and permanent idea of a complete invention—the inventor must be ready to make it, but need not be

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173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.* at 8.

177. Hardy, *supra* note 166.

178. DEPT OF ENERGY, PRINCIPLES TO GUIDE BIOENERGY RESEARCH CENTER (BRC) INTELLECTUAL PROPERTY NEGOTIATIONS DRAFT OF 8/01/07 (2007), [http://bayhdolecentral.com/3\\_DIV\\_SCAN/2564\\_001\\_OCR\\_NEXT\\_3.pdf](http://bayhdolecentral.com/3_DIV_SCAN/2564_001_OCR_NEXT_3.pdf).

179. 35 U.S.C. § 202(c).

180. 48 C.F.R. § 52.227–11 (2013).

181. JOHN GLADSTONE MILLS, DONALD REILEY III & ROBERT HIGHLEY, PATENT LAW BASICS (2008).

certain it will work.<sup>182</sup> Reduction to practice occurs when an inventor makes a working model of an invention and appreciates its success (“actual reduction to practice”).<sup>183</sup> The working model must encompass all elements claimed. An invention may also be “constructively” reduced to practice with the filing of a patent application that includes sufficient detail in order to enable one skilled in the art of the field to make the invention.<sup>184</sup> However, defining “in performance of” in Bayh-Dole has not been cut and dry, resulting in litigation.

Prior to Bayh-Dole, *Technical Development Corp. v. United States* established the frequently-cited proposition that courts should liberally interpret the phrase invented “in performance of” in favor of the government.<sup>185</sup> In the case, the inventor sued the government for infringing his patents, which he argued were invented prior to a contract.<sup>186</sup> The government contended that the invention was reduced to practice under the contract, entitling them to a license.<sup>187</sup> The Court of Claims found for the government, “constru[ing] the general phrase ‘in performance of’ liberally.”<sup>188</sup> Using this standard, it was sufficient that “a significant feature of the invention . . . resulted directly from the course of the contract performance.”<sup>189</sup> Thus, it is not necessary for the government to physically receive the product as a result of the contract, but rather it is enough for the invention’s crystallization to have been funded by the contract.<sup>190</sup> Additionally, it is not even necessary that the invention be the subject of the contract—government licensing rights apply to any invention “emerging from the process of ongoing study, inquiry, and creation.”<sup>191</sup>

In *Pilley v. United States*, the government was granted a license to practice an invention conceived, and arguably reduced to practice, years prior to a government contract.<sup>192</sup> Pilley owned nine patents in the field of air traffic control, and brought suit against the government for infringement

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182. *Id.*

183. *Id.*

184. *Id.*

185. *Technical Dev. Corp. v. United States*, 597 F.2d 733, 745 (Ct. Cl. 1979).

186. *Id.* at 742–43.

187. *Id.* at 736.

188. *Id.* at 738 (*quoting Mine Safety Appliances Co. v. United States*, 364 F.2d 385, 392 (1966)).

189. *Id.* at 745.

190. *Id.* at 746–47.

191. *Id.* (*quoting Technitrol, Inc. v. United States*, 440 F.2d 1362, 1373 (1971)).

192. *Pilley v. United States*, 74 Fed. Cl. 489, 491 (Fed. Cl. 2006).

of these patents.<sup>193</sup> Pilley entered a government contract to research and develop collision prediction and avoidance systems using enhanced GPS, with the end goal of providing and demonstrating such a system. The contract incorporated 48 C.F.R. § 52.227-11.<sup>194</sup> In particular, the regulation states that the government receives a nonexclusive, paid-up license to any invention conceived or reduced to practice “in performance of” the contract.<sup>195</sup> It was uncontested that the invention was conceived prior to the contract.<sup>196</sup> Pilley argued that the invention was constructively reduced to practice when he filed a patent application in 1990 before entering into the contract, precluding the government from claiming licensing rights. The court rejected this argument and held that filing a patent application is “immaterial to determination of the time of first actual reduction to practice of an invention under the patent rights clause.”<sup>197</sup> In the context of the patent rights clause, “[r]eduction to practice occurs when it is established that the invention will perform its intended function beyond a probability of failure.”<sup>198</sup> The court also followed *Technical Development* in liberally interpreting “under the contract.”<sup>199</sup> Although Pilley put forth evidence showing he had made all the individual parts of the invention work independently prior to entering the contract, this was not enough to meet the heightened standard; the court held that the invention was not reduced to practice until all the parts were made to work together.<sup>200</sup>

