



February 6, 2024

Dr. Laurie E. Locascio  
Under Secretary of Commerce  
National Institute of Standards and Technology  
Department of Commerce  
100 Bureau Drive  
Gaithersburg, MD 20899  
Via e-mail: [roi@nist.gov](mailto:roi@nist.gov)

**Re: Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No.: 230831-0207**

Dear Under Secretary Locascio,

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to your request for comments on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights of the Bayh-Dole Act. IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes about 200 companies and close to 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries. IPO advocates for effective and reliable intellectual property rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO's members invest tens of billions of dollars annually in research and development, employing hundreds of thousands of scientists, engineers, and others in the U.S. to develop, manufacture, and market innovative new products and services. Many IPO members partner with government-funded entities such as universities, start-ups, and small companies to transform their basic research into commercial products. Turning basic research into commercial products requires years of additional research, development, and refinement and is often accompanied by missteps and outright failure.

As IPO explained in 2018 comments to the National Institutes of Health (NIH), the Bayh-Dole Act has been highly successful in facilitating timely and effective commercialization of federally-funded research.<sup>1</sup> It has allowed start-ups, small companies, and universities that received federal government support to retain title to patents covering inventions arising from federally-funded research and to license these inventions to private sector partners who can then further develop and commercialize them. Additionally, Bayh-Dole supports job creation and capital investment needed to further develop these inventions and bring them to the public.

<sup>1</sup> Intell. Prop. Owners Ass'n, Comment Letter on Federal Technology Transfer Authorities and Processes (July 30, 2018), [ipo.org/wp-content/uploads/2018/08/IPO-Comments-to-NIST-on-Federal-Technology-Transfer-Authorities-and-Processes.pdf](https://ipo.org/wp-content/uploads/2018/08/IPO-Comments-to-NIST-on-Federal-Technology-Transfer-Authorities-and-Processes.pdf).

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Bayh-Dole provides federal funding agencies limited authority, known as “march-in rights,” to require the owner of a patent developed through federal funding to grant additional licenses under certain circumstances, such as if the contractor or its assignee fails to achieve practical application of the invention or the invention as commercialized fails to reasonably satisfy public health and safety needs. IPO is unaware of any federal funding agency having difficulty interpreting the march-in rights provision.

There is no statutory basis for march-in based on price, and NIST lacks the authority to consider grounds for march-in beyond those listed in the statute. Doing so would undermine one of the core strengths and principles of the Bayh-Dole Act. As a 2012 Congressional Research Service report notes, “one of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property.”<sup>2</sup> Guidance with new, non-statutory considerations would risk recreating the circumstances Bayh-Dole sought to eliminate. Broadening march-in rights beyond what was contemplated by the statute would create uncertainty, impacting the willingness of private industry to invest in commercializing inventions that received government funding support and undermining the goals of such government funding. The proposed framework would have a chilling effect on collaboration and innovation, leaving promising inventions to languish on academic shelves as they did before Bayh-Dole or open to exploitation contrary to U.S. interests. The adverse impact would fall largely upon universities, start-ups, and small companies that receive federal funding and do not independently have commercial development and/or manufacturing capabilities to bring products to market.

In addition to proposing unnecessary changes to march-in rights, the proposed Guidance Framework ignores the commercial realities of industries in which a single product might be covered by many patents, often extending beyond the product itself to manufacturing and other methods. By focusing on simplistic examples, nearly half of which relate to medical technologies, each involving a clearly-defined set of patents tied to a clearly-defined set of products, with each product covered only by one set of patents potentially subject to march-in rights, the Guidance Framework fails to recognize the enormous administrative burden and uncertainty changes to march-in rights would impose on a wide array of industries with a history of very successfully commercializing government-funded research through complex, multi-technology products.

## **1. The Bayh-Dole Act Has Worked Well to Incentivize Innovation**

Congress enacted the Bayh-Dole Act to incentivize the private sector to license inventions resulting from early-stage government-funded research and further develop those inventions into useful, commercial products. By allowing federally funded entities (contractors) to retain ownership rights in patents covering their inventions and enabling them to license early-stage technologies to private sector partners, Bayh-Dole has been hugely successful in facilitating the development of commercially available products including medicines, high-technology, green energy, agricultural, and other products. Notable examples include the Google search algorithm, nicotine patches, and Honeycrisp

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<sup>2</sup> WENDY H. SCHACHT, CONG. RESEARCH SERV., RL32076, THE BAYH-DOLE ACT: ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 9 (2012), <https://sgp.fas.org/crs/misc/RL32076.pdf>.

apples.<sup>3</sup> This success has maximized taxpayer benefit for government-funded research and been instrumental in achieving the primary purpose of providing government support.

