



July 30, 2018

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 National Academy of Inventors (NAI) has several perspectives and appreciates the opportunity to share these in the context of increasing the commercialization of federally funded research and development.

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

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

Founded in 2010 at the University of South Florida, The mission of the National Academy of Inventors (NAI) is to recognize and encourage academic invention, enhance the visibility of academic technology and innovation, encourage the disclosure of intellectual property, educate and mentor innovative students, and translate the inventions of its members to benefit society. Since its founding, the NAI has played a vital role in changing the culture of valuing patents and commercialization within its membership of 215+ academic institutions worldwide.

The NAI's efforts have spurred the important conversation about the culture of academic institutions in supporting commercialization that resulted in a paper, "Changing the academic culture: Valuing patents and commercialization toward tenure and career advancement," 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 evolving their respective cultures by incorporating technology transfer activities as a factor for gaining tenure and promotion, and bringing on new hires.

The NAI specifically wants increased membership of the Federal Labs and federal agencies. The NAI board consists of two non-voting board members representing the United States Patent and Trademark Office and the Department of Defense (SPAWAR). The NAI would be receptive to representation from the Federal Labs to help show and develop best practices among all our members.

We enthusiastically endorse the Federal Labs participation in the NAI. We anticipate that such participation will catalyze positive change resulting in the growth of commercialization. Making commercialization a priority will, over time, demonstrably change the culture and, likely, the professional development of Federal Lab scientists. The alignment of additional incentives that we have observed in the academic sector has driven new behavior and productivity, an outcome that is expected when applied in other sectors, including the Federal Labs. Inclusion of technology transfer in performance reviews, promotions or funding allocations will favorably disrupt cultural barriers extant in the federal system, from top management to bench scientists. The best practices learned from member institutions of the NAI could make a large impact on the culture within Federal Labs.

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.

Bayh-Dole is widely acknowledged as a success

The Bayh-Dole Act of 1980 (35 USC 200 et seq.) is an exemplar of effective legislation 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. NAI supports the statements on these matters provided by the Association of University Technology Managers (AUTM) and the Higher Ed Associations (The Association of American Universities, Association of Public and Land-grant Universities, and the Association of American Medical Colleges).

Consistent interpretation and development of Conflict of Interest Rules

NAI 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. NAI supports the Higher Ed association's submitted comments on issues related to conflicts of interest. This is another key area where the federal agencies would gain benefit from membership in the NAI.

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 more focused on applied research and business objectives that are frequented by industry.

This can be done formally through contractual methods like CRADAs and NSF GOALI program engagement, 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 the nonprofit and for-profit sectors.

Participating in the NAI annual meeting would provide an avenue for scientists within the federal agencies to interact with industry and also learn best practices from top research universities and non-profit institutes. Furthermore, many NAI member institutions have a federal lab affiliation that would allow these labs to learn from the technology transfer offices and their industry partners for commercialization.

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, NAI 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: 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 prepares 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 exploring 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.

NAI 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 Spencer Montgomery at smontgomery@academyofinventors.org.

Sincerely,

A handwritten signature in blue ink that reads "Paul R. Sanberg". The signature is fluid and cursive, with the first name "Paul" being the most prominent.

Paul R. Sanberg, Ph.D., D.Sc.
President
National Academy of Inventors