However, constructive reduction to practice can be used to establish an invention date during a contract term. In *Hazeltine Corp. v. United States*, Hazeltine entered into a contract to create an air traffic control radar system.<sup>201</sup> During contract negotiations, he asserted the system had already been reduced to practice.<sup>202</sup> The contract incorporated a now-defunct Department of Transportation regulation that stipulated “[w]henever any invention . . . is constructively reduced to practice . . . during the period of

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193. *Id.*

194. *Id.* at 493.

195. 48 C.F.R. § 52.227–11. (2013).

196. Pilley, 74 Fed. Cl. at 493–94.

197. *Id.* at 497.

198. *Id.* at 497–98 (quoting *Hazeltine v. United States*, 820 F.2d 1190, 1196 (Fed. Cir. 1987)).

This makes the standard for reduction to practice higher in the context of government contracts than in general, where the invention needs to work, but not necessarily beyond the probability of failure.

199. *Id.* at 494–95.

200. *Id.* at 501.

201. *Hazeltine*, 820 F.2d at 1192.

202. *Id.* at 1192–93.

performance of the contract, there shall be a *prima facie* presumption that such invention . . . was conceived or first actually reduced to practice . . . under the terms of this contract.”<sup>203</sup> Hazeltine filed a patent application for his antenna system in June 1973, shortly after entering the contract.<sup>204</sup> In light of the regulations, the court presumed *prima facie* that reduction to practice had occurred under the contract, shifting the burden of proof directly to Hazeltine.<sup>205</sup> Hazeltine failed to produce sufficient evidence that the invention would have “perform[ed] its intended function beyond a probability of failure” prior to the inception of the contract.<sup>206</sup>

In sum, by extending licensing rights to the time of conception or reduction to practice, the government has obtained rights to inventions that the inventor believed were invented completely outside of the contract.

#### D. DEFINING THE SCOPE OF “PRACTICED ON BEHALF OF”

Section 202(c)(4), in addition to granting a nonexclusive license to the funding agency, permits the agency to “have practiced for or on behalf of the United States any subject invention throughout the world.”<sup>207</sup>

Funding agencies rarely have inventions practiced on their behalf under § 202(c)(4). A 2003 Government Accountability Office study reported that the Department of Veteran’s Affairs and DoD officials were not aware of their agencies ever having invoked the right to have a third party manufacture products, and the right had never been used for biomedical products.<sup>208</sup> Agencies have, however, used the right for the development of “mission-critical hardware,” such as weapons.<sup>209</sup>

There is one case of a university using § 202(c)(4) as a defense in an infringement suit. In *Madey v. Duke University*, physicist Dr. Madey developed and patented systems for microwave electron guns while working at Stanford University.<sup>210</sup> Madey then left Stanford to work at Duke University, later leaving Duke and suing them for infringing the

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203. *Id.* at 1192 (emphasis added).

204. *Id.* at 1196.

205. *Id.*

206. *Id.*

207. 35 U.S.C. § 202(c)(4) (2012).

208. AGENCIES’ RIGHTS, *supra* note 63, at 5, 12.

209. *Id.* at 6.

210. *Madey v. Duke Univ.*, 336 F. Supp. 2d 583, 585 (M.D.N.C. 2004).

2015]

*The State Giveth and the State Taketh Away*

517

patents.<sup>211</sup> As a defense, Duke claimed they had a “license to practice the patents for government research purposes pursuant to the Bayh-Dole Act.”<sup>212</sup>

On remand, the court denied Duke’s motion for summary judgment for lack of evidence, noting that the defense could work if Duke could show that the alleged infringement was performed “on behalf of the government,” but not if Duke “used the patents for other means.”<sup>213</sup> In an earlier proceeding, the Court conceded that uses “that have been authorized by the Government do not constitute patent infringement to the extent that such uses are protected by an irrevocable government license.”<sup>214</sup> Although the defense did not pan out for Duke, dicta suggests that the defense could work when the use is actually at the government’s behest or for the government’s benefit, without necessarily requiring an explicit agreement or license.

