USF
UNIVERSITY OF
SOUTH FLORIDA

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National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Re: Docket ID No. 180220199-819-01

Upon reviewing the docket listed above, the University of South Florida (USF) has several thoughts it appreciates the opportunity to share regarding increasing the commercialization of federally funded research and development.

Bayh-Dole is widely acknowledged as a success

The Bayh-Dole Act of 1980 (35 USC 200 et seq.) is one of the most effective pieces of legislation enacted and its fundamental principles must be preserved. Bayh-Dole created incentives and authority for universities and non-profit organizations to create best practices and models that enabled the United States to become the acknowledged leader for transferring government funded R&D to industry and new startups. Because the clear, predictable rules of Bayh-Dole have been in place for almost 40 years, partnering companies have confidence that universities and other non-profit organizations can be reliable research partners. Since its passage, the United States has seen a huge positive impact on its economy from the many developments of inventions created at universities across the nation. It is estimated that well over $1 trillion of economic impact has benefited the nation, creating with it thousands of new products and companies and millions of jobs.

A strong patent system is a requirement to the successful commercialization of federally funded R&D

One of the foundations that Bayh-Dole depends upon is a strong, reliable U.S. patent system. Uncertainties and inconsistencies in our current U.S. patent system create significant hurdles for the successful commercialization of federally-supported R&D and must be rectified if the United States wants to continue to be the leader in bringing new technologies to market.

To ensure the strength of our patent system, issues related to uncertainties in the scope of patent eligible subject matter; the Inter Partes Review (IPR) process; and the grace period (35 USC sec. 102(b)(1)(B)), as interpreted by the USPTO, must be addressed. USF supports the statements on these matters provided by the Association of University Technology Managers (AUTM) and the

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Higher Ed Associations (The Association of American Universities, Association of Public and Land-grant Universities, and the Association of American Medical Colleges).

A culture supportive of innovation may be the most critical factor for sustained successful commercialization

Universities, research institutions and federal labs all fill an important role in performing fundamental, federally funded R&D, but effective innovation and commercialization flourishes where the institutional culture provides real rewards and incentives for participation.

Founded in 2010 at the University of South Florida, The National Academy of Inventors (NAI) recognizes and encourages academic invention, enhances the visibility of academic technology and innovation, encourages the disclosure of intellectual property, educates and mentors innovative students, and translates the inventions of its members to benefit society. Since its founding, the NAI has played a vital role in changing the academic culture of valuing patents and commercialization within its 215+ member institutions worldwide.

The NAI's efforts, which have spurred the important conversation about the culture of academic institutions in supporting commercialization, resulted in a paper titled, "Changing the academic culture: Valuing patents and commercialization toward tenure and career advancement," that was published in Proceedings of the National Academy of Sciences (PNAS). Since then, this important initiative continues to gain national attention with a number of universities successfully changing their culture by incorporating technology transfer activities as a factor for gaining tenure and promotion, and bringing on new hires.

Encourage the Federal Labs to participate and join associations such as the NAI to help start the conversation that has been so successfully sparked in universities and effect a change in culture supportive of commercialization. Make commercialization a federal lab priority by developing and providing real rewards for programs and individuals who take the initiative to heart. In any organization, employees are not going to adopt new behavior when it is apparent that incentives and rewards do not match administrative directives. If technology transfer does not factor into performance reviews, promotions or funding allocations, this leads to cultural barriers in the federal system, from top management to bench scientists.

Success of these efforts should not be measured primarily by revenue, but by contributions to broader economic prosperity and societal impact. New methods and metrics with universal definitions should be developed to effectively capture impacts and improve measurements of effectiveness across the various recipients of federal funding.

Consistent interpretation and development of Conflict of Interest Rules

USF supports the easing of barriers for federally-funded investigators to participate in commercialization and startup activities. If any federal agencies other than NIH plan to promulgate conflict of interest rules, they should align with the standard conflict of interest

policies of NSF for a consistent application of conflict of interest rules across agencies. In addition, individual programs, such as the NSF SBIR program, should not add more restrictions beyond the standard agency policy. USF supports the Higher Ed association's submitted comments on issues related to conflicts of interest, which are reproduced below.

The National Academies' 2016 report, Optimizing the Nation's Investment in Academic Research (https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory), correctly observed that "[Conflicts of Interest] are inevitable at research institutions, whose missions include the promotion of the public good by both creating new knowledge and facilitating the transfer of that knowledge to the private sector."[1] As the Academies note, because the academic mission is to benefit the larger society, academic research institutions and individual faculty and scientists must closely monitor research activities for conflicts of interest, and ensure that, "an individual's decisions or actions are not unduly influenced by considerations of personal financial gain."

