# 21C The Coalition for 21st Century Patent Reform

February 6, 2024

#### VIA ELECTRONIC SUBMISSION

Alicia Chambers Executive Secretariat National Institute of Standards and Technology Attention: Mojdeh Bahar, Associate Director for Innovation and Industry Services 100 Bureau Drive Gaithersburg, MD 20899

#### Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No. 230831-0207, NIST-2023-0008

Dear Ms. Chambers:

The Coalition for 21<sup>st</sup> Century Patent Reform ("21C") appreciates the opportunity to respond to the *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* ("Proposal").<sup>1</sup> 21C represents a diverse coalition of American companies across various industries that invest heavily in research and development ("R&D") in the United States to produce the many inventions that these companies bring to market.<sup>2</sup> 21C members develop and manufacture a variety of products and technologies protected by patents and license these patents to and from others. Members rely on patents and a robust U.S. patent system to protect their inventions. Because 21C members collectively employ millions of people, invest billions of dollars in R&D each year, work closely with universities developing new technology, and commercialize products that benefit the everyday lives of countless Americans, 21C is well positioned to respond to the Proposal.

For the reasons discussed below, 21C respectfully opposes the adoption of the Proposal. The Proposal contemplates the expansion of a never-before-used provision in the Bayh-Dole Act,<sup>3</sup> to encourage the government to exercise "march-in" rights to compel licenses to patents on private-sector inventions that are derived at least in part from federal funding in a manner inconsistent with both the letter and spirit of the law. As written, the Proposal would have ramifications on U.S. innovation culture, the economy, technology-based startup companies, and our academic and

<sup>&</sup>lt;sup>1</sup> See National Institute of Standards and Technology, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, 88 Fed. Reg. 85,593 (posted Dec. 8, 2023) [hereinafter, "Proposal"].

<sup>&</sup>lt;sup>2</sup> See The Coalition, THE COALITION FOR 21<sup>ST</sup> CENTURY PATENT REFORM (accessed on Jan. 23, 2024), available at https://www.patentsmatter.com/coalition.

<sup>&</sup>lt;sup>3</sup> See The Patent and Trademark Law Amendments Act, Pub. L. 96-517, 94 Stat. 3015 (1980) (codified as 35 U.S.C. §§ 200-212) [hereinafter, "Bayh-Dole Act"].

research communities. As the Proposal states, it is "not meant to apply to just one type of technology or product;" rather, it would apply to all technologies and products, and would affect companies both large and small, investors, and research universities and laboratories across the country (and the communities surrounding these universities and laboratories).<sup>4</sup>

If enacted, the Proposal would inject uncertainty into the federally-funded patent space. It would do this by adding price as a consideration to the government's "march-in" analysis, which was intentionally omitted as a consideration by the Act's authors. The Bayh-Dole Act has encouraged the development in the United States of a powerful technological development ecosystem that leverages key federal funding directed toward fundamental technology to encourage the private investment needed to develop and ultimately commercialize those technologies. The Proposal, if finalized, would discourage investment in federally-funded technologies and the advancement of these technologies to produce products that benefit society.

This letter first details the statutory text and legislative purpose behind the Bayh-Dole Act, the effect that the Act has had on sparking innovation in the United States, and the Proposal's departure from the text and purpose of the Act. Next, this letter describes the consequences that the Proposal would have across all technologies, industries, R&D and investment, our broader American innovation culture, and the economy. Then, this letter explains why the Proposal does not comport with the government's otherwise thoughtful initiatives to boost American competitiveness and innovation in a global economy. Each of these considerations independently merits the withdrawal of the Proposal.

<sup>&</sup>lt;sup>4</sup> Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,595.

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## I. The Proposal Departs From The Statutory Text And Legislative Purpose Behind The Bayh-Dole Act.

In 1980, Congress passed the Bayh-Dole Act to enhance American innovation and revitalize the economy. Over the 44 years since its passage, the Act has been a tremendous success. Despite this success, the Proposal departs from the text and purpose of the Act. In so doing, the Proposal would adversely affect American innovation culture and the U.S. economy. For this reason alone, the Proposal should not be adopted.

