



**SAINT LOUIS UNIVERSITY SCHOOL OF LAW**  
Legal Studies Research Paper Series

No. 2021-24

Comments on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, National Institute of Standards and Technology (NIST), United States Department of Commerce, Notice of proposed rulemaking. 86 FR 35. Agency/Docket Number: 201207-0327

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April 5, 2021

National Institute of Standards and Technology (NIST)  
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions  
Docket ID: 201207-0327  
Document ID: NIST-2021-0001-0001  
Federal Register 2020-27581

**RE: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, National Institute of Standards and Technology (NIST), United States Department of Commerce, Notice of proposed rulemaking. 86 FR 35. Agency/Docket Number: 201207-0327**

This letter is written in response to the notice of proposed rulemaking published in the Federal Register on January 4, 2021, seeking public comments on the revised regulations proposed by NIST to the University and Small Business Patent Procedure Act of 1980 (the “Bayh-Dole Act”). We submit this letter as academics who engage in research on patent law and biomedical innovation. The arguments also reflect practical knowledge that one of us has acquired from a decade of working with U.S. universities and biotech companies in the process of technology transfer as a lawyer practicing in two highly regarded Boston law firms, and experience that others of us have gained from working in the U.S. government and engaging in intellectual property policy work on Bayh-Dole related issues. We submit that the proposed rule-making includes changes that are contrary to the intent and the stated purpose of the Bayh-Dole Act and that unduly limit the interpretive authority of the Federal Government in administering the Act.

We suggest alternative ways in which regulations implementing the Bayh-Dole Act could be changed to further the Act's intent and purpose.<sup>1</sup>

1. *The proposed rule will substantially alter the bargain that the Bayh-Dole Act strikes between private and public rights in technology developed with federal funds, significantly diminishing the public rights provided by the Bayh-Dole Act, and it should be debated as such and, ultimately, rejected.*

The notice of proposed rulemaking characterizes the proposed changes to the Bayh-Dole Act primarily as technical corrections, clarifications, reorganization, the removal of outdated information, and other minor and ministerial changes.<sup>2</sup> But the effects of the proposed changes are far reaching and act to substantially change the balance of public and private rights that the Bayh-Dole Act was designed to strike. This substantial shift in the balance of public and private rights to the detriment of the public interest is deserving of significant scrutiny and a broader debate that allows for greater consideration of the public interest in preserving, and even expanding, the government's reserved rights over publicly funded inventions and technology.

Specifically, the proposed rule includes changes to: (1) eliminate unreasonable prices as a stand-alone basis for the exercise of march-in rights (modifications to 37 CFR Section 401.6); (2) redefine "subject inventions" in a way that narrows the inventions to which government rights attach (modifications to 37 CFR Section 401.14); (3) restrict the ability of members of the public to appeal government licenses to those who can show they lost the ability to commercialize the technology (modifications to 37 CFR Section 404.11); (4) weaken the working requirements for government patent licensing by treating the payment of license fees as a form of practical application (modifications to 37 CFR Section 404.2); and (5) make the licensing process less transparent by removing the requirement of the government to identify the prospective licensee (modifications to 37 CFR Section 404.7).

Collectively, the proposed modifications would act to limit the ability of the government to protect the public interest in accessing and benefiting from publicly funded technologies and inventions that are transferred to the private sector pursuant to the Bayh-Dole Act. As further described below, the proposed changes to the Bayh-Dole Act will have the effect of significantly curtailing the scope of public rights in federally funded research and development (R&D), while also making it more difficult for those seeking to protect the public interest to identify and enforce public rights to access federally funded technology. These are not minor, technical, or ministerial changes, but rather a significant transfer of rights to the private sector that deserves more careful scrutiny than provided in the proposal. It should be withdrawn, and a more transparent and comprehensive process should be adopted to address any concerns with the

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<sup>1</sup> 35 USC Section 200 – Policy and Objectives (purposes include the objectives “to promote the public availability of inventions” and “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government **and protect the public against nonuse or unreasonable use of inventions**”) (emphasis added). 35 USC Section 203 – March-in Rights specifically identifies the reserved rights retained by the government as a mechanism for protecting the public interest in access to subject inventions.

