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**Comments of the Information Technology and Innovation Foundation**

**Before the:**

**National Institute of Standards and Technology**

**Regarding:**

**“Rights to Federally Funded Inventions and  
Licensing of Government Owned Inventions”**

**Docket No.: 201207-0327**

**March 23, 2021**

The Information Technology and Innovation Foundation (ITIF) is a non-profit, non-partisan science, technology, and economic policy think tank based in Washington, D.C. Its mission is to advocate for innovation-enabling policies in nations throughout the world. As this submission further elaborates, ITIF supports the National Institute of Standards and Technology's (NIST's) efforts to clarify the intent of Bayh-Dole march-in right provisions as part of its reexamination of "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions."

The Patent and Trademark Law Amendments Act of 1980, more commonly known as the Bayh-Dole Act, represents an essential, well-functioning component of America's national innovation system. *The Economist* magazine has called the Bayh-Dole Act:

Possibly the most inspired piece of legislation to be enacted in America over the past half-century. Together with amendments in 1984 and augmentation in 1986, this [Act] unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.<sup>1</sup>

Countries throughout the world—including Brazil, China, Indonesia, Japan, Korea, Malaysia, the Philippines, Singapore, South Africa, and Taiwan, among many others—have been inspired by the legislation and since followed the United States' lead in establishing similar policies.<sup>2</sup>

The Bayh-Dole Act, which affords universities rights to the intellectual property (IP) generated from federal funding, has played a pivotal role in catalyzing American competitiveness by achieving three key accomplishments.<sup>3</sup>

First, before Bayh-Dole, the vast majority of federally funded research simply sat on shelves. As late as 1978, the federal government had licensed less than 5 percent of the as many as 30,000 patents it owned.<sup>4</sup> Moreover, as former Comptroller General Elmer Staats found, "not a single drug had been developed when patents were taken from universities [by the federal government]."<sup>5</sup>

Second, in creating a pathway for technology commercialization of federally funded research and development (R&D), it transformed American universities into engines of innovation. As Harvard University's Naomi Hausman has written, "The sort of large scale technology transfer from universities that exists today would have been very difficult and likely impossible to achieve without the strengthened property rights, standardized across granting agencies, that were set into law in 1980."<sup>6</sup>

Allowing U.S. institutions to earn royalties through the licensing of their research provided a powerful incentive for universities and other institutions to pursue commercialization opportunities.<sup>7</sup> The Bayh-Dole Act almost immediately led to an increase in academic patenting activity. For instance, while only 55 U.S. universities had been granted a patent in 1976, 240 universities had been issued at least one patent by 2006.<sup>8</sup> Similarly, while only 390 patents were awarded to universities in 1980, by 2009, that number had increased to 3,088—and by 2015, to 6,680. Another analysis found that in the first two decades of Bayh-Dole (i.e., 1980 to 2002) American universities experienced a tenfold increase in their patents, and created more than 2,200 companies to exploit their technology.<sup>9</sup> In total, over 80,000 U.S. patents have been issued to academic research institutions over the past 25 years.<sup>10</sup> Moreover, academic technology transfer has supported the launch of over 12,000 start-ups since 1995.<sup>11</sup> According to a report prepared for the Association of University Technology Managers (AUTM) and the Biotechnology Industry Organization (BIO), from 1996 to 2015, academic patents and their subsequent licensing to industry—substantially stimulated by the Bayh-Dole Act—bolstered U.S. GDP by up to \$591 billion, contributed to \$1.3 trillion in gross U.S. industrial output, and supported 4,272,000 person years of employment.<sup>12</sup>

Third, Bayh-Dole has been particularly impactful in stimulating American biomedical innovation. Most don't know it, but the United States used to be a global also-ran in life-sciences innovation: European-headquartered companies innovated twice as many new-to-the-world drugs as American ones did in the latter half of the 1970s (149 to 66) and as late as 1988 less than 5 percent of the world's drugs were introduced first in the United States (now that share stands at over 60 percent).<sup>13</sup> The Bayh-Dole Act played a pivotal role in helping change that, facilitating a pathway through which the intellectual property derived from government-funded, university-conducted basic life-sciences research could be licensed, predominantly to small companies, for commercialization and development. This process has now contributed to the development of, at least, well over 200 (and probably closer to more than 300) novel drugs.<sup>14</sup>

The architects of Bayh-Dole included provisions for march-in rights. However, these were principally designed to ensure patent owners commercialized their inventions. As Senator Birch Bayh himself explained, “When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions.”<sup>15</sup>