#### E. FORFEITURE AND DISCLOSURE REQUIREMENTS

In addition to broad allowances for governmental usage of subject inventions, there are also restrictions regarding a contractor’s rights to patent the invention. If a contractor does not disclose a subject invention within a “reasonable” time, the government can take title to the invention.<sup>215</sup> This is also known as “forfeiture” of an invention, and failure to comply can occur through untimeliness or failure to report using the proper procedure.<sup>216</sup> The reporting requirements are “incredibly complex” and few companies or government agencies fully understand them.<sup>217</sup> Additionally, reporting times are quite short and many contractors do not find this short timeframe adequate to properly determine whether to elect title.<sup>218</sup> More often than not, the contracting party does not comply, creating a myriad of situations in which the government could conceivably take title.<sup>219</sup> However, rights are not automatically forfeited—the

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211. *Id.* at 585, 592.

212. *Id.* at 592–93.

213. *Id.* at 594–95.

214. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420, 429 n.3 (M.D.N.C. 2001).

215. 35 U.S.C. § 202(c) (2012).

216. E.g., April Butler, *Stealing Thunder from Government Contractors: Thwarting the Intent of the Bayh-Dole Act in Campbell Plastics v. Brownlee*, 31 U. DAYTON L. REV. 477, 482 (2006).

217. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT, *supra* note 7, at 5.

218. *Id.* at 72.

219. *Id.*

government may elect not to enforce its right.<sup>220</sup> In fact, the government often does not enforce this right, because the government is frequently unaware of which inventions it has rights to.<sup>221</sup> However, in the rare occurrence this provision is used, it is simultaneously extremely effective for the agency and devastating for the contracting party.

For example, in *Campbell Plastics v. Brownlee*, the Army took title to a patent after Campbell Plastics failed to comply with disclosure procedures.<sup>222</sup> Campbell, a small business, entered into a contract with the Army to develop parts for an aircrew protective mask.<sup>223</sup> Under FAR, a contractor “must disclose any subject invention developed pursuant to a government contract” within two months or the government “may obtain title.”<sup>224</sup> Although Campbell developed the mask required under the contract, making progress reports to the Army and disclosing it to patent counsel, he filed a form declaring “no invention.”<sup>225</sup>

Although Campbell disclosed the features of the invention with detailed progress reports, failure to follow the minutiae of the disclosure requirements was enough to forfeit title.<sup>226</sup> The disclosure provisions of a procurement contract are to be strictly followed, and the fact that “forfeiture is a disfavored remedy” cannot “thwart the government’s right to enforce the terms of [a] contract.”<sup>227</sup>

As forfeiture is rarely used, this case is a bit of an outlier. Some commentators believe this holding “undermined the Bayh-Dole Act’s stated goal of encouraging commercialization by allowing contractors to retain title to their own inventions.”<sup>228</sup> The court in *Campbell*, however,

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220. See *Cent. Admixture Pharmacy Svcs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347 (Fed. Cir. 2007).

221. TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES (1998), *supra* note 115, at 2.

222. *Campbell Plastics Eng’g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1249 (Fed. Cir. 2004).

223. *Id.* at 1244.

224. *Id.*; 48 C.F.R. § 52.227 (2013).

225. *Campbell*, 389 F.3d at 1248–49.

226. *Id.* at 1249.

227. *Id.*

228. Michael Kenneth Greene, *Patent Law in Government Contracts: Does it Best Serve the Department of Defense’s Mission?*, 36 PUB. CONT. L.J. 331, 340 (2007), referring to Ralph C. Nash & John Cibinic, *Postscript: Forfeiture of Title to Patent*, 19 NO. 1 NASH & CIBINIC REP. ¶ 2 (2005). See also April L. Butler, Case Note, *Stealing Thunder from Government Contractors: Thwarting the Intent of the Bayh-Dole Act in Campbell Plastics v. Brownlee*, 31 U. DAYTON L. REV. 477 (2006).

stressed that strict adherence to the disclosure requirement is in the spirit of Congress's intent.<sup>229</sup>

