IV. Effectiveness of the Bayh-Dole Act

This chapter will analyze two particular areas of the Bayh-Dole statute and use case studies and empirical evidence to determine their effects on the university technology transfer system. The areas of focus include the march-in provision and the general shift of title towards the universities.

A. Is the March-In Right Provision (§ 203) Effective?

The march-in provision invites criticism from both sides of the spectrum; while some consider the march-in right contrary to the very premise of the transfer of ownership away from the government,[108] many criticize the provision as too infrequently used and unable to assist the government in ensuring an invention gets commercialized.[109]

Congress codified the march-in provision because it considered the government's "free and irrevocable license" insufficient to protect the "public's need for competition in the marketplace."[110] Industry disapproved of the provision, citing that "it is not a good concept that government should go into competition with private enterprise."[111] Though there have been several march-in petitions to various

108 For views criticizing march-in rights as contravening the premise of Bayh-Dole, see 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 TULANE L. REV. 631, 661 (2001), *citing* Patent Policy: Joint Hearing Before the S. Comm. on Commerce, Sci., & Transp. & the S. Comm. on the Judiciary, 96th Cong. 458-60 (1980), (testimony of Robert B. Benson, Dir., Patent Dep't, Allis-Chalmers Corp.); *see* Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-in Petition,* 14 BERKLEY TECH L.J. 1095, 1109-1113 (1999) (denouncing the march-in provision as procedurally burdensome and as an unwieldy safeguard).

109 For a view criticizing the government's nonuse of the march-in provision, s*ee* Conley, *supra* note 66 (arguing government's failure to grant march-in rights in CellPro case was dubious); *see* Rai and Eisenberg, *supra* note 73 (stating that the requirement that march-in requires exhaustion of all court appeals by the contractor should be changed).

110 Arno and Davis, *supra* note , at 660.

111 *Id.* at 661.

agencies over the years, the chief agencies dealing with university-owned patents have never exercised any rights under the provision.[112]

1. Cases in Point: CellPro, Fabrazyme, and the Government Refusal to March-in

Over the past two decades, four petitions to the National Institute of Health (hereinafter NIH) involving a march-in request have been heard: *CellPro, Norvir, Pfizer, and Fabyrzyme.* The NIH has denied each petition.[113] A brief review of *CellPro*, the most known and heavily criticized refusal, and *Fabyrzyme*, the most recent decision, bring to light some major concerns regarding the (non)use of the march-in right.

a) The 1997 CellPro Decision

Johns Hopkins University (hereinafter JHU) developed a biotechnological invention with federal funding from the NIH.[114] Ultimately, the patent on the invention ("Civin") was licensed by JHU to Baxter, a biotechnology company which performed work related to stem cell selection.[115]

CellPro, a potential competitor in the market, had negotiations with Baxter but was not awarded a license, and was ultimately sued and found liable for patent infringement.[116] CellPro proceeded to petition the NIH to march-in and grant it a license based upon 35 USC § 203 (1) and (2).[117] At the time, CellPro had the only licensed and marketable end-product based off this patent available in the U.S.[118]

NIH rejected CellPro's decision on both grounds. With respect to the first ground, the NIH noted that Baxter had taken the requisite steps to achieve practical

112 *See* David Halperin, *The Bayh-Dole Act and March-in Rights*, May 2001, prepared at the request of Consumer Project on Technology, *available at* http://www.ott.nih.gov/policy/meeting/David-Halperin-Attorney-Counselor.pdf. Recent publications have affirmed the fact that march-in has still not been granted, despite numerous petitions. *See* Posting of J. Steven Rutt to Nano & Cleantech Blog, http://www.nanocleantechblog.com/2010/04/articles/legislation/federal-government-clarifies-marchin-rights-under-bayhdole-system/ (April 23, 2010). For examples of the petition and march-in granting procedure, see Chapter II, *supra.*

113 *See* Conley, *supra* note 66.

114 *See* Determination in the Case of Petition of CellPro, Inc. (Nat'l Inst. Of Health, 1997) at 3, *hereinafter* "NIH-CellPro", *available at* http://www.nih.gov/news/pr/aug97/nihb-01.htm.

115 *See* NIH-CellPro, *supra* note 114, at 3.

116 *See id*.

117 The two grounds were that Baxter had not taken or was not expected to take effective steps to achieve practical application, and that there exists a health or safety need which needs to be alleviated. *See* 35 U.S.C. § 203(a)(1-2) (2009); *See* NIH-CellPro, *supra* note 114, at 3.