Senators Bayh and Dole recognized that the government does not develop new technologies on its own. For that, America relies heavily on the private sector.<sup>4</sup> That's because most academic and government laboratories conduct early-stage research and do not have the capacity or resources to bring products to market.

It has been said that the Bayh-Dole Act is innovation's golden goose.<sup>5</sup> Prior to the enactment of Bayh-Dole, the government claimed ownership in inventions resulting from government-funded research. That undermined the commercialization of those inventions given the absence of property rights that form the legal basis for contracts and other commercial activities.<sup>6</sup> Only 5% of those patents were ever licensed for use in the private sector.<sup>7</sup> Since its passage, the benefits society and the economy have realized from the Bayh-Dole innovation ecosystem are enormous: \$1.9 trillion contributed to U.S. gross industrial output, \$1 trillion contributed to U.S. gross domestic product, 6.5 million jobs supported, 495,000 inventions disclosed, 126,000 patents issued, 17,000 startups formed, and more than 200 drugs and vaccines developed through public-private partnerships.<sup>8</sup>

Other countries have followed the U.S. in passing similar legislation. However, success is largely dependent upon the degree of collaboration between universities and industry in those countries.<sup>9</sup> Japan presents an interesting example of how universities can benefit from similar laws, with nearly an 8-fold increase in collaborative research between 1985 and 1995.<sup>10</sup>

Private-sector involvement in technology transfer has created and expanded businesses, jobs, and economic prosperity. For example, science-based innovations from USDA intramural research, often developed through public-private partnerships (PPPs), create new or improved technologies,

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<sup>3</sup> Almesha L. Campbell, *Biden Voted for the Bayh-Dole Act 44 Years Ago—But the Administration's Plans to Reinterpret It Could Undermine Decades of World-Leading U.S. Innovation*, FORTUNE, Jan. 5, 2024, <http://fortune.com/2024/01/05/biden-bayh-dole-act-administrations-plans-undermine-us-innovation-education-almesha-campbell/>.

<sup>4</sup> See Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST, Apr. 11, 2002, <http://ww.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>.

<sup>5</sup> *Innovation's Golden Goose*, THE ECONOMIST, Dec. 14, 2002, <http://ww.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose>.

<sup>6</sup> See, e.g., S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979) (explaining that the government's policy of owning patents on inventions arising from government-funded research and offering nonexclusive licenses "has proven to be an ineffective policy" and that "the private sector simply needs more protection for the time and effort needed to develop and commercialize new products than is afforded by a nonexclusive license").

<sup>7</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-742, FEDERAL RESEARCH: INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 2 (2009), <https://www.gao.gov/assets/gao-09-742.pdf>.

<sup>8</sup> AUTM, *Driving the Innovation Economy* (2022), [AUTM-Infographic-22-for-uploading.pdf](#).

<sup>9</sup> Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States*, 59 MAINE L.R. 259, 266 (2007).

<sup>10</sup> *Id.* at 270.

processes, products, and services that benefit the U.S. by increasing productivity, increasing efficiency (keeping costs low), and enhancing global competitiveness for the U.S. agriculture sector. Thus, technology-transfer functions are critical to accelerating the utility of public research and development investments, creating economic activity, job creation, and sustainable economic development. USDA's total number of income-bearing licenses in Fiscal Year 2019 was 510, total number of active Cooperative Research and Development Agreements (CRADAs) was 278, total number of CRADAs entered by USDA was 95, and total number of new patent applications filed was 97.<sup>11</sup>

## 2. "Reasonable Pricing" is Not a Basis for March-In Under the Bayh-Dole Act

March-in rights were never intended to serve as a mechanism for regulating the pricing of products. The law makes no reference to a "reasonable price" that should be dictated by the government.<sup>12</sup> The U.S. Supreme Court recently explained, in an analogous situation, that "[a] decision of such magnitude and consequence rests with Congress itself, or an agency acting pursuant to a clear delegation from that representative body."<sup>13</sup> Congress has never amended Bayh-Dole to incorporate reasonable pricing as a basis for march-in rights, so there is no basis to incorporate that consideration into march-in guidelines interpreting the statute. Congress knows how to enact price-control laws, such as the Emergency Price Control Act of 1942, or rate-regulation laws that authorize the setting of "prices" or "rates."<sup>14</sup> This is not what Bayh-Dole does.