<sup>2</sup> See Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, A Proposed Rule, Summary, <https://www.federalregister.gov/documents/2021/01/04/2020-27581/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions>.

current regulations, including concerns that the Act does not do enough to protect the public interest.

2. *By substantially limiting the ability of the government to protect the public interest in publicly funded R&D, the proposed rule will undermine the objectives of the Bayh-Dole Act and harm the public interest in ensuring reasonable access to federally funded inventions and technology.*

The Bayh-Dole Act was designed as a mechanism for enabling the use of publicly funded inventions and technology in ways that further the public interest by harnessing the private sector capacity for commercialization of publicly funded inventions and technology while preserving the government's ability to ensure meaningful public access to these inventions. The private sector is given the right to elect title to and patent inventions developed at least in part with the use of federal funds in return for certain statutory obligations designed to ensure that the resulting inventions and technology are made reasonably available to the public. The Act includes a mechanism for the government to enforce this bargain in the form of "march-in rights"<sup>3</sup> where public access is insufficient.

The proposed rule changes make it significantly more difficult for the government and interested members of the public to exercise the government's rights to protect the public interest in publicly funded inventions and technology by, among other things, restricting the grounds for exercising the march-in rights, narrowing the inventions to which government rights attach, restricting standing to appeal government licenses, and making the licensing process less transparent. The totality of the changes introduced by the proposed rule alter the bargain that the Act was designed to strike between private incentives to develop publicly funded technology and the public interest in accessing the resulting products and services in ways that undermine the public interest with no evidence of any countervailing public benefit from the proposed changes. The result is a net transfer of ownership interests and control rights in publicly funded technology to the private sector at the expense of the public interest.

3. *There is no basis in the Bayh-Dole Act for restricting "march-in rights" to exclude consideration of excessive pricing as the sole grounds for the government to exercise its march-in authority.*

There has been an ongoing public outcry about the lack of affordability of prescription drugs. Indeed, many drugs are so expensive that they remain out of reach for patients who cannot afford the most comprehensive health insurance coverage. High drug prices also create unsustainable burdens for government entities tasked with paying the bill for publicly insured patients. Most of the petitions for the exercise of march-in rights under the Bayh-Dole Act involve issues of reasonable access to life-saving drugs that have been developed at least in part through the use of federal taxpayer dollars.<sup>4</sup> In many cases the largest, or even the sole, barrier to public access is the excessive price of the life-saving drug, with the most recent petition involving a wholesale

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<sup>3</sup> See 35 USC 203 – March-in Rights.

<sup>4</sup> See Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will The Agencies Ever Go Marching In?*, 109 NORTHWESTERN UNIVERSITY LAW REVIEW 1083, 1099 (2015) (discusses the march-in petitions that have been brought since the Bayh-Dole Act was passed).

price of over \$100,000 a year.<sup>5</sup> In an era of soaring drug costs where federal and state measures to control drug prices have largely failed, removing a mechanism that could be harnessed to tackle the problem of excessive drug pricings seems not only unsupported, but also unwise. It is in this context of heated controversy over drug prices that the NIST proposal over march-in rights, a proposal that is aligned with the pharmaceutical industry position on drug pricing, should be reconsidered.

Pursuant to 35 USC Section 203 and 37 CFR Section 401, the Bayh-Dole Act authorizes the government to “march-in” and issue a compulsory license to a federally funded invention if the contractor fails to achieve “practical application” of the invention. “Practical application” under this section is defined as manufacturing, practicing, or operating a subject invention “under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulation available to the public on reasonable terms.”<sup>6</sup> There is no further definition of or restriction on what constitutes “reasonable terms.” Indeed, this language has previously been recognized to include excessively priced inventions<sup>7</sup> and some members of Congress have previously suggested a contrary approach – to provide more guidance to the NIH to grant rights based on price.<sup>8</sup> The NIST proposal would unduly limit the march-in authority by stating that such authority “shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.”

