



OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
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Submitted through: www.regulations.gov

April 5, 2021

Courtney Silverthorn, PhD
National Institute of Standards and Technology
U.S. Department of Commerce

RE: UC Comments in Response to Notice of Proposed Rulemaking (Docket No. 201207-0327), "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions"

Dear Dr. Silverthorn:

I write on behalf of the University of California (UC) system with regard to the above Notice of Proposed Rulemaking (NPRM) published in the Federal Register on January 4, 2021. We appreciate the opportunity to provide input on the proposed revisions to the Bayh-Dole implementing regulations.

The UC system – comprised of ten campuses, five medical centers, and three affiliated U.S. Department of Energy national laboratories – stands at the forefront of cutting-edge research and technology development. As a system, UC receives more than \$7.5 billion annually of extramural awards to support research conducted throughout all UC locations. UC is a leader in the technology transfer world, and has had the most U.S. utility patents issued annually for at least the last five years. Many of these patents resulted from research carried out under federal funding, illustrating the continued success of the Bayh-Dole Act and its importance to the UC technology transfer enterprise.

UC supports and endorses the March 28, 2021 Association of University Technology Managers (AUTM) comment letter submitted in response to the NPRM and would like to emphasize specific points.

1. March-in Rights (37 CFR 401.6)

UC is concerned that the march-in provision of the Bayh-Dole Act will be misused to allow the government to set consumer prices on successfully commercialized products. This action is not

supported by the statute itself and the authors (Senators Bayh and Dole) have clarified that this is not the legislative intent. Stakeholders active in the innovation ecosystem (e.g., universities, prospective licensees, and investors) need reassurance that this provision will not be changed. Any perceived possibility for misuse or added uncertainty on the interpretation of this provision will have significant harmful effects on the University's ability to collaborate with or license federally funded inventions to an industry partner. The private sector possesses the infrastructure and ability to translate research results and technology into an actual product that can be used by the public. Without a licensee and substantial industry investment of time and resources, the federally funded technology may never be translated into a product as intended by the Bayh-Dole Act. Small startup companies may not be launched if investors shy away from financing entities pursuing federally funded inventions.

According to the Bayh-Dole Act, the government can march in if the patent owner or their 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 the field of use" (35 USC 203(a)(1)). The definition of "practical application" states that the invention's benefits are "available to the public on reasonable terms." However, the reference to "reasonable terms" applies to the terms of the license between the university and the licensee, not the price to the consumer of the resulting product. The law does not provide the government the authority to set prices for successfully commercialized inventions. Such a possibility inevitably discourages licensees and provides a disincentive to research collaborations and the commercialization of federally-funded inventions. Such outcome would be counter to the intent and purpose of the Bayh-Dole Act.

Aside from the plain language and historical intent of the Bayh-Dole Act, it is essential from a public policy perspective to clarify that pricing should not be used as a basis for exercising march-in rights. Allowing the government to indirectly impose price restrictions could consequently harm the careful balance between protecting the public's investment in federally funded research and maintaining industry's incentive to accept the risk involved in developing new technology into a useful product. Preserving the enormous benefits that the Bayh-Dole Act has had on public welfare and growing the U.S. economy requires that this balance be protected.

UC believes that important university-industry partnerships under the current understanding of the Bayh-Dole Act have accelerated the progress of science and technology for the public benefit. Therefore, while in principle UC supports clarifying the march-in provision of the statute with the proposed new regulation, 37 C.F.R. § 401.6(a)(7)(e), it does recommend two (2) modifications to the proposed language. The current proposed language states that "March-in rights shall not be exercised *exclusively* based on the business decisions *of the contractor* regarding the pricing of commercial goods and services arising from practical application of the invention" (emphasis added). **To avoid potential confusion or ambiguity, UC recommends removing (i) the word "exclusively" and (ii) the phrase "of the contractor" so there is needed clarity that consumer pricing may not be used as a factor in determining whether to exercise march-in rights.**

2. Licensing Procedures and the Small Business Preference (37 CFR 401.14(k)(5))

Section 401.14(k)(5) is a new section stating that the contractor “*will* negotiate changes to its licensing policies, procedures, or practices” (emphasis added) when a federal agency determines that the contractor could take “reasonable” steps to more effectively implement the small business preference. Although the small business preference is found in the current Bayh-Dole regulations (401.14(k)(4)) and UC campuses are setting up incubators to foster startup activity, UC remains concerned that this requirement does not take into account the nuances involved around institutional policies and practices that are informed by various elements, including state laws or regulations.. **UC recommends changing “negotiate” to “consider” in the proposed language to encourage a meaningful discussion.**

3. Ten Month Rule (37 CFR 401.14(c)(3))

The proposed revisions to section 401.14(c)(3) would continue to require the contractor to file the non-provisional application within ten months of filing a provisional application, unless the timeframe is extended under 401.14(c)(5). However, universities are at the cutting edge of research and often may file provisional patent applications with minimal data to allow university researchers to contribute to the state-of-the-art body of knowledge through publications and seek grant funding to further explore the discovery. The ten-month period shortens the critical time for researchers to conduct such follow-on research, forcing institutions and inventors to make decisions with reduced information at around the eight-month mark in order to give licensing offices sufficient time to prepare the non-provisional application. In practice, universities typically request an extension, often at the time of notifying the Federal agency of the provisional filing, to allow sufficient time to conduct the additional research, gather data, and make more thoughtful decisions.

UC urges NIST to consider increasing the time period between provisional and non-provisional applications to the full twelve months. This would relieve administrative burden for both federal agencies and institution licensing offices as the number of extension requests would likely decrease. Additionally, the extra time would allow for non-provisional patent applications to contain more robust data.

Finally, UC asks that NIST consider the important points raised by AUTM with regard to the following:

- Information Sharing (AUTM letter, Section II)
- Refiling of and follow-on provisional applications (AUTM letter, Section V)
- U.S. manufacturing waiver (AUTM letter, Section VI)
- Reporting (AUTM letter, Section VII)
- Defining the scope of the government use license (AUTM letter, Section VIII)

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Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Motton", written over a thin horizontal line.

Deborah Motton
Executive Director
Research Policy Analysis & Coordination