March-in rights have always been intended to ensure that government-funded inventions do not sit on the shelf and collect dust.<sup>15</sup> The ability of an agency to set price controls on innovation would recreate the balkanized and often arbitrary implementation of government licensing in place before Bayh-Dole.

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<sup>11</sup> Press Release, U.S. Dep't of Agric., USDA Continues to Deliver Innovative Solutions to its Customers (June 29, 2020), <http://www.usda.gov/media/press-releases/2020/06/29/usda-continues-deliver-innovative-solutions-its-customers>.

<sup>12</sup> Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST, Apr. 11, 2002, <http://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>.

<sup>13</sup> *West Virginia v. EPA*, 142 S. Ct. 2587, 2616 (2022).

<sup>14</sup> See Pub. L. No. 77-421, 56 Stat. 23 (1942); see also Economic Stabilization Act of 1970, Pub. L. No. 91-379, § 202, 84 Stat. 799, 799-800 ("The President is authorized to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970."); Housing and Rent Act of 1947, Pub. L. No. 129, 61 Stat. 193, 198 (imposing rent controls on existing structures set at levels permitted to be charged under the Economic Price Control Act of 1942); *Nebbia v. People of New York*, 291 U.S. 502, 515 (1934) ("The Legislature of New York established by chapter 158 of the Laws of 1933, a Milk Control Board with power, among other things to 'fix minimum and maximum ... retail prices to be charged by ... stores to consumers for consumption off the premises where sold.'"); *Stone v. Farmers' Loan & Trust Co.*, 116 U.S. 307, 308 (1886) (reviewing "the statute of Mississippi passed March 11, 1884, entitled 'An act to provide for the regulation of freight and passenger rates on railroads in this state, and to create a commission to supervise the same, and for other purposes'").

<sup>15</sup> S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979) (Identifying as a cause of "a slowdown in technological innovation" in the U.S. "the inability of the Federal agencies to deliver new inventions and processes from their research and development programs to the marketplace where they can benefit the public.")

In the more than 40 years since Bayh-Dole was enacted, no federal agency has exercised its power to march-in. Eight petitions have been filed, with the federal funding agency denying each one.<sup>16</sup> “A common theme of each of the denials was the agency’s view that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights.”<sup>17</sup> NIH has made clear that “practical application” does not apply to actions by a licensee. This contrasts with the other grounds for march-in, and it was intentional. The practical application ground ensures that a contractor (or assignee) takes steps to commercialize or license a patent in a timely and reasonable manner. Otherwise, the product will never get developed. NIH offered some observations on march-in rights during prior march-in petition proceedings:

- **CellPro:** In its response to the 1997 CellPro petition, the agency stated its reluctance to undermine the exclusivities offered by the patent system:  
“We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.”<sup>18</sup>
- **Norvir/Ritonair:** In the 2004 proceedings regarding Norvir/ritonavir, the agency spoke more specifically about drug pricing:  
“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. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.”<sup>19</sup>

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<sup>16</sup> See Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, CTR. FOR STRATEGIC AND INT’L STUDIES (March 24, 2022), <http://www.csis.org/analysis/march-rights-and-us-global-competitiveness>.

<sup>17</sup> CONG. RESEARCH SERV., MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016), <http://crsreports.congress.gov/product/pdf/R/R44597/3>.

<sup>18</sup> Nat’l Inst. of Health Determination in the Case of Petition of CellPro, Inc. 8 (Aug. 1, 1997), [http://web.archive.org/web/20070102183356/http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia\\_cellpro39.pdf](http://web.archive.org/web/20070102183356/http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf).

<sup>19</sup> Nat’l Inst. of Health Determination in the Case of Norvir® Manufactured by Abbott Laboratories, Inc. 5 (July 29, 2004), <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf>.

