

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.

The GAO finally advises that the commercialization of an invention may be jeopardized if a licensee with specialized knowledge loses the knowledge subsequent to a march-in.¹⁵³ If an agency forces a contractor to license to someone subsequent to a march-in, the contractor would have to "consider whether the other patented technologies would be available to the new licensee and whether the new licensee would have the knowledge, resources, and commitment needed to commercialize the product."¹⁵⁴

b) Nonuse of the Provision has Rendered it Unnecessary

A contingent of scholars have taken the stance that because the march-in provision has never been used, it is an unnecessary provision of the BDA.¹⁵⁵ Kevin McCabe analyzes the NIH's decision in CellPro and determines that economic theory suggests that "the Government will never initiate a march-in proceeding against a biotechnology company."¹⁵⁶ He explains that rational actors seek to maximize their investment return, and the government will rarely need to force a company to "take effective steps to achieve practical application."¹⁵⁷ McCabe also notes that investors, who are generally risk averse, would be "less willing to invest in biotechnology if the threat of government march-in ever became a reality."¹⁵⁸

March-in has further been criticized as ineffective in serving the legislators' original goal to limit "the dark side of granting proprietary rights in publicly-funded technology," specifically the potential for contractors to take advantage of the Act without allowing the public to reap the fruits of an invention.¹⁵⁹ By explicitly rejecting four march-in petitions, it has been argued that the NIH is rejecting Congress's concerns that led it to coin the march-in provision.¹⁶⁰

153 *See id.* at 12.

154 Thus, even if the license happened, it may hamper commercialization of an invention. *Id.* at 14.

155 *See McCabe, supra* note 37, at 661.

156 *Id.* Though McCabe's article specifically analyzes biotechnology, it can be inferred to relate to all aspects of technology transfer. To date, the only *petitions* ever filed for march-in were to the NIH, on biotechnological products. Thus, it seems that if the Government would ever use its march-in right, that biotechnology would be the likely industry of the invention. *See id.*

157 *Id.* In other words, no company would refuse to commercialize a product when it is in their best interest.

158 *Id.* This partially conflicts with the rationale of some agency representatives and scholars advocating for march-in under the theory that involved parties fear march-in, which drives the contractor to license to an investor. *See GAO Report, supra* note 68, at 11; *See McGarey, supra* note 108, at 1116.

159 Conley, *supra* note 66.

160 *See id.*

4. Evaluating the March-in Provision

a) Analysis

It is fairly certain that a correctly drafted and enforced provision regarding march-in would have a positive effect on the public without severely negatively affecting technology transfer.¹⁶¹ Increasing access to technological products will increase the public good. However, the current march-in provision as drafted and enforced is entirely ineffective. The fact that the provision has never been used is *per se* evidence of its failure in the marketplace.

The arguments that march-in rights amount to a "scare tactic" and incentivize universities and other contractors to license their technology are unconvincing. Instead, I agree with the contention that the market forces are the true incentives behind technology transfer.¹⁶²

Currently, the march-in right can only be used as a true "last resort." The government contractor must exhaust all court appeals before march-in can be granted.¹⁶³ This requirement will effectively continue to limit the number of march-in petitions that an entity will serve the government, and also will be crippling to the government if it ever wants to exercise its right.

b) Recommendations for Change

For the march-in right to become effective, it needs to be easy for the government to utilize, and it needs to embrace instead of conflict with the "economic theory" arguments that McCabe presented.¹⁶⁴

The march-in procedure is covered in 37 C.F.R. § 401.6.¹⁶⁵ The agency can initiate a proceeding "whenever it receives information that it believes might warrant the exercise of march-in rights."¹⁶⁶ This shows that the agency has full power to initiate march-in, even without a petition from another party. Hence, the law governing exercise of march-in is not constricting in itself; the interpretations and fears of the government need to be relaxed to ensure an effective procedure.

161 See Eberle, *supra* note 144, at 179.

162 See generally McCabe, *supra* note 37, at 661.

163 See Rai and Eisenberg, *supra* note 73, at 311.

164 See McCabe, *supra* note 37, at 661-662; See Chapter IV-A-3-b, *infra*.

165 See 37 C.F.R. § 401.6 (2006).

166 John H. Raubitschek and Norman J. Latker, *Reasonable Pricing – A New Twist for March-In Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH L.J. 149, 156 (2005).