As the Congressional Research Service notes, the Bayh-Dole Act proscribes four specific instances in which the government is permitted to exercise march-in rights:

- 1) If the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;

- 2) If action is necessary to alleviate health or safety needs not reasonably satisfied by the patent holder or its licensees;
- 3) If action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- 4) If action is necessary, in exigent cases, because the patented product cannot be manufactured substantially in the United States.<sup>16</sup>

In other words, lower prices are not one of the rationales laid out in the act. In fact, as senators Bayh and Dole themselves noted, the Bayh-Dole Act's march-in rights were never intended to control or ensure "reasonable prices."<sup>17</sup> As the twain wrote in a 2002 *Washington Post* op-ed titled, "Our Law Helps Patients Get New Drugs Sooner:"

Bayh-Dole did not intend that government set prices on resulting products...The law makes no reference to a reasonable price that should be dictated by government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.<sup>18</sup>

The op-ed reiterated that the price of a product or service was not a legitimate basis for the government to use march-in rights, noting:

The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.<sup>19</sup>

Likewise, as John Rabitschek and Norman Latker write in their *Santa Clara University High Technology Law Journal* article, "Reasonable Pricing—A New Twist for March-in Rights Under the Bayh-Dole Act," "A review of the [Bayh-Dole] statute makes it clear that the price charged by a licensee for a patented product has no direct relevance to march-in rights."<sup>20</sup>

As the authors concluded:

There is no reasonable pricing requirement under 35 U.S.C. §203(l)(a)(1), considering the language of this section, the legislative history, and the prior history and practice of march-in rights. Rather, this provision is to assure that the contractor utilizes or commercializes the funded invention.<sup>21</sup>

The argument that Bayh-Dole march-in rights could be used to control drug prices was originally advanced in an article by Peter S. Arno and Michael H. Davis.<sup>22</sup> They contended that “[t]he requirement for ‘practical application’ seems clear to authorize the federal government to review the prices of drugs developed with public funding under Bayh-Dole terms and to mandate march-in when prices exceed a reasonable level” and suggested that under Bayh-Dole, the contractor may have the burden of showing that it charged a reasonable price.<sup>23</sup> While Arno and Davis admitted there was no clear legislative history on the meaning of the phrase “available to the public on reasonable terms,” they still concluded that, “[t]here was never any doubt that this meant the control of profits, prices, and competitive conditions.”<sup>24</sup>

But as Rabitschek and Latker explain, there are several problems with this analysis. First, the notion that “reasonable terms” of licensing means “reasonable prices” arose in unrelated testimony during the Bayh-Dole hearings. Most importantly, they note, “If Congress meant to add a reasonable pricing requirement, it would have explicitly set one forth in the law, or at least described it in the accompanying reports.”<sup>25</sup> As Rabitschek and Latker continue, “There was no discussion of the shift from the ‘practical application’ language in the Presidential Memoranda and benefits being reasonably available to the public, to benefits being available on reasonable terms under 35 U.S.C. § 203.”<sup>26</sup> As they conclude, “The interpretation taken by Arno and Davis is inconsistent with the intent of Bayh-Dole, especially since the Act was intended to promote the utilization of federally funded inventions and to minimize the costs of administering the technology transfer policies.... [The Bayh-Dole Act] neither provides for, nor mentions, ‘unreasonable prices.’”<sup>27</sup>

And that’s why pricing-based march-in right petitions have been rightly and repeatedly rejected over the years. The National Institutes of Health (NIH) has denied all six price-based petitions to apply march-in rights, noting that the drugs in question were in virtually all cases adequately supplied and that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights.<sup>28</sup> NIH itself has expressed skepticism about the use of march-in rights to control drug prices, noting:

Finally, the issue of the cost or pricing of drugs that include inventive technologies made using federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices.<sup>29</sup>

This is also why efforts in the early 1990s to apply “reasonable pricing” clauses on cooperative research and development agreements (CRADAs) failed, “driving industry away from potentially

beneficial scientific collaborations” as then-NIH Director Varmus noted, and were thus withdrawn in 1995. Recognizing that the only impact of the reasonable pricing requirement was undermining scientific cooperation without generating any public benefits, NIH eliminated the reasonable pricing requirement in 1995. In removing the requirement, Dr. Varmus explained, “An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people.”<sup>30</sup>