- **Xalatan:** In 2004, NIH director Zerhouni denied a petition on Xalatan again because march-in is not a legislative tool for price control.<sup>20</sup>
- **Fabrazyme:** With the drug Fabrazyme®, there was a manufacturing shortage of the drug. The Petition decision did require that monthly reports be given regarding the Fabrazyme® supply shortage, the allotment of the supply to Fabry patients and to notify the NIH within 48 hours after receiving any request from a third party for a license to the patent to market the enzyme, agalsidase, during the shortage.<sup>21</sup>
- **Norvir:** In 2013, the NIH denied another Norvir® petition. The petition had argued that “AbbVie had failed to achieve practical application of Norvir® because of its high, differential pricing structure between publicly funded and private sector health care plans.”<sup>22</sup> Among other showings, AbbVie showed that the availability and use around the world of the drug achieved practical application as required under the Act.<sup>23</sup> NIH found that pricing differences between the U.S. and other countries do not trigger any of the Bayh-Dole criteria for march-in.<sup>24</sup>
- **Xtandi:** In 2016, a Petition on Xtandi® was submitted to the NIH and the Department of Defense. The petition on Xtandi was rejected in three months by NIH. The entities who filed the petition appealed the denial. The appeal was rejected. Two more petitions were submitted: one in 2019, and another in 2021. The petitions had one common petitioner. In rejecting the 2021 petition, the NIH noted that, per the manufacturer's estimate, more than 200,000 patients were treated with Xtandi between 2012 and 2021, concluding that the patent owner had not failed the requirement for bringing Xtandi to practical application.<sup>25</sup>

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<sup>20</sup> Nat’l Inst. of Health Determination in the Case of Xalatan® Manufactured by Pfizer, Inc. (Sept. 17, 2004), <http://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf>.

<sup>21</sup> Nat’l Inst. of Health Determination in the Case of Fabrazyme® Manufactured by Genzyme Corp., (Dec. 1, 2010), <http://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf>.

<sup>22</sup> Nat’l Inst. of Health Determination in the Case of Norvir® Manufactured by AbbVie (Nov. 1, 2013) 4 <http://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf>.

<sup>23</sup> *Id.* at 4

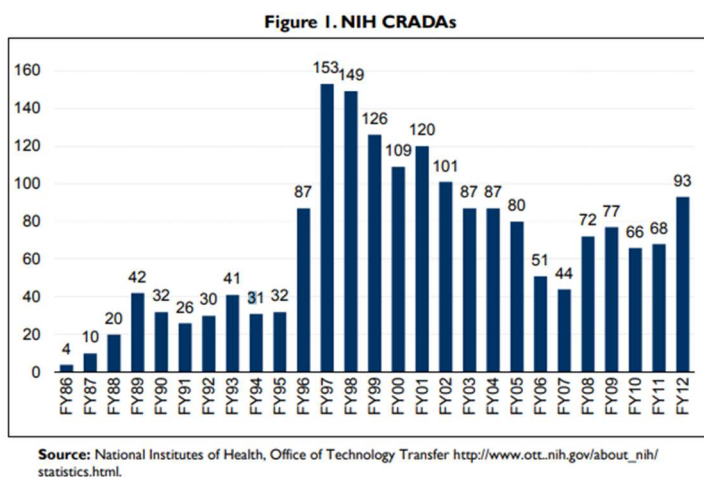
<sup>24</sup> *Id.* at 6.

<sup>25</sup> Dep’t of Health and Human Serv. Letter Denying Xtandi Petition 2 (March 12, 2023), <http://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf>.

### 3. NIH Experimented with Price Control Requirements and Determined They Stifle Innovation

A mechanism by which NIH facilitates innovation is through partnerships with private industry via CRADAs, collaborative agreements that govern how the public and private sectors work together on specific research projects. In Fiscal Years 1990-1995, NIH incorporated what it termed a “reasonable pricing” clause into its CRADAs.<sup>26</sup> “While there was no statutory requirement mandating this type of clause, it was instituted in response to public and political pressures resulting from concern over the cost of AZT, a drug used in the treatment of HIV infection.”<sup>27</sup> Under the clause, NIH could compel a company taking an exclusive license to bring an NIH invention to market to submit documentation showing a “reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public.”<sup>28</sup>

Subsequently, the number of new CRADAs dropped, resulting in fewer collaborative research projects.<sup>29</sup> NIH stopped this experiment in FY 1995 by removing the “reasonable pricing” clause from its CRADAs after it became clear that the “reasonable pricing” clause stifled innovation, as reflected in the figure below.<sup>30</sup>



The then Director of the NIH, Dr. Harold Varmus, stated:

An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations . . . without providing an

<sup>26</sup>MARK L. ROHRBAUGH & JENNIFER WONG, OFF. OF SCIENCE POL’Y, NAT’L INST. OF HEALTH, THE NIH EXPERIENCE WITH THE REASONABLE PRICING CLAUSE IN CRADAs FY1990-1995 2 (2021) <http://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>

<sup>27</sup> WENDY H. SCHACHT, CONG. RESEARCH SERV., FEDERAL R&D, DRUG DISCOVERY, AND PRICING: INSIGHTS FROM THE NIH-UNIVERSITY-INDUSTRY RELATIONSHIP 16 (2012), <http://sgp.fas.org/crs/misc/RL32324.pdf>.

