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Submitted via Email and Regulations.gov

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From:

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Subject: Joint Association Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327)

Dear Dr. Silverthorn,

Our associations jointly provided comments on NIST's Return on Investment Initiative (ROI) in July 2018. Our comments expressed appreciation of NIST's evaluation of existing practices, policies, regulations, and/or laws that promote the transfer of Federal technologies and their practical application through commercialization by the private sector. We noted that our member institutions long have engaged in the transfer of federally funded technologies for commercialization, and the remarkable success of these activities under the framework provided by the Bayh-Dole Act. As set forth in the NPRM, the ROI "Green Paper" findings noted potential changes to the Bayh-Dole implementing regulations that could improve compliance, enhance a contractor's ability to commercialize subject inventions, and increase the return on investment of Federal funding through new goods and services to the public. The NPRM implements a number of these findings through proposed changes to the Bayh-Dole implementing regulations (37 CFR 401 and 404).

Our comments deal primarily with the changes proposed to Part 401 *Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants Contracts and Cooperative Agreements*.

1. **March-in Rights.**

Included in the NPRM is a provision that **march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention (**401.6 (e)). In our previous comments we stated that "misuse of Bayh-Dole march-in rights to control drug prices, will impede the creation of new drugs by discouraging university and medical school licensees from making the substantial additional investments necessary to take federally funded university-based research from the laboratory to the bedside. … if the scope of applicability of march-in rights is broadened beyond Congress's original intent, the private sector will be hesitant or unwilling to license federally funded inventions from universities, potentially chilling progress against some of our costliest and most formidable diseases, to the detriment of public health and safety."

Our associations fully share the widespread public concerns about the high costs of prescription drugs and therapeutics. We appreciate that finding solutions to this issue is a priority for policymakers. However, it also is crucial that the solutions are appropriate and effective in addressing the problem, and do not create significant unintended deleterious consequences, such as discouraging critical innovations and the ability of our institutions to transfer their discoveries to the private sector for further development to benefit the public. While there have been repeated calls for the use of march-in rights to address this problem, we do not believe it is an appropriate remedy. Focusing on one subset of patents—those that have received federal government funding—and failing to address the larger issue of drug pricing is not good public policy.

We generally concur in the comments on the march-in provisions submitted by the Association of University Technology Managers (AUTM). As AUTM states, "concerns remain among universities and their licensees that the march-in provision of the statute will be misused to allow the government to set end user prices on successfully commercialized products… it is important to provide reassurance to stakeholders (e.g., universities, licensees and prospective licensees, investors) and federal agencies implementing the law, as even the slightest perceived potential for misuse will have severe detrimental effects on our ability to continue to successfully translate federally funded inventions to the marketplace to improve the standard of living and contribute to the growth of the U.S. economy." For these reasons, our associations support a clarification that **consumer price may not be used as a basis for exercising march-in rights**, as provided in the proposed change to 37 CFR 401.6(e). A similar clarification could be added to 401.14(j). We believe other remedies need to be explored to address consumer pricing issues, that will better address the concerns without adversely affecting the successful Bayh-Dole Act balance that has resulted in the availability of drugs and therapeutics that would not have existed otherwise.

We also agree with AUTM's suggestion to delete the term "exclusively" from the proposed clarification. Consumer price should not be considered regardless of the grounds for the march-in request. We are neutral with regard to AUTM's other suggestion to delete the phrase "of the contractor." We recognize the phrase is consistently used throughout the regulations.

2. **Government Use License**

In the NPRM NIST asks for comments on specific revisions to the language in § 401.14(b) that could help clarify the existing scope of the Government Use License for owners and licensees working to achieve practical application of subject inventions. We agree with AUTM that licensees frequently misunderstand or incorrectly interpret the breadth and scope of the statutory language defining the government's right to use resulting inventions, which can complicate licensing negotiations. Our associations strongly supported Finding 1 in the final ROI Green Paper that **the scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use, provide, or consume those goods and services.** We were disappointed that this provision was not included in the NPRM, and strongly urge NIST to include it in the final rule, for the reasons stated in the Green Paper. This could be accomplished by an addition to 37 CFR 401.2 and a corresponding clarification to 401.14(b).

3. **U.S. Manufacturing Waiver**

The NPRM also asks about other changes to these regulations, consistent with current law, that would accelerate the transfer of federally funded research and technology to entrepreneurs, or otherwise strengthen the nation's innovation system. We concur with AUTM's suggestions to consolidate the agency waiver process; provide for automatic grant of waivers when there is a lack of agency response within a specified time period, and to use iEdison to manage the waiver process. In our comments on the ROI we expressed concerns about the compliance difficulties. These are compounded by slow or, in some cases, complete lack of responses by agencies to waiver requests. The AUTM suggestions would significantly improve the process.

4. **Other Changes**

We generally concur with the other AUTM suggestions as well. We previously had expressed concerns to NIST about the ten-month rule for filing non-provisional applications, and had urged NIST to extend the period. The AUTM recommendations reinforce that point. We also share the concerns about possible requirements for agency approval of follow-on provisional applications. We have consistently advocated for a requirement for all agencies to use iEdison, and strongly agree with the AUTM comments on this point. We urge NIST to consider AUTM's other suggestions with regard to protection of confidential or proprietary information and the licensing provisions implementing the small business preference.

While not directly affecting our member institutions, we believe the changes proposed to Part 404, *Licensing of Government Owned Inventions*, are generally sound and consistent with the ROI goals of accelerating the transfer of federally funded research and strengthening the nation's innovation system. These include particularly the changes to 404.1(b) on royalties, 404.2 on licensing payments, 404.7 on exclusive and partially exclusive licenses, and 404.11(a)(3) on standing for appeals.

5. Clarification

The definition of *subject invention* in the second sentence of 401.14(a)(2) is inconsistent with the statutory definition and the correctly stated definition in the first sentence of the section. We presume this is inadvertent and will be corrected in the final rule.

Conclusion

We want to express appreciation to NIST for its continued stewardship of the Bayh-Dole Act. The Act has been critical in enabling American innovation and the tremendous success of university technology transfer over the past forty years. We believe the proposed changes overall will enhance and strengthen the transfer of federally funded inventions and further the objectives of the RFI. However, we also understand that many concerns have been expressed to NIST about the need to address the high costs of drugs, which is an extraordinarily significant problem in this country. While we do not believe use of march-in rights is an appropriate remedy for these concerns as discussed above, we stand ready to work with NIST and other federal agencies on possible solutions.

We would be happy to provide more information and further discuss our comments with NIST.

The American Council on Education (ACE) is the major coordinating body for American higher education. Its more than 1,700 members reflect the extraordinary breadth and contributions of four-year, two-year, public and private colleges and universities. ACE members educate two out of every three students in accredited, degree-granting U.S. institutions. The Association of American Medical Colleges (AAMC) is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. The Association of American Universities (AAU) is an association of 63 U.S. and two Canadian leading research universities that transform lives through education, research, and innovation. AAU member universities collectively help shape policy for higher education, science, and innovation; promote best practices in undergraduate and graduate education and strengthen the contributions of leading research universities to American society. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of over 240 public research universities, landgrant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.