In order to maintain the balance of public and private interests that sustain the current model of public funding of R&D that is provided to the private sector for commercialization, there must be some mechanism for limiting the private sector control over the price of the resulting technology. This mechanism must be robust enough to allow for reasonable access to the resulting technology. The intended role of the march-in mechanism is precisely to balance private interests in profit and the public interest in reasonable access. What is reasonable may take into account a variety of economic factors, including the cost of production, the need to earn a reasonable return on investments in commercialization, a reward for risk taking, on the one hand, but also the ability to manufacture and supply the product in quantities sufficient to meet critical public health needs and the affordability of the price that is charged for the product on the other. In at least some cases, the price of technology developed under the Bayh-Dole Act is a crucial if not *the* singularly most important element of this calculus.

If life-saving technologies are only made available at prices that are prohibitively expensive to large segments of the public, and therefore those who are most in need cannot access the relevant products, this would defy the plain meaning of the words “reasonable access.” The NIST proposal thus effectively rewrites the bargain struck under the Bayh-Dole Act to diminish the

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<sup>5</sup> See, e.g. John R. Thomas, *March-In Rights under the Bayh-Dole Act*, Congressional Research Service, 9 (2016).

<sup>6</sup> 37 CFR Section 401.14.

<sup>7</sup> See, e.g., Peter Arno & 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*, 75 TUL. L. REV. 631 (2001).

<sup>8</sup> See, e.g., Michael Mezer, *Lawmakers urge NHS to exercise march-in rights to fight drug costs*, Raps.org (Jan 11, 2016), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/1/lawmakers-urge-hhs-to-exercise-march-in-rights-to-fight-higher-drug-costs>.

scope of the public interest without any countervailing requirement on the private sector to justify the reasonableness of its prices and the resulting negative implications for access.

4. *There is already too little transparency in the licensing of government funded inventions to the private sector, and the proposed change to 37 CFR 404.7 to further limit disclosure requirements by removing the requirement that agencies notify the public of the identity of prospective licensees should be rejected.*

We note that, as currently structured, processes governing the transfer of publicly funded technologies from the public to the private sector already occur under circumstances that, although facially compliant with disclosure requirements established in the Patent Act, provide the public with virtually no meaningful information about the underlying licensing agreements.<sup>9</sup> Additional erosions to the notification and disclosure safeguards currently in place, as contemplated in the proposed NIST regulations, will further accentuate these transparency deficits. To be an effective mechanism for balancing private and public interests in publicly funded inventions, the Bayh-Dole Act must preserve a meaningful ability for the public to hold federal agencies accountable for their decisions regarding the licensing of federally-owned inventions.

Further, NIST should adopt regulations to require that the nature of all pricing and non-pricing terms of any licenses that are proposed or entered into be reported on as required under 35 U.S.C. Section 202(c)(5)'s periodic reporting on utilization requirement, and 37 C.F.R. Section 401.8. This additional level of regulatory clarity is needed in order for the Federal Government to be able to review and understand whether utilization is occurring in ways that comport with the requirements of the Bayh-Dole Act.

5. *The proposed rule moves in the wrong direction, by limiting the ability to march-in when life-saving technologies are effectively unavailable to the people who need them. To give force to the bargain that the Bayh-Dole Act was intended to strike between the public interest in access and private rights, the Bayh-Dole Act regulations should be amended to: (a) require producers to justify the prices of products that incorporate subject inventions where the prices have been challenged as unreasonable; and (b) specifically allow for the ability to march-in when prices are unreasonable.*

The fact that no march in petition has ever been granted despite repeated requests for march-in to provide public access to life-saving technologies would seem to indicate that the mechanism needs to be strengthened, not weakened. The track record of failure to enforce the public interest in access to life-saving technologies through limited use of march-in rights indicates that it should be easier, not harder, to protect the public interest, and suggests that the proposed rule changes are thus moving in the wrong direction.