A bankruptcy court recently agreed that "lack of disclosure undermines the policy and objectives of the Bayh-Dole Act."<sup>230</sup> In *Evergreen Solar v. United States*, the United States made a motion to take title to patents involved in a bankruptcy proceeding on behalf of the DoE.<sup>231</sup> Evergreen was a well-publicized flop in terms of government funding; after coming up with "string ribbon technology" for efficient solar panels under a DoE contract, Evergreen filed for bankruptcy.<sup>232</sup> Evergreen went bankrupt because it was unable to compete with foreign competitors.<sup>233</sup> Because the invention was government-funded, Evergreen had to manufacture substantially in the United States, which priced them out of the market. Bankrupt Evergreen needed to liquidate its assets, and the most likely buyers were these foreign competitors.<sup>234</sup>

The DoE balked at the proposition of government-funded IP being sold to a foreign competitor. Because Evergreen had failed to disclose subject inventions within the required time limits,<sup>235</sup> "the Bayh-Dole Act gave the DoE the right to own Evergreen's Subject Inventions."<sup>236</sup> In its motion, the United States asserted that bankruptcy law does not preempt a demand for title to the inventions from the DoE,<sup>237</sup> arguing that they were better off controlling the patents so they could "prevent foreign entities

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229. Campbell, 389 F.3d at 1248.

230. United States' Motion for Determination that the Automatic Stay Does Not Bar the United States Department of Energy from Protecting its Rights Under the Bayh-Dole Act, Evergreen Solar, Inc. v. United States, No. 11-12590 at 15 (D. Del. 2011).

231. Although the DoE is generally allowed to take title to all inventions conceived under its funding agreements, there is an exception for domestic small businesses and non-profits. See 37 C.F.R. § 401.3 (2013).

232. Eric Lane, *Auction Block: DOE Asserts Ownership and Tries to Stop Sale of Evergreen Ribbon Patents*, GREEN PATENT BLOG (Oct. 27, 2011), <http://www.greenpatentblog.com/2011/10/27/auction-block-doe-asserts-ownership-and-tries-to-stop-sale-of-evergreen-ribbon-patents/>.

233. Martin LaMonica, *Harsh Lessons from Evergreen Solar Flame-Out*, CNET, (Aug. 17, 2011, 11:06 AM), [http://news.cnet.com/8301-11128\\_3-20093503-54/harsh-lessons-from-evergreen-solar-flame-out/](http://news.cnet.com/8301-11128_3-20093503-54/harsh-lessons-from-evergreen-solar-flame-out/). "Chinese manufacturers that make solar panels with traditional polycrystalline silicon cells now hold 50 percent market share." *Id.*

234. Daniel Scotto, *U.S.-Funded Alternative Energy Patents Fall into Foreign Hands*, IP CLOSE UP (Nov 21, 2011), <http://ipcloseup.wordpress.com/2011/11/21/u-s-funded-alternative-energy-patents-fall-into-foreign-hands/>.

235. Evergreen, No. 11-12590 at 2.

236. *Id.* at 10.

237. *Id.* at 18.

from gaining control over federally-funded technology and competing with American industry unfairly.”<sup>238</sup> In the end, Evergreen liquidated all its intellectual property aside from the patents that the DOE went after: an apparent success for the government.<sup>239</sup>

Rights are only forfeited if the government chooses to enforce the disclosure provision.<sup>240</sup> In *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions*, the court held that Bayh-Dole does not automatically take away patent rights upon failure to disclose; it is at the government’s discretion.

When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish its title and invoke forfeiture.<sup>241</sup>

#### F. MARCH-IN RIGHTS

A government agency can “march-in” and mandate that a patent holder must license his or her invention to a third party under § 203 in four situations, including (1) if the patent holder has failed to adequately commercialize the invention, or (2) if the contractor has failed to alleviate health and safety needs.<sup>242</sup> However, there is no evidence that any federal agency has actually used march-in rights.<sup>243</sup> As such, march-in rights are a bit of a “red herring.”<sup>244</sup> Nevertheless, companies considering entering into a federal funding agreement are extremely concerned about march-in rights. Due to this widespread fear of march-in rights, they are effective leverage for obtaining concessions from contractors.<sup>245</sup>

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238. Lane, *supra* note 232.