#### A. The text and purpose of the Act has led to the Act's great success.

Congress passed the Bayh-Dole Act, during a time of economic and innovative stagnation. The United States had emerged from World War II as the most-advanced innovative and industrial economy in the world, but, as the United States entered the last quarter of the 20<sup>th</sup> Century, innovation and the U.S. economy began to stagnate. To remedy this stagnation and return the United States to economic prominence, Senators Birch Bayh (D-IN) and Bob Dole (R-KS) authored the bipartisan Bayh-Dole Act. The Act was meant to spark American innovation and competiveness by unlocking private-sector use of technologies derived from federal funding. Specifically, the Act allowed federally-funded researchers or the institutions sponsoring research, such as private businesses or universities, "to use the patent system to promote the utilization of inventions arising from federally supported research or development."<sup>5</sup> In short, the Act allowed private persons, businesses, and universities to obtain title to patents covering technologies derived from federal funding and bring the underlying technologies to market. As Senators Bayh and Dole explained: "Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector .... [T]he primary purpose of the [A]ct was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."<sup>6</sup>

The Act sought to reverse the trend of the private sector largely avoiding federally-funded patents, causing the underlying technology to languish. Prior to the Act's passage, the government held approximately 28,000 patents<sup>7</sup> but the government only licensed fewer than 4 percent of these patents.<sup>8</sup> This is because the government would only license its patents on a *nonexclusive* basis.<sup>9</sup> In turn, private-sector participants viewed these patents as "[c]ontaminated by government funding" and avoided nonexclusive licenses since they could not be assured of returns on their investments in bringing products to market, as competitors could easily copy successful products

<sup>9</sup> Id.

<sup>&</sup>lt;sup>5</sup> Bayh-Dole Act, *supra* n.3, 35 U.S.C. § 200.

<sup>&</sup>lt;sup>6</sup> U.S. Sens. Birch Bayh & Bob Dole, Our Law Helps Patients Get New Drugs Sooner, WASHINGTON POST (Apr. 11, 2002), available at https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

<sup>&</sup>lt;sup>7</sup> Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, at 1, SCIENCE (Oct. 6, 2010), *available at* https://www.science.org/doi/pdf/10.1126/scitranslmed.3001481.

<sup>&</sup>lt;sup>8</sup> *Id.* 

by obtaining their own nonexclusive licenses from the government.<sup>10</sup> There simply was little reason for the private sector to collaborate with research universities and laboratories through R&D and investment prior to the Act's passage.

The Act achieved its goal: It reversed the trend of the private sector's avoiding "[c]ontaminated," federally-funded patents and has been a tremendous success in sparking innovation and promoting economic growth. Indeed, as of 2020, there were over 7,911 Bayh-Dole-licensed patents.<sup>11</sup> The use of these patents has added nearly \$2 trillion to U.S. gross domestic product and has sustained over six million jobs since the Act's inception.<sup>12</sup> Much of this success is because the Act has fostered public-private partnerships between industry participants, universities, and laboratories that enhanced funding for universities through patent licenses, and contributed greatly to the overall success of the innovation ecosystem and educational system in the United States. Indeed, over 11,210 startups have been created through technology transfer activities from public-private partnerships since the Act's inception, and universities have reaped billions of dollars of annual licensing fees from these partnerships.<sup>13</sup> Today, universities create approximately two startups each day, which leads to American jobs and support for local economies.<sup>14</sup> For these reasons and more, one outlet has deemed the Act as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century .... [The 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>15</sup> Given these successes, it is no surprise that "America's Bayh-Dole legislation has been copied by more than two-dozen countries."<sup>16</sup>

<sup>&</sup>lt;sup>10</sup> See David Kappos & Andrei Iancu, Opinion: President Biden's domestic technology seizure plan, THE HILL (Jan. 14, 2024), available at https://thehill.com/opinion/4407846-president-bidens-domestic-technology-seizure-plan/.