Somewhat similarly, as the California Senate Office of Research has noted, “Granting agencies such as the National Institutes of Health ultimately have abandoned policies that require a financial return to the government after concluding that removing barriers to the rapid commercialization of products represents a greater public benefit than any potential revenue stream to the government.”<sup>31</sup>

Weakening the certainty of access to IP rights provided under Bayh-Dole by employing march-in to address drug pricing issues—especially if it meant a government entity could walk in and retroactively commandeer innovations private-sector enterprises invested hundreds of millions, if not billions, to create—would significantly diminish private businesses’ incentives to commercialize products supported by federally funded research.<sup>32</sup> As David Bloch notes, “The reluctance of such [biopharmaceutical] companies to do business with the government is almost invariably tied up in concerns over the government’s right to appropriate private sector intellectual property.”<sup>33</sup> As he continues, “Each march-in petition potentially puts at risk the staggeringly massive investment that branded pharmaceutical companies make in developing new drug therapies.”<sup>34</sup> Put simply, using march-in rights to control drug prices could seriously compromise medical discovery and innovation.

For these reasons, ITIF supports the National Institute of Standards and Technology’s efforts to clarify the intent of Bayh-Dole march-in right provisions as part of its reexamination of “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions.” NIST proposes a revision to 37 CFR part 401 “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Co-operative Agreements” section 401.6(e) to “include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.”<sup>35</sup> While ITIF generally supports this clarification, it would call for ideally further improving it by clarifying that the pricing of commercial goods and services arising from the practical application of the invention provides no basis for the exercise of march-in rights, whatsoever. As noted, the architects of the legislation never

intended for the price of the resulting innovation to constitute a justification for the exercise of march-in rights. However, at a minimum, ITIF believes that revising the proposed clarification by removing the words “exclusively” and “of the contractor” would improve the regulation by making its intent clearer.

The Bayh-Dole Act has played a pivotal role in restoring American competitiveness; driving the latent potential of federally funded, university-conducted innovation; and making the United States the global leader in life-sciences innovation. ITIF commends NIST for taking steps to codify the (clearly proscribed and intentionally limited) intent and parameters of march-in rights at they pertain to the Bayh-Dole Act.

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## ENDNOTES

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1. “Innovation’s Golden Goose,” *The Economist*, December 12, 2002, <http://www.economist.com/node/1476653>.
2. Robert D. Atkinson, Stephen J. Ezell, and Luke A. Stewart, “The Global Innovation Policy Index” (Information Technology and Innovation Foundation and the Ewing Marion Kauffman Foundation, March 2012), 65, <http://www2.itif.org/2012-global-innovation-policy-index.pdf>.
3. Stephen Ezell, “The Bayh-Dole Act’s Vital Importance to the U.S. Life-Sciences Innovation System” (Information Technology and Innovation Foundation, March 2019), <https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system>.
4. B. Graham, “Patent Bill Seeks Shift to Bolster Innovation,” *The Washington Post*, April 8, 1978.
5. Joseph P. Allen, “When Government Tried March In Rights to Control Health Care Costs,” *IPWatchdog*, May 2, 2016, <http://www.ipwatchdog.com/2016/05/02/march-in-rights-health-care-costs/id=68816/>.
6. Naomi Hausman, “University Innovation, Local Economic Growth, and Entrepreneurship” U.S. Census Bureau Center for Economic Studies Paper No. CES-WP- 12–10 (July 2012): 8, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2097842](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2097842).
7. Wendy H. Schacht, “Patent Ownership and Federal Research and Development (R&D): A Discussion of the Bayh-Dole Act and the Stevenson-Wydler Act” (Congressional Research Service, 2000), <http://ncseonline.org/nle/crsreports/science/st-66.cfm>.
8. Hausman, “University Innovation, Local Economic Growth, and Entrepreneurship,” 7. (Calculation based on NBER patent data.)
9. John H. Rabitschek and Norman J. Latker, “Reasonable Pricing—A New Twist for March-in Rights Under the Bayh-Dole Act,” *Santa Clara High Technology Law Journal* Vol. 22, Issue 1 (2005), 150, <https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1399&context=chtlj>; *The Economist*, “Innovation’s Golden Goose.”
10. Association of University Technology Managers (AUTM), “Driving the Innovation Economy: Academic Technology Transfer in Numbers,” <https://www.autm.net/AUTMMain/media/SurveyReportsPDF/AUTM-FY2016-Infographic-WEB.pdf>.
11. Dan Garcia, Duke University, Office of Licensing & Ventures, “The Bayh-Dole Act: Fueling Innovation for 38 Years,” news release, December 10, 2018, <https://olv.duke.edu/news/bayh-dole-38-years/>.
12. Lori Pressman et al., “The Economic Contribution of University/Nonprofit Inventions in the United States: 1996–2015” (Report prepared for AUTM and Biotechnology Industry Organization (BIO), June 2017), 3, <https://www.bio.org/sites/default/files/June%202017%20Update%20of%20I-0%20%20Economic%20Impact%20Model.pdf>.
13. European Federation of Pharmaceutical Industries and Associations, “The Research Based Pharmaceutical Industry: A Key Actor for a Healthy Europe,” (EFPIA, 2006); Shanker Singham, “Improving U.S. Competitiveness—Eliminating Anti-Market Distortions” (working paper, International Roundtable on Trade and Competition Policy, 2012); John K. Jenkins, M.D., “CDER New Drug Review: 2015 Update,” (PowerPoint presentation, U.S. Food and Drug Administration/CMS Summit, Washington, DC, December 14, 2015),