Indeed, federal regulators, agencies and universities moved diligently to address and manage the review of such conflicts, beginning with new regulations in the 1990s and subsequent reforms. However, in 2012, the Public Health Service (PHS), responding to intense political and public pressure, revised the regulations around financial conflicts of interest, substantially "ratcheting up" the obligations of PHS-funded research institutions, including those performing research funded through the National Institutes of Health.

Among other requirements, the new rule expanded disclosure and review of researchers' financial interests beyond those related to their funded research to any that related to their academic responsibilities, including those for education, administration, and clinical care, and all reimbursements of sponsored travel. The rule requires investigators to disclose all financial interests meeting certain criteria to their institutions, and transfers responsibility for judging whether those interests were related to the investigators' ongoing research from the investigator to the institution. It extended review of financial interests to include compensation received from many nonprofit entities and organizations. Notably, the rule reduced the threshold for a financial interest an investigator would need to disclose to an institution for review from $10,000 to $5,000, without any empirical basis for why the new threshold would be more effective.

We believe that the PHS conflict of interest regulations have both dissuaded some faculty from working with industry to commercialize their ideas and placed significant new cost burdens on universities without a concomitant measurable reduction in conflicts of interest.

When the PHS conflict of interest rules were proposed, the Higher Ed associations, along with several other scientific societies, associations, and companies, expressed concerns that the new rules could have a "chilling effect" on universities' and their faculty members' willingness to

[1] National Academies, Optimizing the Nation's Investment in Academic Research (2016), available at https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.

engage in relationships with industry or other technology commercialization activities.[2] We continue to believe that the PHS disclosure requirements discourage rather than encourage researchers' interest in pursuing activities and relationships that can help lead to commercialization of government-funded ideas.

At the same time, the conflict of interest regulations have added significant additional costs to institutions for what appears to be a very limited benefit. A study conducted by the Association of American Medical Colleges (AAMC) with the assistance of its member medical schools and teaching hospitals found that the 2012 rule substantially increased the administrative burden for institutions complying with the new regulation.[3] Despite the increased regulatory burden, the number of actual financial conflicts identified did not show a commensurate increase. The study could not ascertain the degree to which the new rules have discouraged investigators from engaging in activities that could potentially promote the transfer of new knowledge into commercial activity, out of concerns for the additional—and we believe non-productive—requirements of the 2012 rule. Section 2034(a) of the 21st Century Cures Act requires that the Department of Health and Human Services (HHS) review all conflict of interest regulations and policies of funding agencies, including: the minimum threshold for reporting financial conflicts of interest; the timeline for such reporting by NIH-funded institutions; whether reporting requirements are appropriate for, and relevant to, research funding awards; and whether training modules the NIH has created for financial interest disclosure should be updated.[4]

Create a collaborative R&D tax credit to encourage increased industry collaboration

To facilitate increased collaborative efforts between universities, industry, and federal laboratories, language in the basic research tax credit which narrowly defines basic research projects as "not having a specific commercial objective" should be broadened. At a minimum, Congress should delete such language from current law and allow any research expenditures at universities to qualify for the basic research credit. Also, industry should receive an additional tax incentive to conduct collaborative research with universities and federal laboratories.

Remove barriers for universities with bond-financed facilities to work with industry

Amend current tax law to allow for increased public-private use of bond financed facilities. For example: H.R. 1819 of the 114th Congress would amend the Internal Revenue Code to create

[2] "Proposed Revisions to DHHS Conflict of Interest Policies: Concerns About Effects on Commercialization of Research," Summary of public comments on May 21, 2010 Department of Health and Human Services public comments on proposed revisions to "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" regulations. Compiled by the Association of American Universities, September 9, 2010. See https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Research-Administration-Regulation/Conflicts-of-Interest/Conflict-of-Interest-Regs-Concerns-about-Chilling-Impact-of-Changes.pdf.
[3] Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project (April 2015), available at https://www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf.
[4] 21st Century Cures Act (Public Law 114-255), available at https://www.congress.gov/bill/114th-congress/house-bill/34/.

more flexible standards under which public-private research activities at tax-exempt bond financed research facilities can occur.

Commerce should explore streamlining procedures and adopt best practices across all federal agencies

Individual agencies may have certain practices that provide clarity on implementation of the Bayh-Dole Act and encourage commercialization of the technology that should be applicable across agencies. Under Bayh-Dole, universities and non-profit organizations have created best practices and models that enabled effective transfer of government funded R&D to startups and industry while providing partnering companies the confidence that universities and other non-profit organizations can be reliable research partners. Expanding the toolkit and expertise of the federal labs and other federally funded licensors to license intellectual property other than patents, including copyrights, materials, and data, would enhance flexibility in licensing practices and mirror common commercial licensing practices. Encourage the Federal Labs to provide greater transparency on their licensing processes.