<sup>&</sup>lt;sup>11</sup> Sara Abdulla & Jack Corrigan, *Bayh-Dole Patent Trends* 2, GEORGETOWN UNIVERSITY CENTER FOR SECURITY AND EMERGING TECHNOLOGY (Aug. 2023), *available at* https://cset.georgetown.edu/publication/bayh-dole-patent-trends/.

<sup>&</sup>lt;sup>12</sup> Press Release, Bayh-Dole Coalition Statement on Biden Administration's Proposed March-in Framework, BAYH-DOLE COALITION (Dec. 7, 2023), available at https://bayhdolecoalition.org/bayh-dole-coalition-statement-onbiden-administrations-proposed-march-in-framework/.

<sup>&</sup>lt;sup>13</sup> The Role Of The Bayh-Dole Act In Fostering Technology Transfer And Implications for Innovation 11-12, PHRMA (Feb. 2020), available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Bayh-Dole-Whitepaper-FINAL---21820.pdf.

<sup>&</sup>lt;sup>14</sup> *Id.* at 12.

<sup>&</sup>lt;sup>15</sup> *Innovation's golden goose*, THE ECONOMIST (Dec. 14, 2002), *available at* https://bayhdolecoalition.org/wp-content/uploads/2023/05/The-Economist-December-14-2002-Innovation\_s-Golden-Goose-Article.doc.pdf.

<sup>&</sup>lt;sup>16</sup> National Innovation Policies: What Countries Do Best And How They Can Improve 5, GLOBAL TRADE & INNOVATION POLICY ALLIANCE (June 2019), available at https://www2.itif.org/2019-national-innovation-policies.pdf; see also Michael S. Mireles, Adoption Of The Bayh-Dole Act In Developed Countries: Added Pressure For A Broad Research Exemption In The United States? 260, MAINE L. REV. Vol. 59:2 (2007) ("Numerous developed countries, most if not all members of the Organisation of Economic Cooperation and Development [], including Japan, France, the United Kingdom, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland, have or are considering adopting legislation similar to the Bayh-Dole Act.").

To be sure, the Act, as written, contains the "march-in" right for the government to compel licenses to federally-funded patents in limited circumstances. The Act provides: "With respect to any subject invention ..., the Federal agency under whose funding agreement the subject invention was made shall have the right... to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself....<sup>17</sup> A federal agency may exercise this right only if it determines: (1) "action is necessary because 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 in such field of use;" (2) "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;" (3) "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) "action is necessary because" a licensee has not met certain obligations regarding the Act's preference for federally-funded inventions to be substantially manufactured in the United States.<sup>18</sup>

Despite this "march-in" right, the government, under successive administrations of both parties, has never invoked this right over the Act's 44 years of existence. The "march-in" right is intended to be used only in these limited statutorily defined circumstances. As explained by Senators Bayh and Dole, the Act is intended to allow the government to step in "only when the private industry collaborator ha[d] not successfully commercialized the invention as a product."<sup>19</sup> Importantly, the plain text of the Act does not allow for the price of a product to justify the invocation of the government's "march-in" right.<sup>20</sup> As noted by Senators Bayh and Dole, the Act "did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional[.]"<sup>21</sup> Thus, only the four statutory criteria described above are lawfully applicable to the government's "march-in" analysis.

### B. The Proposal does not adhere to the Act's text and purpose and would jeopardize the Act's success.

The Proposal departs from the Act's text and purpose in at least two respects. First, in a variety of instances, the Proposal considers the "reasonableness of the price" of a product in determining whether the government should "march in."<sup>22</sup> But price is not a consideration under the Act. The authors of the Act intentionally omitted price as a consideration.<sup>23</sup> As stated by the

- <sup>21</sup> U.S. Sens. Bayh & Dole, *supra* n.6.
- <sup>22</sup> See, e.g., Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,598.

<sup>&</sup>lt;sup>17</sup> Bayh-Dole Act, *supra* n.3, 35 U.S.C. § 203(a).

<sup>&</sup>lt;sup>18</sup> *Id.*; *see also id.* at 35 U.S.C. § 204 (detailing preference for inventions to be manufactured in the United States).