239. Michael Bathon, *Evergreen Solar Wins Approval to Sell Most of Its Assets*, BLOOMBERG NEWS (Nov. 10, 2011), available at <http://www.bloomberg.com/news/2011-11-10/evergreen-solar-wins-court-approval-to-sell-most-of-its-assets.html>.

240. Cent. Admixture Pharmacy Svcs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1352 (Fed. Cir. 2007).

241. *Id.* at 1352–53.

242. 35 U.S.C. § 203(a) (2012).

243. *The Government’s Patent Policy*, *supra* note 4.

244. Sean O’Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH L.J. 1017, 1045 (2006).

245. *Id.* at 1032, 1045–46.

2015]

*The State Giveth and the State Taketh Away*

521

It is up to the government to determine whether adequate commercialization has occurred, which many companies find problematic.<sup>246</sup> Federal agencies do not generally keep tabs on how well an invention is being utilized. Instead, agency officials rely on outside reports such as news stories and complaints from competitors or concerned citizens.<sup>247</sup> As of 2009, the DoD, DoE, and NASA have never discovered or received sufficient information compelling them to initiate march-in proceedings.<sup>248</sup> The NIH has been petitioned to exercise march-in rights several times, with no direct success; the NIH declined in each instance.<sup>249</sup>

### *1. March-In Petitions*

Each of the six times the NIH was petitioned to exercise march-in rights, the agency went through a five to eight month fact-finding process and concluded that the situation did not fall under the limited march-in categories enumerated in Bayh-Dole.<sup>250</sup> First, the NIH was petitioned in 1997 by a party asserting that the patent holder to a stem-cell device was not taking “reasonable measures” to market the device, adversely affecting health and safety.<sup>251</sup> NIH fact-finding proved otherwise: the owner was marketing and developing the device.<sup>252</sup>

The NIH was petitioned twice to march-in on the HIV/AIDS drug Norvir: once in 2004 and again in 2012.<sup>253</sup> In the United States, Abbot charges four to ten times as much for Norvir than it does in comparable countries.<sup>254</sup> The petitioners expressed concern about unfair pricing, arguing that the prohibitively high cost of the drug made it unaffordable to many, endangering health and safety.<sup>255</sup> The NIH rejected the petitions

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246. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 77–78.

247. FEDERAL RESEARCH, *supra* note 5, at 9, 10.

248. *Id.* at 9. The Government Accountability Office focused on the DoD, DoE, NASA, and NIH, because these four agencies accounted for 89 percent of federal research funding in 2006, providing a good representation of the overall picture. *Id.* at 18.

249. James Love, *Birch Bayh’s Competing Interests and Evolving Views*, KNOWLEDGE ECOLOGY INT’L (Aug. 27, 2012, 7:07 PM), <http://keionline.org/node/1537>.

250. FEDERAL RESEARCH, *supra* note 5, at 10.

251. *Id.*

252. *Id.* Interestingly, founder Birch Bayh was one of the petitioners. Love, *supra* note 249.

253. FEDERAL RESEARCH, *supra* note 5, at 11; John T. Aquino, *NIH Exercising “March-In” Rights—Is the Fifth Time the Charm?*, BLOOMBERG BNA HEALTH CARE BLOG (Nov. 6, 2012), <http://www.bna.com/nih-exercising-marchin-b17179870773/>.

254. FEDERAL RESEARCH, *supra* note 5, at 11; Aquino, *supra* note 253.

255. FEDERAL RESEARCH, *supra* note 5, at 11.

because the drugs were widely prescribed, indicating that the drug was effectively serving health and safety needs.<sup>256</sup> The NIH received and rejected a similar 2004 petition regarding the pricing of a glaucoma drug.<sup>257</sup>