118 *See* NIH-CellPro, *supra* note 114, at 4.

application of the subject invention.[119] Specifically, Baxter had developed a prototype, filed for pre-market Approval with the FDA, and was licensing and developing the technology.[120]

The NIH had considerably more trouble rejecting the second ground. In denying the petition, the NIH stated that it is "premature, and inappropriate, for NIH to substitute its judgment for that of clinicians and patients seeking to avail themselves of an FDA-approved medical device."[121] The NIH further noted that Baxter and Hopkins "refrained from enforcing their patent to the full extent of the law," and they weren't effectively stopping CellPro's product from being available.[122] The agency posited that even if CellPro's product becomes less available, there would be no concern as Hopkins and Baxter have "pledged to reasonably satisfy any health need created by the loss of the CellPro product."[123] The NIH hinges on the policy ground that marching in would cause "broader public health implications" which include "the potential loss of new health care products yet to be developed from federally funded research."[124]

Criticism of the CellPro determination is fairly widespread and attacks the march-in provision from all directions. Duke University argued that government should "shoulder more responsibility" for technology that arises from federally funded research.[125] In analyzing the NIH's reluctance to grant the petition, Kevin McCabe forms the argument that the government will never march in.[126] Rai and Eisenberg contend that march-in is not strong enough, and that the NIH should be able to exercise the right more readily.[127] Conversely, McGarey and Levy argue that CellPro highlights the potential danger if march-in *is* ever used, as it may "undermine the process of federal technology transfer by disrupting the existing synergy between the academic community and the private sector.[128]

119 The NIH defines practical application based upon 37 C.F.R. § 404.3(d), specifically "to manufacture... under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." 35 C.F.R. § 404.3(d) (2006).
120 *See* NIH-CellPro, *supra* note 114, at 4.
121 *Id.*
122 *Id.* at 5. Baxter and Hopkins allowed the injunction to be modified so that "CellPro may continue to make, have made, use and sell... within the United States, until such time as an alternative stem cell concentration device... is approved [by the FDA]." *Id*.
123 *Id.* at 6.
124 *Id.* This argument will be further examined as a weakness of the march-in provision later in this chapter.
125 Duke News Release, *supra* note 69.
126 *See* McCabe, *supra* note 37, at 661.
127 *See* Rai and Eisenberg, *supra* note 73, at 311.
128 McGarey and Levey, *supra* note , at 1116.

b) The 2010 Fabrazyme Decision

The NIH recently denied another petition for march-in.[129] This case involved the only effective and FDA approved treatment for Fabry, a rare disease.[130] In denying a march-in petition, the NIH noted that marching-in would not solve the supply shortage of the drug. It concludes that any competitor would need to seek regulatory approval, which would take longer than it would take for Genzyme (the patentee) to solve the shortage.[131] Furthermore, the NIH notes that no company with a substitute drug has asked Genzyme for a license.[132]

Critics of this decision have determined that NIH has created a "self-fulfilling prophecy" in that no one would even attempt to invest in developing a substitute for the drug until the patent runs out or until a license is guaranteed.[133] Secondly, this refusal to march-in in yet another case sends a signal that the government will never march-in, which would effectively distort the market as contractors will not fear government intervention.[134] Section 3 of this chapter will address many of the concerns addressed by critics of these two decisions.

2. Perceived Advantages of the March-in Provision

The government contends that march-in is more powerful than its nonexclusive license, and will help to ensure commercialization.[135]

As a threshold matter, empirical analysis showing benefits of the march-in provision is nearly impossible to produce, for the simple reason that a march-in petition have never been granted. However, a 2009 GAO report has undertaken to poll numerous officials of agencies, and serves to show some positive opinions regarding the force of the provision.[136]

GAO concluded that while none of the four agencies (DOD DOE NASA and NIH) polled have ever exercised march-in authority, the agencies generally agreed

129 *See* Conley, *supra* note 66.
130 *See id.*
131 *See* Determination in the Case of Fabrazyme (Nat'l Inst. Of Health, 2010) at 1, *hereinafter* "NIH-Fabrazyme", *available at* http://www.ott.nih.gov/policy/March-in-Fabrazyme.pdf.
132 This implied to the NIH that no one had an alternative drug (that would infringe the patent absent a license) available, and thus marching-in would do no good. *See* NIH-Fabrazyme, *supra* note 131 at 9.
133 *See* Conley, *supra* note 66. Thus, by not marching-in, the NIH is limiting the options that will ultimately be available to market.
134 *See id.*
135 *See* McCabe, *supra* note 37, at 653. (noting that a policy of the Act is to ensure the Government obtains sufficient rights to ensure commercialization, in addition to the right to maintain its own license).
136 *See* GAO Report, *supra* note 68, at 10.