<sup>&</sup>lt;sup>19</sup> U.S. Sens. Bayh & Dole, *supra* n.6.

<sup>&</sup>lt;sup>20</sup> See Kappos & Iancu, supra n.10.

<sup>&</sup>lt;sup>23</sup> U.S. Sens. Bayh & Dole, *supra* n.6.

Association of University Technology Managers ("AUTM"), whose member universities rely on the technology transfer system created by the Act: "[A]ny assertion that pricing can or should be used as a basis for exercising march-in rights on a product developed, commercialized and sold by . . . licensees . . . is inconsistent with both the letter and the spirit" of the Act.<sup>24</sup>

Moreover, even if it were proper to consider price under the Proposal (it is not), it would be bad policy. The government has tried to regulate pricing in federally-funded patent licenses in the past, and the results were counter-productive. In 1989, the National Institutes of Health ("NIH") mandated a reasonable pricing clause for its cooperative research and development agreements and patent licenses. This led the private sector to avoid collaborations with the NIH. Six years later, the NIH "[e]liminat[ed] the clause [to] promote research that can enhance the health of the American people" after "[a]n extensive review . . . indicated that the pricing clause [drove] industry away from potentially beneficial scientific collaborations with . . . scientists without providing an offsetting benefit to the public."<sup>25</sup>

Second, the Proposal introduces eight scenarios, illustrating when the government might invoke its "march-in" right.<sup>26</sup> These fact-specific scenarios highlight the subjective nature of the government's decision-making as to when to "march in." They also lower the thresholds, as compared to prior practice, for when it is appropriate for the government to statutorily "march in," injecting after-the-fact review by the government agency of private-sector business decisions. If the Proposal is enacted, the surrounding uncertainty about the government's "march-in" right, as set forth through the hypothetical scenarios, would inject uncertainty into the private sector and markets (as well as into the federal agencies reviewing "march-in" petitions)—the very uncertainty that the Act was meant to correct.

#### II. The Proposal Would Have Downstream Consequences On All Technologies, Industries, And Research Universities And Laboratories.

Aside from the Proposal's departure from the text and purpose of the Bayh-Dole Act, as well as 44 years of tradition, the Proposal would have numerous, downstream consequences. If enacted, the Proposal would chill innovation, stymie investment, and hinder public-private research collaboration. Because of these consequences, the Proposal should not be adopted.

<sup>&</sup>lt;sup>24</sup> Stephen J. Susalka, AUTM's Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327), at 3, ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (Mar. 28, 2021), available at https://autm.net/AUTM/ media/About-Tech-Transfer/Documents/AUTM-Comments-on-NIST-Bayh-Dole-NPRM-(Docket-no-201207-0327).pdf.

<sup>&</sup>lt;sup>25</sup> NIH News Press Release, NATIONAL INSTITUTES OF HEALTH (Apr. 11, 1995), available at https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.

<sup>&</sup>lt;sup>26</sup> Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,601-85,605.

### A. The Proposal would disproportionally affect startups and the important innovations that they bring to market.

As illustrated by many of the Proposal's scenarios, startups and small- and medium-sized companies would be disproportionately impacted should the Proposal be enacted.<sup>27</sup> This would have deleterious economic consequences and hurt a vanguard of innovation in our country. Indeed, startups license approximately 70 percent of patents that are associated with federally-funded university research.<sup>28</sup> And small businesses contribute roughly 50 percent to U.S. gross domestic product.<sup>29</sup> Despite these significant contributions to U.S. innovation culture and the economy, the Proposal would subject startups and small- and medium-sized businesses, in addition to all companies, to the uncertainty of potential "march in" based upon the price of their product only after they have invested significant sums to develop the product. This would hinder innovation, as companies would either choose to engage in their own proprietary research or seek out collaborations with parties that did not rely upon government funding.