While the first three march-in petitions led the NIH to conclude that there was no legitimate problem that needed to be addressed by marching in, in the fourth petition the agency's fact-finding confirmed that there was a legitimate health concern. In the case of Fabrazyme, one company, Genzyme, controlled the only drug available in the United States to treat Fabry disease.<sup>258</sup> When the company suffered production setbacks and became unable to meet the demand for the drug, many people went without it and their symptoms resumed, which can include increased risk of premature death.<sup>259</sup> This led a group of patients to file a march-in petition, requesting an open license that would allow anyone to manufacture the drug in light of "health or safety needs which [were] not reasonably satisfied" by the company.<sup>260</sup>

While NIH agreed that there was a legitimate health and safety concern, it concluded that march-in was not warranted.<sup>261</sup> When a new company manufactures a drug, it must go through the entire FDA approval process, which can take years.<sup>262</sup> Because Genzyme proffered evidence it would have production up and running within a year, and other drugs for Fabry disease were still in the process of entering the American market, NIH concluded that granting an open license was not the best solution to the drug shortage.<sup>263</sup>

Recently, Senator Patrick Leahy of Vermont petitioned the NIH to march in on Myriad Genetics.<sup>264</sup> Because unfair pricing makes Myriad's

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256. *Id.*

257. *Id.*

258. OFFICE OF THE DIRECTOR, NAT'L INST. OF HEALTH, DETERMINATION IN THE CASE OF FABRAZyme MANUFACTURED BY GENZYME CORPORATION 1 (2010). The patented treatment method had been invented under an NIH grant to Mount Sinai School of Medicine. *Id.*

259. *Id.* at 4.

260. *Id.* at 1; Petition to use Authority under the Bayh-Dole Act to Promote Access to Fabrazyme, an Invention Supported by and Licensed by the National Institutes of Health under Grant no. DK-34045, 1–3, 6, available at [http://keionline.org/sites/default/files/fabrazyme\\_petition\\_2aug2010.doc](http://keionline.org/sites/default/files/fabrazyme_petition_2aug2010.doc) (2010).

261. NAT'L INST. OF HEALTH, *supra* note 258, at 1.

262. *Id.* at 5–6.

263. *Id.* at 9.

264. David Schwartz, *Senator Leahy Asks for March-in Rights to Force Myriad To License Cancer Tests*, TECH TRANSFER CENTRAL (July 24, 2013), available at

2015]

*The State Giveth and the State Taketh Away*

523

genetic testing methods used for breast and ovarian cancers hard to obtain, the petition seeks a license allowing others to use the tests.<sup>265</sup> Although the NIH has not yet considered the petition, experts doubt that they will march in. Duke University law professor Arti K. Rai commented that the patents at issue may not cover subject inventions at all.<sup>266</sup> After several failed march-in petitions, many have postulated that the government never will exercise march-in rights.<sup>267</sup>

While there is no evidence of any agency other than the NIH being petitioned to march in, the DoE has used the march-in framework to assess a dispute.<sup>268</sup> Although the dispute did not fall under the Bayh-Dole Act, one company argued that a competitor did not effectively utilize its gene sequencing technologies.<sup>269</sup> DoE suggested that the dispute be settled according to march-in procedures. Ultimately, DoE elected not to intervene after determining that the patent holder's licensing system was fair and the complaining company had not provided sufficient evidence.<sup>270</sup>

## 2. March-In as Leverage

If nothing else, march-in rights have proven to be useful leverage for the government to obtain concessions from contractors.<sup>271</sup> While licensing to the government is not a major concern for a patent's profitability, licensing to a competitor has potentially devastating effects on a company's bottom line. As a result, government agencies value march-in rights as a successful tool when negotiating with a contractor.<sup>272</sup> Natural Resources

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<http://techtransfercentral.com/2013/07/24/senator-leahy-asks-for-march-in-rights-to-force-myriad-to-license-cancer-tests/>. Senator Leahy is very influential, having spearheaded the America Invents Act, the recent major overhaul of U.S. patent law. Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. (2013).

265. Schwartz, *supra* note 264.

266. Schwartz, *supra* note 264. Further, a recent Supreme Court holding involving Myriad established that it could not patent naturally-occurring genes, returning some of the subject matter at issue to the public domain. Bill Donahue, *Leahy Wants NIH to Make Myriad License Out Patents*, LAW 360 (July 15, 2013, 4:53 PM), <http://www.law360.com/articles/457266/leahy-wants-nih-to-make-myriad-license-out-patents>.