<sup>28</sup> ROHRBAUGH & WONG, *supra* note 26, at 2.

<sup>29</sup> *Id.*

<sup>30</sup> SCHACHT, *supra* note 27, at 19.

offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people.<sup>31</sup>

In making the determination to remove the “reasonable pricing” clause, NIH sought and received input from “scientist, patient advocacy groups, and representatives of academic institutions and industry” (i.e., a broad scope of stakeholders).<sup>32</sup> It is significant that NIH did not use march-in to attempt to regulate price and chose to abandon this effort. This, in addition to the denials of march-in petitions based on price discussed above, demonstrates NIH’s consistent and long-standing understanding that price is not a basis for march-in. In summary, this experiment has already been conducted, and the outcome was clear.

#### **4. The Guidance Threatens U.S. Innovation and Collaboration Across All Technology Sectors**

The guidelines indicate that if a company “has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted.”<sup>33</sup> The guidelines also make clear that a march-in petition can be filed if someone thinks a company is taking too long to commercialize a product.<sup>34</sup>

The risk of government march-in creates a poison pill for inventions created through government-funded research. Universities and startup companies will be the hardest hit. Small companies and start-ups receive more than 70% of academic patent licenses.<sup>35</sup> They depend on attracting high-risk investment to survive. But what reasonable venture capitalist would want to invest in these technologies when the government has signaled that it welcomes march-in petitions?

The guidance also creates a barrier for private companies to partner with universities and start-ups to transform early-stage research into commercialized products. A company will be disincentivized to partner with a government-funded university or startup company and invest millions or billions of dollars to develop and bring an innovative product to market if there is a risk the government could seize the patent rights to the invention if it determines the company has priced the product unreasonably or taken too long to bring it to the market.

Exclusive licensees—not just the contractors who received government funding—are at risk of march-in. This is demonstrated by Scenario 8 in the guidelines, in which a government-funded university granted an exclusive license without disclosing to the licensee that the “initial stages of development” of the invention received government funding, and the march-in affected the licensee’s rights and ability to bring a product to market using the licensed technology.<sup>36</sup>

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<sup>31</sup> NIH NEWS 1 (Apr. 11, 2995),

<http://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>

<sup>32</sup> *Id.*

<sup>33</sup> Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593, 85598 (Dec. 8, 2023), <http://www.govinfo.gov/content/pkg/FR-2023-12-08/pdf/2023-26930.pdf>.

<sup>34</sup> *Id.*

<sup>35</sup> AUTM, *supra* note 7, at 1.

<sup>36</sup> Fed. Reg., *supra* note 33, at 85604.



Under the proposed guidelines, anyone who develops a revolutionary breakthrough in a technology area such as medicine, clean energy, environmental protection, or agriculture will face a new barrier to bringing that innovation to market because the guidelines affect all federal agencies and technology sectors across the economy. The Congressional Research Service reported that eight agencies were to receive 97% of total federal R&D funding: Department of Defense (DOD) (40.9%), Department of Health and Human Services (DHS) (30.2%), Department of Energy (DOE) (11.6%), National Aeronautics and Space Administration (6.6%), National Science Foundation (4.1%), Department of Agriculture (1.7%), Department of Commerce (1.4%), and Department of Veterans Affairs (0.8%).<sup>37</sup>

Furthermore, the guidelines impact multiagency R&D initiatives intended to propel important policy initiatives, such as the Networking and Information Technology Research and Development Program (supercomputing, high-speed networking, cybersecurity, software engineering, and information management), the U.S. Global Change Research Program (global climate change), and the National Nanotechnology Initiative (an initiative to advance understanding and control of matter at the nanoscale).<sup>38</sup> Scenarios 1-8 in the guidelines highlight the diversity of technologies subject to these sweeping programs, such as pharmaceuticals (Scenarios 1, 4, and 8), 3D printing technology (Scenario 2), transportation technology (Scenarios 3 and 7), water purification technology (Scenario 5), and personal protective equipment (Scenario 6).<sup>39</sup> However, the Scenarios do not represent technologies from the eight major federal funding agencies listed above.