Instead of the proposed restriction on grounds for exercising march-in rights based on price, we propose that 37 CFR 401.6 be amended to allow specifically for march-in where prices place products that are essential in preventing death or serious illness beyond the reach of a significant

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<sup>9</sup> See Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE LAW JOURNAL FORUM 651 (2018).

segment of the public and the producer fails to provide adequate justifications for the prices that it charges. For purposes of this proposal, we suggest that “reasonable pricing” could be interpreted in accordance with the framework developed by the World Health Organization’s Advisory Group on Fair Pricing, which specifically considers the setting of prices for pharmaceutical and biopharmaceutical products in ways that are fair to sellers and purchasers alike.<sup>10</sup>

Application of this framework – or of any other operative framework chosen for the purpose of determining reasonable pricing in the context of Bayh-Dole technology transfers – can be made on an *ex post*, case-by-case basis that allows the price-setter to take into account the specificities of each situation, both on the side of the drug manufacturer and on the side of indicated patients who cannot afford overpriced health goods. The current regulations should be amended to assure that such authority is made explicit.

*6. There is no evidence that the proposed changes will increase public welfare or that they are needed to meet any existing public health needs. In contrast, there is evidence that public welfare is being harmed from the excessive pricing of drugs and vaccines that have been developed through the use of public funding. This suggests that the public would be better off, given our current knowledge, with expanded rather than retracted march-in rights.*

To the best of our knowledge, there is no clear evidence that the Bayh-Dole Act in its current form has resulted in the failure to develop and bring to market valuable publicly funded inventions. There is also no clear evidence that a reasonable increase in the scope of march-in rights will have any significant negative effect on biomedical innovation given the magnitude of public funding and the value of the inventions that it generates. In contrast, there is compelling evidence that life-saving drugs covered by the Bayh-Dole Act are being sold at prices that prevent reasonable public access and impose substantial burdens on public payors via programs such as Medicare and Medicaid.<sup>11</sup>

In sum, and in light of the above, we call on the Department of Commerce to reject the changes proposed by NIST and to instead develop a rule that would expand march-in rights along the lines that we have proposed. While it is beyond the scope of this comment, we also express concern about the growing use of measures such as an expanded use of Other Transactions

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<sup>10</sup> See Suerie Moon et al., *Defining the Concept of Fair Pricing for Medicines*, 368 *BMJ* 14726 (2020). Moon and colleagues provide a “framework in which a fair pricing zone lies between a price floor and ceiling. The price floor is the lowest sustainable price at which suppliers can sell a medicine. It can include the cost of R&D, manufacturing, and distribution, other costs, and a fair profit. The price floor should incentivize innovation and maintain competition. The price ceiling is the maximum the buyer can afford. Prices above the ceiling are defined as excessive.” *Id.*, *ib.*

<sup>11</sup> See, e.g. Ways and Means Committee Staff, *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, September 2019 at [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf).

Authority by federal agencies such as The Biomedical Research and Development Authority to evade the limited reserved rights provided for under the Bayh-Dole Act.<sup>12</sup>

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<sup>12</sup> A discussion of issues with the use of Other Transactions Authority in the context of the Department of Defense contracting can be found in M. Schwartz and H. Peters, Department of Defense Use of Other Transaction Authority: Background, Analysis and Issues for Congress, February 22, 2019 <https://fas.org/sgp/crs/natsec/R45521.pdf>, incorporated by reference. Some of the ways in which Other Transactions Authority has been used to avoid Bayh-Dole requirements on publicly funded intellectual property and data are provided in J. Love, KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five using “Other Transactions Authority: that weaken or eliminate Bayh-Dole and FAR Safeguards, July 1, 2020 at <https://www.keionline.org/covid19-ota-contracts>,