267. Mary Eberle, Comment, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 175 (1999); Kevin W. McCabe, Note, *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, 651–52 (1998).

268. FEDERAL RESEARCH, *supra* note 5 at 11.

269. *Id.*

270. *Id.*

271. *The Government's Patent Policy*, *supra* note 4.

272. FEDERAL RESEARCH, *supra* note 5, at 9.

and Environment Director Anu K. Mittal explained, “[M]arch-in authority is particularly valuable as leverage in informal discussions between contractors and sponsoring agencies and in license negotiations between contractors and potential licensees to encourage the commercialization of technologies.”<sup>273</sup> The threat of marching-in can work implicitly as well: “[T]he parties to licensing negotiations are usually sufficiently aware of the potential for march-in that it may not be necessary to explicitly discuss this possibility during meetings.”<sup>274</sup>

March-in discussions have led to concessions from contractors. In the case of Norvir, Abbot Labs reduced prices in settling a march-in matter.<sup>275</sup> In the wake of the march-in petition, discussed above, Abbot rolled back the price increase for certain U.S. government-funded programs.<sup>276</sup> NIH also may have used its authority to march-in as leverage to obtain an open license to patents on stem-cell lines.<sup>277</sup> WiCell Research Institute successfully developed stem cell lines for several years, and then incongruously granted rights to the NIH.<sup>278</sup> The parties signed a Memorandum of Understanding giving NIH scientists access to WiCell’s cell lines and allowing NIH scientists to patent any inventions arising from the resulting research.<sup>279</sup>

## VI. REALITY VS. CONVENTIONAL WISDOM

In reality, Bayh-Dole’s shift of patent rights to a contractor is limited. Although Bayh-Dole is commonly construed to merely allow the government to reserve limited rights as a “safety valve,” sometimes agencies use it as a way to “take every last right.”<sup>280</sup>

The exceptional circumstances provision under § 202(a)(ii) has been applied quite broadly. The government has used it to grant a third party

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273. *Id.* at 11–12.

274. *Id.* at 12.

275. *15 Frequently Asked Questions About the 2012-2013 Ritonavir March-In Petition*, KNOWLEDGE ECOLOGY INTERNATIONAL, <http://keionline.org/node/1815> (last visited Oct. 10, 2014).

276. *Id.* Abbot did not lower the price for private purchases, however. *Id.*

277. *Bayh-Dole Timeline*, KNOWLEDGE ECOLOGY INTERNATIONAL, <http://keionline.org/timeline-bayh-dole> (last visited Oct. 10, 2014).

278. O’Connor, *supra* note 244, at 1040–46; *National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement*, NIH News Release, (Sept. 5, 2001), available at <http://www.nih.gov/news/pr/sep2001/od-05.htm>.

279. NIH News Release, *supra* note 278.

280. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 47.

2015]

*The State Giveth and the State Taketh Away*

525

license and even take full title to an invention.<sup>281</sup> Although it is often stressed that the complex procedures required make it an exceptional and rare course of action,<sup>282</sup> this is not the case. The procedures for this exception are undoubtedly complex, but are still considerably less complex than those required to march in.<sup>283</sup> As a result, agencies find it relatively easy to limit or even contract out of the right to retain title by obtaining a determination of exceptional circumstances.

Some agencies have even begun dispensing with determinations of exceptional circumstances altogether. The NIH's Intellectual Property Option to the Collaborator clause and DoE's Bioenergy Research Center Intellectual Property Principles are commonly used without going through the lengthy procedure mandated by Bayh-Dole.<sup>284</sup> Taking what was intended to be extreme measure, useable only in truly exceptional circumstances without any clearance, flies in the face of the carefully crafted provisions that make such a set-up difficult. As the Intellectual Property Option to the Collaborator clause has become increasingly prevalent in university research agreements, universities are objecting.<sup>285</sup> Several universities have attempted to get the NIH to remove the clause.<sup>286</sup> However, the NIH has not budged, reflecting the current balance of unequal bargaining power.<sup>287</sup>

Going further still, NIH is attempting to change the regulations to explicitly circumvent Bayh-Dole's requirement of obtaining clearance for the exceptional circumstances provision.<sup>288</sup> If finalized, this amendment could result in much wider application of the experimental use exception in the future, and should be interesting to monitor.