Another reason the Draft Interagency Guidance Framework should not be adopted is that the fundamental inquiry—whether a company is commercializing a patented invention—would be unmanageable in industries such as information technology, where it is common for hundreds of patented inventions to be incorporated into a single product. In these industries, companies often have no cost-effective way to track the use of each patent in their portfolios, so they obtain freedom of action by entering broad cross-licenses of their entire portfolios with any companies willing to agree to reasonable terms. Providing the government with the information to perform the march-in analysis specified in the guidelines could impose a significant burden on companies who had made the reasonable business decision not to track use of each of their patents. The administrative burden on the government to conduct fact-finding and validate the information contained in a march-in petition would be similarly onerous.

Not only does the possibility of march-in rights in all technology sectors harm companies who might otherwise commercialize government-funded inventions, and taxpayers who would benefit from the resulting products, it also undermines the purpose of many government programs, which will lead to waste of taxpayer money and harming U.S. interests. The electric vehicle industry is an excellent case-in-point. Foreign dominance of electric vehicle technologies and manufacturing capacity is a concern being addressed by several high-dollar U.S. government programs under the “Investing in America Initiative”<sup>40</sup> and the “Bipartisan Infrastructure Law.”<sup>41</sup> In November 2023, the White House

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<sup>37</sup> CONG. RESEARCH SERV., FEDERAL RESEARCH AND DEVELOPMENT (R&D) FUNDING: FY2023 3 (2022), <http://crsreports.congress.gov/product/pdf/R/R47161>.

<sup>38</sup> *Id.* at 7-11.

<sup>39</sup> Fed. Reg., *supra* note 33, at 85601.

<sup>40</sup> INVESTING IN AMERICA, <http://www.whitehouse.gov/invest/> (last visited Feb 3, 2024).

<sup>41</sup> Public Law No. 117-58 (2021), <http://www.congress.gov/bill/117th-congress/house-bill/3684/text>.

announced a \$3.5 billion DOE initiative to strengthen domestic battery manufacturing.<sup>42</sup> This follows hundreds of electric vehicle initiatives by DOE and DOD.<sup>43</sup>

Domestic electric vehicle development and production capacity is so significant that DOE has developed a “National Blueprint for Lithium Batteries”<sup>44</sup> and DOD has, similarly, set forth a “Lithium Battery Strategy.”<sup>45</sup> The importance of lithium batteries and electric vehicles to DOE and DOD, and their independent funding of technologies likely to be incorporated in a single final product, an electric vehicle, coupled with the distinct needs addressed by DOE with its interest in consumer and commercial vehicles and DOD with its interest in military vehicles, highlights the potential for vastly disparate interpretations of “reasonable pricing.”

Patents play a significant role in protecting DOE-funded renewable energy projects, as detailed in a DOE report noting that “[p]atents in the twenty EERE R&D portfolios have had a strong influence on subsequent technological developments.”<sup>46</sup> Other technologies highlighted “represent longstanding technology areas that comprise a substantial share of the offices’ R&D budgets, or are relatively nascent technologies with growth expected to continue into the future,” demonstrating the wide-ranging harm pricing-based march-in rights will inflict in the green energy sector alone.<sup>47</sup> Expanded march-in rights could have a strong negative impact on the technological developments these programs are intended to promote.

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<sup>42</sup> Press release, U.S. Dep’t of Energy, Biden-Harris Administration Announces \$35 Billion to Strengthen Domestic Battery Manufacturing (Nov. 15, 2023) <http://www.energy.gov/articles/biden-harris-administration-announces-35-billion-strengthen-domestic-battery-manufacturing#:~:text=WASHINGTON%2C%20D.C.%20%E2%80%94%20Today%2C%20two,batt%20eries%20and%20battery%20materials%20nationwide>

<sup>43</sup> See, e.g., Press Release, U.S. Dep’t of Energy, DOE Announces \$209 Million for Electric Vehicles Battery Research (Oct. 27, 2021), <http://www.energy.gov/articles/doe-announces-209-million-electric-vehicles-battery-research>; U.S. Dep’t of Energy, Critical Materials Accelerator Initiative (Nov. 27, 2023), <http://www.energy.gov/eere/vehicles/battery-policies-and-incentives-search#/?show=result&id=292>; U.S. Dep’t of Energy, Critical Materials Collaborative, <http://www.energy.gov/cmm/critical-materials-collaborative>; U.S. Dep’t of Energy, Advanced Manufacturing and Materials Research Support Incentive (Sept. 19, 2022), <http://www.energy.gov/eere/vehicles/battery-policies-and-incentives-search#/?show=result&id=224>.

