

April 2, 2021

RE: Docket ID Number: 201207-0327 regarding 37 CFR Parts 401 and 404

Via eRulemaking portal at www.regulations.gov

**University of Wisconsin-Madison and Wisconsin Alumni Research Foundation Comments
on Proposed Rulemaking for Regulations in Support of the Bayh-Dole Act of 1980**

Dear Dr. Silverthorn,

The University of Wisconsin-Madison (“UW-Madison”) and the Wisconsin Alumni Research Foundation (“WARF”) appreciate the opportunity to respond to the National Institute of Standards and Technology (“NIST”) request for comments on the proposed rulemaking for “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions” under the University and Small Business Patent Procedures Act of 1980, commonly known as the “Bayh-Dole Act” and as part of NIST’s Return on Investment (“ROI”) initiative.

This letter marks our fourth response to requests in some way related to the ROI initiative, following the original “Federal Technology Transfer Authorities and Processes” request in 2018 (Docket Number: 180220199-819-01), comments on the resulting Green Paper in 2019 (Special Publication 1234), and our response regarding improvements to the iEdison System for reporting federally funded inventions in 2020 (Docket Number: 191126-0092).

WARF and UW-Madison reiterate our comments from those early submissions commending NIST for its continued leadership in guiding and strengthening the Bayh-Dole regulatory regime. We continue to be impressed with the thoughtful, professional, and collaborative nature of the ROI Initiative. As the process completed the rulemaking stage, we congratulate Acting Director of the Technology Partnerships, Dr. Courtney Silverthorn, now former Undersecretary of Commerce and NIST Director, Dr. Walter Copan, and everyone at the agency for everything they have accomplished with this initiative.

As partners for almost a century in the oldest continually operating university technology transfer operation, UW-Madison and WARF understand the importance of strong relationships for realizing the full potential of federally funded research. We are aware and



wish to fully associate ourselves with the comments submitted by our colleagues at AUTM, the leading professional association for the technology transfer profession, as well as by Joseph P. Allen, Executive Director of the Bayh-Dole Coalition and friend of longtime WARF patent counsel, the late Howard Bremer. Howard and Joe worked closely together to help pass the Bayh-Dole Act. We are proud to support and continue their legacy.

We wish to offer our overall support for the proposed rulemaking, while also offering the following specific comments to emphasize changes we believe to be of particular importance and to offer select opportunities where additional edits would offer further clarification.

Section 401.6 – Exercise of March-in Rights

Price should not be a factor in considering the exercise of march-in rights under the Bayh-Dole Act. The original authors and sponsors of the legislation added a march-in provision to the act to ensure the successful licensing of an invention. The language has no bearing on the consumer market for that invention. This was true of the original intent of Congress and has continued to be true over more than forty years of widespread practice between technology transfer professionals and federal funding agencies.

We therefore appreciate the rulemaking clarification “that march-in rights shall not be exercised” on the basis of “the pricing of commercial goods and services arising from the practical application of the invention.” However, we also agree with AUTM and Joe Allen that removing the words “exclusively” and “of the contractor” would further clarify that price controls have no bearing on march-in rights.

As academic institutions involved in technology transfer, UW-Madison and WARF rely on strong, clear intellectual property protections to ensure our researchers retain control over the ideas produced in their laboratories. Patents also enable us to build relationships with external partners capable of building the capacity to turn those ideas into tangible goods and services that benefit society.

But patents do not allow us to determine the price of the final product. In fact, antitrust regulations prohibit patent holders from setting the prices charged by our licensees. Further, many of the products that result from our research combine our patented technologies with intellectual property from other owners. For these reasons, marching in due to price would violate our rights as government contractors, interfere with contractual relationships necessary to develop technologies, and prevent those technologies from reaching the market.

In short, the misuse of march-in rights for the purpose of price control would punish academic patent holders like us for a result over which we have no control.



We understand that many of those expressing concerns about this proposed change have cited access to medicines as their primary motivation. We share their motivation to provide health access, but we disagree with their interpretation of the law, and oppose abuse of march-in rights they propose. Our university campus includes the UW-Madison School of Medicine, the hospital and clinics at UW Health, and dozens of experts in medical research, regenerative medicine, biology, and related academic disciplines across multiple academic departments and the Morgridge Institute for Research. Curing disease, treating patients, and providing access to medicines are core components of the purpose of all research universities and to the specific public service mission we call the Wisconsin Idea. That longstanding mission informs our conclusion that march-in rights for price control would be ineffective, inappropriate, and counterproductive to public welfare.

Section 401.14 – Licensing Procedures, Ten-Month Rule, Refiling of Follow-On Provisional Patent Applications, U.S. Manufacturing Waiver, Defining the

For the proposed changes to section 401.14, we support the recommendations as enumerated under roman numerals II-VI and VIII in the comments submitted to AUTM under this same docket number.

Section 401.14 – Federal Reporting

We welcome the annual reporting based on the data that federal agencies already collect as part of the Bayh-Dole regulatory process. We would like to emphasize the importance of strong database tools for the collection of this information, which is why we support the continued adoption of an improved iEdison system across all federal agencies.

We therefore concur with AUTM’s recommendation that all federal agencies be required to use iEdison and that reporting required by agencies be limited to the information required by federal law. In addition to creating a uniform set of contractor-provided metrics, the universal adoption of iEdison would avoid any additional burden being placed on our staff as a result of the new annual reporting.

About University of Wisconsin–Madison

The University of Wisconsin–Madison is a public land-grant university and prolific research institution, with 13 schools and colleges; 9,000-plus courses; 200-plus undergraduate majors and certificates; 250-plus master’s, doctoral, and professional programs; 2,000-plus faculty experts; and more than 45,000 students. The Office of the Vice Chancellor for Research and Graduate Education (OVCRGE) oversees more than \$1.2 billion in annual research expenditures, a figure that puts UW–Madison among the top 10 in the nation among universities for volume of research. The office also includes administration of 17 cross-campus research and service centers, and maintains oversight of the Graduate School, which has an



annual budget of \$160 million and is responsible for 9,400 graduate students in 150 master's and 120 doctoral fields.

About WARF

A nonprofit foundation incorporated in 1925, WARF has a founding purpose "to promote, encourage, and aid scientific investigation and research at and within the University of Wisconsin-Madison." In pursuit of that mission, we have funded more than \$3.4 billion in cumulative research grants to UW-Madison when adjusted for inflation. WARF also serves as the designated technology transfer office for UW-Madison, and in that capacity, we have acquired close to 4,000 patents, including 2,000 active patents with an additional 375 invention disclosures and 60 revenue-generating licenses each year. WARF's efforts are devoted to furthering the historic outreach mission of our state university known as the "Wisconsin Idea."

Sincerely,

Erik Iverson
Chief Executive Officer

Michael Falk
Chief IP & Licensing Officer

Stephanie Adamany
General Counsel