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- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM477020.pdf>.
14. AUTM, “Driving the Innovation Economy Academic Technology Transfer in Numbers,” (AUTM, 2019), <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-2019-Infographic.pdf>; Ashley J. Stevens et al., “The Role of Public-Sector Research in the Discovery of Drugs and Vaccines,” *The New England Journal of Medicine* Vol. 364:6 (February 2011): 536, <https://www.nejm.org/doi/full/10.1056/NEJMsa1008268>.
  15. Statement of Senator Birch Bayh to the National Institutes of Health (May 24, 2004), <https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>.
  16. John R. Thomas, “March-In Rights Under the Bayh-Dole Act” (Congressional Research Service, August 2016), 7, <https://fas.org/sgp/crs/misc/R44597.pdf>.
  17. Birch Bayh, “Statement of Birch Bayh to the National Institutes of Health,” May 25, 2014, <http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf>.
  18. Birch Bayh and Bob Dole, “Our Law Helps Patients Get New Drugs Sooner,” *The Washington Post*, April 11, 2002, [https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?utm\\_term=.ddb6876a380](https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?utm_term=.ddb6876a380).
  19. *Ibid.*
  20. Rabitschek and Latker, “Reasonable Pricing—A New Twist for March-in Rights Under the Bayh-Dole Act,” 160.
  21. *Ibid.*, 167.
  22. Peter Amo and 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” *Tulane Law Review* Vol. 75, 631 (2001), [https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1754&context=fac\\_articles](https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1754&context=fac_articles).
  23. *Ibid.*
  24. Rabitschek and Latker, “Reasonable Pricing,” 162–163.
  25. *Ibid.*, 163.
  26. *Ibid.* Here, the Presidential Memoranda refers to memoranda produced by the Kennedy and Nixon administrations that pertained to government policy related to contractor ownership of inventions.
  27. *Ibid.*
  28. Thomas, “March-In Rights Under the Bayh-Dole Act,” 11–12.
  29. Elias A. Zerhouni, director, NIH, “In the Case of Norvir Manufactured by Abbott Laboratories, Inc.,” July 29, 2004, <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf>.
  30. National Institutes of Health, “NIH News Release Rescinding Reasonable Pricing Clause” news release, April 11, 1995, <https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>.
  31. California Senate Office of Research, “Optimizing Benefits From State-Funded Research” *Policy Matters* (March 2018), 11, <https://sor.senate.ca.gov/sites/sor.senate.ca.gov/files/0842%20policy%20matters%20Research%2003.18%20Final.pdf>.

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32. Stephen J. Ezell, "Why Exploiting Bayh-Dole 'March-In' Provisions Would Harm Medical Discovery," *The Innovation Files*, April 29, 2016, <https://www.innovationfiles.org/why-exploiting-bayh-dole-march-in-provisions-would-harm-medical-discovery/>.
  33. David S. Bloch, "Alternatives to March-In Rights" *Vanderbilt Journal of Entertainment and Technology Law* Vol. 18:2:247 (2016): 261, [http://www.jetlaw.org/wp-content/uploads/2016/03/Bloch\\_SPE\\_6-FINAL.pdf](http://www.jetlaw.org/wp-content/uploads/2016/03/Bloch_SPE_6-FINAL.pdf).
  34. *Ibid.*
  35. National Institute of Standards and Technology (NIST), "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions: Notice of Proposed Rulemaking," <https://www.federalregister.gov/documents/2021/01/04/2020-27581/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions>.