<sup>44</sup> U.S. Dep’t of Energy, National Blueprint for Lithium Batteries (June 7, 2021), <http://www.energy.gov/eere/vehicles/articles/national-blueprint-lithium-batteries>

<sup>45</sup> U.S. Dep’t of Defense, 2023-2030 DoD Lithium Battery Strategy, <http://www.businessdefense.gov/ibr/pat/battery-strategy.html>.

<sup>46</sup> PATRICK THOMAS, 1790 ANALYTICS LLC FOR U.S. DEP’T OF ENERGY, THE INFLUENCE OF PATENTS IN TWENTY R&D PORTFOLIOS FUNDED BY THE U.S. DEPARTMENT OF ENERGY’S OFFICE OF ENERGY EFFICIENCY AND RENEWABLE ENERGY i (2022), <https://www.energy.gov/sites/default/files/2022-03/The%20Influence%20of%20Patents%20in%20Twenty%20R%26D%20Portfolios%20Funded%20by%20the%20U.S.%20Department%20of%20Energy%27s%20Office%20of%20Energy%20Efficiency%20and%20Renewable%20Energy.pdf>.

<sup>47</sup> *Id.*

Electric vehicle technology also highlights the potential for exercise of march-in rights to become harmful to U.S. interests. As the numerous initiatives above make clear, many such technologies are being developed and commercialized outside the U.S, in competition with domestic companies. What constitutes “reasonable pricing” of a product that is covered by a government-funded patent and is available at a much lower price from a foreign source? How is product quality, which, particularly in the case of lithium-ion batteries, may vary widely by supplier and is often lower in foreign-sourced goods but still acceptable for their price, to be considered? In the absence of patent protection for U.S.-funded research or the inability to meaningfully enforce patents, what is to prevent foreign competitors from appropriating the fruits of taxpayer-funded programs to undercut U.S.-based companies, even in the domestic market? The same foreign dominance of electric vehicle technologies that numerous government programs seek to address, when coupled with the threat of expanded march-in rights, could perversely facilitate such foreign competition.

And there’s significant potential for abuse. Any competitor, hedge fund, or other entity can petition a funding agency to march in, alleging that a price isn’t reasonable or that the invention is taking too long to reach the market. Further, the use of march-in is intended to be used punitively to “deter others” (Scenario 6) and “send a message” (Scenario 8) by an agency.

This uncertainty creates a serious threat to U.S. innovation. The proposed guidance is likely to return us to the pre-Bayh-Dole innovation ecosystem where patents were not licensed to the private sector, leaving many promising inventions uncommercialized. Innovation will be crucial in coming years to address serious concerns such as potable water and water scarcity,<sup>48</sup> food scarcity,<sup>49</sup> and emerging human, animal, and plant diseases, among other global crises. Let’s continue to allow Bayh-Dole to operate as it has over the last four decades to help get promising innovation in the hands of consumers.

Thank you for your attention to these comments. We welcome discussion and the opportunity to provide additional comments.

Sincerely,



Krish Gupta  
President

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<sup>48</sup> Jeffrey Talley, *Water Security: Risks and National Security Implications*, IBM CTR. FOR THE BUS. OF GOV’T (March 15, 2019) <http://www.businessofgovernment.org/blog/water-security-risks-and-national-security-implications>.

<sup>49</sup> See Krista Versteeg, *It’s Time to Talk about Food and Agriculture Security* U.S. DEP’T OF HOMELAND SEC. NEWS ROOM (March 21, 2023), <http://www.dhs.gov/science-and-technology/news/2023/03/21/its-time-talk-about-food-and-agriculture-security> and Patricia Parera, *Addressing the Interplay of Climate Change, Food and National Security: Event Summary 2*, COUNCIL ON STRATEGIC RISKS (June 12, 2023), <http://councilonstrategicrisks.org/wp-content/uploads/2023/08/FoodSecurityEventReport.pdf>.