If enacted, the Proposal could impact the further development of technologies that are ubiquitous and helpful today as well as technologies that will benefit our national security. For example, before Google became the *Google* that we know today, Larry Page and Sergey Brin certified in their first patent for a search algorithm that their "invention was made with Government support under [a contract] awarded by the National Science Foundation."<sup>30</sup> Page and Brin then licensed the search algorithm from Stanford University and launched Google.<sup>31</sup> The Proposal also could impact key defense-related and aerospace technologies. For example, 10 percent of Bayh-Dole patents implicate defense-related technologies, and the Department of Defense funds 21 percent of these patents.<sup>32</sup> If the Proposal were to be enacted, it would be unclear whether inventors like Page and Brin and startups in the national security space, in addition to the investors that these inventors and startups rely on, would be willing to take a risk on bringing a federally-funded technology to market. Simply put, the Proposal would chill innovation, especially when it comes to the attempt by startups and small and medium-sized businesses to create the technologies of the future.

For example, Scenario 2 involves an "advanced manufacturing startup[']s" ability to bring a product to market. Scenario 3 involves a "medium-sized company that is seeking to grow." Scenario 4 involves a "small pharmaceutical company" experiencing a delay in the manufacturing of a monoclonal antibody, due to a flood at its manufacturing plant in California. *See* Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,601-85,602.

<sup>&</sup>lt;sup>28</sup> Joseph Allen, New March-In Guidelines Threaten U.S. Innovation, IPWATCHDOG (Dec. 10, 2023), available at https://ipwatchdog.com/2023/12/10/new-march-guidelines-threaten-u-s-innovation/id=170491/.

<sup>&</sup>lt;sup>29</sup> The Importance of Small Business to the U.S. Economy, UNIVERSITY OF MINNESOTA (accessed on Jan. 15, 2024), available at https://open.lib.umn.edu/exploringbusiness/chapter/5-2-the-importance-of-small-business-to-the-us-economy/.

<sup>&</sup>lt;sup>30</sup> See U.S. Patent No. 6,285,999 (filed Jan. 9, 1998), available at https://patentimages.storage.googleapis.com/37/a9/18/d7c46ea42c4b05/US6285999.pdf.

<sup>&</sup>lt;sup>31</sup> See Kappos & Iancu, supra n.10.

<sup>&</sup>lt;sup>32</sup> See Abdulla & Corrigan, supra n.11, at 2.

#### **B.** The Proposal would stymie investment.

The subjectivity of the government's decision to "march in" under the Proposal adds uncertainty to the market and investment decisions—exactly the things that the Act sought to correct. This uncertainty would stymie private-sector investment, which is pivotal to American innovation and an important supplement to the government's own R&D investments

Today, it is well known that venture-capital funding is "positively associated with firm innovation and growth in the United States."<sup>33</sup> Venture-capital funding has helped to develop and grow technologies behind the Google search, the Apple iPhone, the Moderna COVID-19 vaccine, Twitter, Amazon, Uber, Facebook, and Tesla, among many others.<sup>34</sup> Nearly half of initial public offerings in the United States are made by venture-backed firms.<sup>35</sup> And, as of 2020, seven of the eight top publicly-traded companies measured by market capitalization were backed by venture-capital funding before their initial public offerings.<sup>36</sup> But despite these successes, venture-capital investments are inherently risky endeavors that involve a multitude of uncertainties, ranging from a product's feasibility, to changing consumer sentiments and shifting regulatory environments, among others. Indeed, "over half the investments of even the most successful venture capital investors fail, while the vast majority of returns are generated by a few extremely successful investments that are hard to predict upfront."<sup>37</sup> Thus, "venture capital investors are drawn to sectors in which... uncertainty can be reduced."<sup>38</sup> As the Act intended, the 44 years of the government never invoking its "march-in" right reduced uncertainty for venture-capital investors to invest in companies utilizing federally-funded patents.

If enacted, the Proposal would significantly alter investment decisions made by venture capitalists and other investors. Just as before the passage of the Act, investors would once again refrain from investing in companies that hold licenses to federally-funded patents. This is because investors would not be assured of returns on their investments in portfolio companies due to the threat of "march in."