Increase interactions between federal labs and industry

In order to ensure that federal lab scientists and industry scientists are able to work together in the most productive ways, it would be helpful to increase their interactions and familiarity with both systems through mechanisms such as sabbaticals and permitted consulting. Incentivize and encourage federal lab employees to attend conferences focused more focused on applied research and business objectives that are frequented by industry.

This can be done formally through contractual methods like CRADAs and GOALIs, or informally through events such as participation in various “Industry Days” conferences. Increase interaction with the business community generally, such as grant review committees with members both from nonprofit and from the for-profit sector.

It would be a misuse of Bayh-Dole march-in rights to control drug prices

Twenty years after enactment, opponents of Bayh Dole sought to reinterpret the march-in provision, alleging that agencies can force the licensing of competitors if the price of a successfully commercialized product isn't "reasonable" according to their determined standards. When this theory first arose, Senators Bayh and Dole immediately rejected it as completely contrary to their law. Numerous attempts to petition agencies to march-in as a means of price control have all been correctly rejected by funding agencies. However, the challenge is that individual agencies are being petitioned to interpret the meaning of the statute separately, which threatens the uniform application of Bayh-Dole. Through an oversight office, the Department of Commerce should ensure that the statute continues to work as intended by clarifying that agencies have no authority under the Bayh-Dole Act to question the price of a successfully commercialized product. The current uncertainty is a major concern of the life science industry, which is responsible for many of the most significant benefits generated under the law. Erosion

of this principle would almost certainly result in companies being reluctant to invest in the development of federally-funded inventions.

Provisions in the New Bayh-Dole Implementing Regulations pose systematic challenges to the effective transfer of technology

We believe the changes in the revised Bayh-Dole Act implementing regulations are mostly positive. However, USF supports the statements of AUTM and the Higher Ed Associations expressing concern about some of the changes, particularly regarding certain time periods specified in the regulations. Included in the highlighted changes of concern include: 1. Removal of the 60-day time for funding agencies to request title upon learning of a contractor's failure to disclose an invention or elect title may create an indefinite cloud over the invention title affecting industry relationships and the promotion of commercialization; 2. Increase in the required notification period for contractor decisions not to continue non-provisional patent prosecution is not reflective of the realities of the time it takes to make decisions to proceed with patent protection or supportive of the creation of new start-up companies, and 3. The new requirement for a contractor to file a non-provisional patent application ten months after filing a provisional application is troubling and substantially increases burdens without any clear benefit to the government.

Increase opportunities for funding and development of federal funded R&D

Expand the national I-Corps program

The National Science Foundation (NSF) I-Corps program helps train and prepare scientists, engineers, and graduate students to extend their focus beyond the university laboratory and to accelerate the economic and societal benefits of basic research projects that have commercialization potential. The American Innovation and Competitiveness Act authorized the I-Corps at NSF, and encouraged its expansion. Since its creation in FY2011, several other federal agencies have funded I-Corps cohorts and further expansion should be encouraged.

Support institutional grants to create new funding for institutional proof of concept/translational research awards

Existing SBIR/STTR funding presumes there is already evidence that specific research or technology has enough value to attract further investment. However, in many cases there still exists a dearth of funding needed to push technologies across the "Valley of Death." This often prevents universities from moving new research discoveries and technologies quickly into the marketplace and sometimes prevents such transfer entirely. The high level of risk associated with these early stage technologies has left companies, angel investors, and venture capitalists even less willing to invest in the proof-of-concept, scaling-up, and modeling required to explore the commercial value of such advances. The current SBIR program begins to address this issue, but it falls short of providing the necessary early stage support for "proof-of-concept" research. The proposed TRANSFER ACT, previously passed by the U.S. House of Representatives, builds on

the NIH's Research Evaluation and Commercialization Hub (REACH) program, an early-stage, "phase zero" proof-of-concept pilot program, previously authorized under Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81). Institutional grants such as these would help more universities and federal laboratories develop the required infrastructure to work with their faculty to successfully commercialize their research discoveries.

USF appreciates the opportunity to provide comments on the federal technology transfer process. If there are any questions on the material provided herein, or if further information or clarification is needed, please contact Valerie McDevitt, Associate Vice President for Technology Transfer, at vmcdevitt@usf.edu.

Sincerely,

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