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.

that the march-in right amounts to leverage, and should not be abandoned.[137] Specifically, the idea of march-in authority becomes powerful in "informal discussions between contractors and sponsoring agencies and in license negotiations between contractors and potential licensees to encourage commercialization of technologies developed with federal funding."[138] This carries a positive effect on negotiations and implicitly supports Bayh-Dole's policy goal of promoting the commercialization and public availability of inventions.[139] Thus, these agency representatives maintain that the provision has a substantial deterrent effect.

Commentators also argue that there is a valid case for exercising march-in rights, and the provision, as a whole, can be effective.[140] David Halperin states that there are certain technologies, especially in life-saving drugs, where the requirement that the contractor make inventions available "on reasonable terms" should include a reasonable price, and failure to do so would be grounds for an effective march-in.[141]

Though many who advocate for march-in cite the provision's strength as a "scare tactic," Rai and Eisenberg advocate specific benefits of the provision as it relates to biotechnology. The scholars note that allowing march-in as something more than a last resort will effectively reduce delays and ensure that drug and other time-sensitive inventions can get to the public as soon as possible.[142] Advocates of the march-in provision in this regard often point to the "second" condition under § 203, which states that the action is necessary "to alleviate health or safety needs."[143]

Commentators conclude that companies "will not abandon cost-effective technology transfer if an agency exercises march-in rights." These arguments reconcile with Bayh-Dole's goal to ensure that the government can protect the public against nonuse or unreasonable use of inventions.[144]

137 *See id.* at 10-11.
138 *Id.* at 10-11.
139 *See* 35 U.S.C. § 200 (2009).
140 *See generally* Halperin, *supra* note 112; *see generally* Rai and Eisenberg, *supra* note 73.
141 *See* Halperin, *supra* note 112, at 12-13. § 201(f) of the BDA defined "practical application" as found in the march-in provision at § 203(a)(1). Specifically, the invention must be made available to the public on "reasonable terms." 35 U.S.C. § 201(f) (2009). For a contrary view regarding the scope of the phrase "reasonable term", *see* McCabe, *supra* note 37, at 664.
142 *See* Rai and Eisenberg, *supra* note 73, at 311. Rai and Eisenberg further submit proposals which enhance the use of march-in and the ease at which an agency can assert its rights without fear of violating the BDA. These proposals will be discussed later in this section.
143 *See* 35 U.S.C. § 203(a)(2) (2009). An example of support is shown in Mary Eberle's analysis of the CellPro petition decision. *See* Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research,* 3 Marq. Intell. Prop. L. Rev. 155, 179 (1999) (stating that it appears a public health need indeed would not have been met but for the CellPro product).
144 Eberle, *supra* note 143, at 178.

3. Perceived Weaknesses and Asserted Ineffectiveness of the March-In Provision

Critics of the provision either assert that the idea of march-in has "chilling effects" on technology transfer, or note that its persistent nonuse over the past quarter-century has rendered it ineffective and unnecessary.[145]

a) March-In has Negative Effects on Technology Transfer

The GAO outlines four issues with the existence of the march-in right. First, there could be a "chilling effect" where an action may deter investors from investing in the commercialization, and some researchers from participating in the participating in federal research efforts.[146] Agency officials note that investors "are looking for profitable technologies and inventions that either have, or are close to obtaining a patent."[147] The march-in possibility could lead to uncertainty with respect to ownership of the invention, as well as a decrease in the perceived value of the investment.[148]

The second issue inherent in the march-in scheme is that the process as-is tends to be lengthy and will become unworkable in time-critical situations.[149] Even those supporting the use of march-in provisions note that the system should be amended to ensure that march-in can become effective in situations regarding life-saving drugs and other emergent issues.[150]

The GAO further finds that commercial products based on federal inventions often have multiple patents, some of which are not federally funded.[151] This presents a conflict because march-in will often involve, in effect, an end-product, and not an initial patent. By marching in, the government may not only be asserting the rights inherent in Bayh-Dole, but it may negatively affect another inventor whose invention was not part of the Bayh-Dole funding scheme.[152]

145 "Four key disincentives inhibit federal agencies use of Bayh-Dole march-in authority." GAO Report, *supra* note 68, at 12.
146 *See* GAO Report, *supra* note 68, at 12.
147 *Id.* at 13.
148 *See id.*
149 *See id.* at 12.
150 *See* Rai and Eisenberg, *supra* note 73, at 311. "Indeed, the tolerance for protracted delays inherent in the current process is at odds with the time-sensitive nature of the interests reflected." *Id*.
151 *See* GAO Report, *supra* note 68 , at 12.
152 It is notable that federal agencies may only have the authority to march in on one aspect of the product. However, this will complicate the procedure, rendering the march-in provision inefficient at best. Also, even if this is worked effectively, it may still negatively affect the value of all other patented inventions associated with the marched-in end-product. *See id.* at 14.