<sup>&</sup>lt;sup>33</sup> See, e.g., Jeremy Greenwood, Pengfei Han & Juan M. Sánchez, Venture Capital: A Catalyst for Innovation and Growth 11, FEDERAL RESERVE BANK OF ST. LOUIS (2022), available at https://files.stlouisfed.org/files/htdocs/p ublications/review/2022/04/06/venture-capital-a-catalyst-for-innovation-and-growth.pdf.

<sup>&</sup>lt;sup>34</sup> *Id.* at 1.

<sup>&</sup>lt;sup>35</sup> William Janeway, Ramana Nanda & Matthew Rhodes-Kropf, Venture Capital Booms and Startup Financing 2, HARVARD BUSINESS SCHOOL (2021), available at https://www.hbs.edu/ris/Publication%20Files/21-116\_c8365ab5-7cad-4ba3-9e02-ddec0191413f.pdf.

<sup>&</sup>lt;sup>36</sup> Josh Lerner & Ramana Nanda, *Venture Capital's Role in Financing Innovation: What We Know and How Much We Still Need to Learn* 237, J. ECON. PERSPECTIVES Vol. 34, No. 3 (2020).

<sup>&</sup>lt;sup>37</sup> *Id.* at 255.

<sup>&</sup>lt;sup>38</sup> *Id.* 

#### C. The Proposal would affect research universities and laboratories.

If the Proposal is enacted, private companies would shy away from collaborating with American research universities and laboratories. This would not only impact innovation centers in places like Boston, Pittsburgh, Silicon Valley, and the Research Triangle Park in North Carolina, but also impact all communities with such universities or laboratories. Under the Proposal, research universities would lose an important source of revenue and certain academic positions would be impacted, as would the local economy surrounding those universities. Loss of that revenue would impact technology licensing and transfer functions at research universities, potentially making it harder for those universities to obtain and use commercial funding, thus further limiting fundamental research conducted at American universities.

Today, it is commonplace for universities to have technology transfer offices where employees with expertise craft licensing deals with the private sector.<sup>39</sup> This stands in contrast to 1979—the year before the Act's passage—when only 30 universities had technology transfer offices.<sup>40</sup> The technology transfer deals that these offices oversee often contain certain development and commercialization milestones and allow for the universities to terminate the deals if the milestones are not met. In other words, if licensees are not productively using their licenses, then universities can terminate the deals and reissue the licenses to others that will. In turn, universities benefit from the productive and successful use of patent licenses in the form of licensing fees. Despite the well-functioning technology-transfer system, the Proposal replaces universities' rights to evaluate their licensing deals with the private sector with the government's subjective decision making as to whether to "march in." As companies shy away from collaborations with research universities because of the increase in government involvement, universities would miss out on important revenue streams and positions in tech transfer offices, among others, would be negatively impacted. This, in turn, would impact the economies of the local communities surrounding our country's universities.

Take, for example, the case of Jackson State University. In a recent op-ed, Almesha L. Campbell, the Assistant Vice President for Research and Economic Development at Jackson State and the first representative from a Historically Black College and University ("HBCU") to chair AUTM, explained the extraordinary effect that the Bayh-Dole Act has had on HBCUs and their surrounding communities.<sup>41</sup> Jackson State, like other traditionally underrepresented universities, has benefited from federal funding, such as a \$12 million award from the NIH "to

<sup>&</sup>lt;sup>39</sup> See, e.g., Office of Economic Innovation and Partnerships, About the Office of Economic Innovation and Partnerships, UNIVERSITY OF DELAWARE (accessed on Jan. 21, 2024), available at https://www.udel.edu/research-innovation/oeip/about/.

<sup>&</sup>lt;sup>40</sup> Walter D. Valdivia, University Start-Ups: Critical for Improving Technology Transfer 6, CENTER FOR TECHNOLOGY INFORMATION AT BROOKINGS (Nov. 2013), available at https://www.brookings.edu/wpcontent/uploads/2016/06/Valdivia\_Tech-Transfer\_v29\_No-Embargo.pdf.