Bayh-Dole's paid-up government license further dilutes a contractor's patent rights, particularly in light of the courts' broad interpretation of which inventions are within its purview. Although a contractor cannot use constructive reduction to practice in order to establish a prior invention date,<sup>289</sup> filing a patent application during the phase of a contract can create

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281. Thomas, *supra* note **Error! Bookmark not defined.**.

282. *E.g. id.*; COMM. ON MGMT., *supra* note 14, at 54.

283. Compare 37 C.F.R. § 401.3 with 37 C.F.R. § 401.6.

284. Varmus, *supra* note 162.

285. *Id.*

286. *Id.*

287. *See Id.*

288. Derzko, *supra* note **Error! Bookmark not defined.**, at 2.

289. Pilley v. United States, 74 Fed. Cl. 489, 500 (Fed. Cl. 2006).

a *prima facie* presumption that the invention was reduced to practice under the contract.<sup>290</sup> This double standard means the government can obtain licensing rights a contractor would not expect. The implications can scare off potential grantees, as “companies look at this as . . . the Government getting rights in their background inventions,” which could be a potential economic disaster for a company that invested millions in developing something.<sup>291</sup>

When the government has a license under Bayh-Dole, it can allow a third party to practice the invention on its behalf. Although this does not happen commonly, when it does, it cuts into a company’s bottom line. Patent licensing fees are a major source of revenue, totaling \$37 billion in the United States in 2013.<sup>292</sup> Taking away a patent holder’s control of licensing rights dilutes the patent’s value. A third party license also decreases the value of the patent by taking away the contractor’s exclusive right to produce the invention.

Further, Bayh-Dole’s disclosure requirements give funding agencies the ability to rescind the title to a patent. Agencies could potentially and have done so in many funding agreements. The disclosure procedures in FAR are unworkably obscure and complicated, and as a result few contractors actually comply.<sup>293</sup> This gives the government the right to take full title without any further justification.<sup>294</sup> The government can easily obtain full ownership of a patent if a contractor does not carefully follow disclosure requirements.<sup>295</sup> Although march-in rights never have been explicitly used and agencies have expressed unwillingness to march-in in a

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290. *Hazeltine Corp. v. United States*, 820 F.2d 1190, 1192 (Fed. Cir. 1987).

291. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH & DEVELOPMENT, *supra* note 7, at 71. “[T]he former chief intellectual property counsel for 3M Co. testified before Congress in 1981 that this right was too broad under the Bayh-Dole Act and discouraged participation in Government R&D by commercial companies.” *Id.* at 72.

292. IBISWorld, Intellectual Property Licensing Market Research Report, NAICS 5311, Jun. 2013.

293. TOWARD GREATER PUBLIC-PRIVATE COLLABORATION IN RESEARCH AND DEVELOPMENT, *supra* note 7, at 70.

294. *Id.* at 56.

295. See generally *Campbell Plastics Eng’g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004) (U.S. Army took title to a patent after Campbell Plastics failed to comply with disclosure procedures). United States’ Motion for Determination that the Automatic Stay does not Bar the United States Department of Energy from Protecting its Rights Under the Bayh-Dole Act, *Evergreen Solar, Inc. v. United States*, No. 11-12590 (D. Del. 2011) (Bankruptcy proceedings did not prevent DOE from taking title to patents when Evergreen had failed to disclose subject inventions within the required time limits).

2015]

*The State Giveth and the State Taketh Away*

527

variety of situations, they are quite useful as leverage in obtaining concessions in negotiation.<sup>296</sup>

## VII. CONCLUSION

Ultimately, the Bayh-Dole Act is complex and gives funding agencies a great deal of latitude. However, although the state has the power to take away contractors' patent rights under Bayh-Dole, it has done so only an extremely small percentage of the time. Generally, contractors can benefit greatly from entering into a government funding contract, but they should do so with caution and be keenly aware of potential pitfalls.

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296. FEDERAL RESEARCH, *supra* note 5, at 9–11.

528

*Southern California Interdisciplinary Law Journal* [Vol. 24:491]