<sup>&</sup>lt;sup>41</sup> See 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), available at https://fortune.com/2024/01/05/biden-bayh-dole-act-administrations-plans-undermine-us-innovation-educationalmesha-campbell/.

enhance research, development, and entrepreneurship in biomedical innovation."<sup>42</sup> As Ms. Campbell describes, federal assistance under the Act is "crucial to democratizing access to the benefits of tech transfer, previously the preserve of elite institutions such as Columbia, MIT, and UC Berkeley."<sup>43</sup> "[H]istorically overlooked" "innovators and entrepreneurs" at Jackson State have reaped the benefits of the "more equitable landscape" provided by the Act, which has "help[ed] everyone in [Jackson State's] region by creating new economic opportunities."<sup>44</sup> Jackson State, universities like it, and the regions surrounding universities would be negatively affected by the Proposal.

Similarly, government-led research initiatives to bring the private sector and universities together in the development of critical technologies also would be impacted under the Proposal. To name just one example, in October 2023, the Department of Defense awarded \$40 million to establish "four new research centers of excellence at minority-serving institutions of higher education, as part of its Historically Black Colleges and Universities and Minority-serving Institutions Research and Education Program."<sup>45</sup> The goal of this initiative is to spark "research over a five-year period in technology areas critical to the Department's drive for Combined Joint All-Domain Command and Control" in the areas of "advanced computing and software, future-generation wireless technology, integrated sensing and cyber, and renewable energy generation and storage."<sup>46</sup> Private-sector collaborations with these institutions, such as Florida International University and Georgia State University, serve as a force-multiplier, in terms of bringing both expertise and investment to these research areas. The Proposal would hinder such collaborations for all of the reasons described above.

#### **III.** The Proposal Runs Contrary To Other Government Initiatives.

The Proposal is not in line with the Administration's other efforts to reinvigorate the economy, spark innovation, reorient global supply chains, and bolster American competitiveness in the global economy. For example, the Proposal disregards the aims of the CHIPS and Science Act.<sup>47</sup> In an effort "to revitalize domestic manufacturing, create good-paying American jobs, strengthen American supply chains, and accelerate the industries of the future,"<sup>48</sup> the government named 31 "Tech Hubs" in 32 different states that will obtain millions of dollars in grant funding,

<sup>&</sup>lt;sup>42</sup> *Id.* 

<sup>&</sup>lt;sup>43</sup> *Id.* 

<sup>&</sup>lt;sup>44</sup> *Id*.

<sup>&</sup>lt;sup>45</sup> See Department of Defense Press Release, DOD Invests \$40 Million to Establish Research Centers of Excellence at Minority-serving Institutions (Oct. 17, 2023), available at https://www.defense.gov/News/Release/Release/ Article/3560060/dod-invests-40-million-to-establish-research-centers-of-excellence-at-minority/.

<sup>&</sup>lt;sup>46</sup> *Id.* 

<sup>&</sup>lt;sup>47</sup> See CHIPS and Science Act, Pub. L. No. 117-167, 136 Stat. 1366 (2022).

<sup>&</sup>lt;sup>48</sup> The White House, Fact Sheet: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China (Aug. 9, 2022), available at https://www.whitehouse.gov/briefing-room/statementsreleases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chainsand-counter-china/.

as part of the CHIPS and Science Act.<sup>49</sup> As part of the broader goals of the CHIPS and Science Act, on January 29, 2024, the Administration also pledged \$150 million in R&D funding from the National Science Foundation to create "innovation engines" for industries, "ranging from aerospace to textiles to energy," across 18 states.<sup>50</sup> Likewise, the Administration is planning on announcing \$53 billion in CHIPS funding to industry, in order to "reshore production of advanced microchips and fend off China."<sup>51</sup> The Proposal affects these goals because private-sector participants would not be incentivized to collaborate with recipients of federal funding or take any federal funding themselves, lest it jeopardize their rights to patented technologies.

Similarly, the Proposal departs from the Administration's efforts to "support[] American innovation and research and development" by "cut[ting] red tape . . . in the Federal R&D process," "boost[ing] the incentive to manufacture new inventions in the United States when those inventions are developed using Federal funds," and "encourag[ing] the expansion of the domestic production for critical industries,"<sup>52</sup> as part of the *Executive Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs*.<sup>53</sup> The Proposal further departs from the Administration's similar goal to ensure that U.S. companies remain leaders in the standards-development process through increased R&D funding and enhanced public-private collaborations because companies would avoid research collaborations with universities on the development of standards and the technologies underlying those standards.<sup>54</sup>

<sup>&</sup>lt;sup>49</sup> The White House, Fact Sheet: Biden-Harris Administration Announces 31 Regional Tech Hubs to Spur American Innovation, Strengthen Manufacturing, and Create Good-Paying Jobs in Every Region of the Country, available at https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/23/fact-sheet-biden-harrisadministration-announces-31-regional-tech-hubs-to-spur-american-innovation-strengthen-manufacturing-andcreate-good-paying-jobs-in-every-region-of-the-country/.

<sup>&</sup>lt;sup>50</sup> Eva Dou, *Biden wooing battleground states and red states with research funds*, WASHINGTON POST (Jan. 29, 2024), *available at* https://www.msn.com/en-us/news/politics/biden-wooing-battleground-states-and-red-states-with-research-funds/ar-BB1hqLak.

<sup>&</sup>lt;sup>51</sup> Yuka Hayashi, *Eager for Economic Wins, Biden to Announce Billions for Advanced Chips*, THE WALL STREET JOURNAL (Jan. 27, 2024), *available at* https://www.msn.com/en-us/money/markets/eager-for-economic-wins-biden-to-announce-billions-for-advanced-chips/ar-BB1hlcxv.

<sup>&</sup>lt;sup>52</sup> The White House, Fact Sheet: Amidst Manufacturing Boom, President Biden Will Sign an Executive Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs to Encourage "Invent it Here, Make it Here" in Industries of the Future (July 28, 2023), available at https://www.whitehouse .gov/briefing-room/statements-releases/2023/07/28/fact-sheet-amidst-manufacturing-boom-president-bidenwill-sign-an-executive-order-on-federal-research-and-development-in-support-of-domestic-manufacturing-andunited-states-jobs-to-encourage/.

<sup>&</sup>lt;sup>53</sup> The White House, *Executive Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs* (July 28, 2023), *available at https://www.whitehouse.gov/briefing-room/presidential-actions/2023/07/28/executive-order-on-federal-research-and-development-in-support-of-domestic-manufacturing-and-united-states-jobs/.* 

See, e.g., The White House, United States Government National Standards Strategy For Critical And Emerging Technology 8 (May 2023) ("The U.S. Government will bolster its support for R&D in [critical and emerging technology] and further increase investment in pre-standardization research. Innovation, cutting-edge science, and translational research will remain the drivers of U.S. influence and leadership in international standards development."), available at https://www.whitehouse.gov/wp-content/uploads/2023/05/US-Gov-National-Standards-Strategy-2023.pdf; id. at 11 ("We will also expand efforts to develop standards-related curricula with

Because of the clear contrasts between the Proposal and the Administration's other initiatives, the Proposal should not be adopted. The Proposal would affect the Administration's other efforts to set the United States on a path for innovative and economic success in the 21<sup>st</sup> Century.

#### IV. Conclusion

21C respectfully requests that the Proposal be withdrawn. It departs from the statutory text and legislative purpose of the Act. It would have significant consequences on American innovation culture, public-private collaboration, the economy, jobs, and the national security. It also runs contrary to the Administration's otherwise thoughtful efforts to enhance American competitiveness and economic vitality. All told, these fundamental issues with the Proposal outweigh its claimed benefits.

Respectfully submitted,

/s/ Philip S. Johnson

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Steering Committee Chair Coalition for 21st Century Patent Reform

universities and educational institutions to address technical, business, and policy aspects of standards development and focus on developing standards skillsets on [critical and emerging technology]. We will build capacity and resources for standards professionals, such as supporting a Standards Center of Excellence, to be led by non-federal entities, to engage the private sector, provide training, and assist in engagement with standards activities—particularly for small- and medium-sized companies.").