Office of the Vice Provost for Research

National Institute of Standards and Technology
Via email to roi@nist.gov

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RE: Docket Number 180220199-819-01

The University of Pennsylvania (Penn) is a research intensive institution with a robust infrastructure to support technology transfer. In fiscal year 2016, Penn ranked third in the NSF HERD survey with research expenditures including over 650 million dollars in federal research and development support. In that same year, Penn received 111 U.S. patents, facilitated over 600 commercial agreements with the private sector related to Penn-owned technologies and research programs, and supported the formation of 41 start-up companies. We appreciate the opportunity to comment on the NIST ROI initiative.

1. What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?

We have had the opportunity to review the comments to this RFI submitted by the Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Council on Governmental Relations (COGR), and the Association of American Medical Colleges (AAMC) and largely concur with those comments in support of the Bayh-Dole Act of 1980 (35 USC 200 *et seq.*).

2. What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?

We echo the concerns expressed by AAU/APLU/COGR/AAMC regarding the new Bayh-Dole implementing regulations. Penn is particularly concerned by the removal of the 60-day time limit for federal agencies to request title upon failure of a contractor to timely disclose or elect title to a subject invention. We anticipate that commercial entities will view this change as increasing the risks in licensing technology (whether or not federally supported) from entities that receive significant federal funding. Without a defined period, a Federal agency could at any time assert title over rights for a subject invention. If such rights happen to be under a license to a commercial entity this would be highly problematic. The removal of any time limit could very well result in an overall reduction in the transfer of technology by contractors to the commercial sector for public benefit due to the private sector being hesitant or unwilling to take on this additional risk.

We support the objectives of the US manufacturing requirement under Bayh -Dole for products embodying subject inventions (or produced through use of such inventions), in situations where the associated rights are exclusively licensed. On occasion, however, we are unable to identify a suitable US-based entity to license and commercialize a subject invention. Under such circumstances, exclusively licensing the associated rights to a foreign entity is the only feasible approach to commercialization of the subject invention to the benefit of the public. Securing a waiver from a federal agency to the substantial US manufacturing requirement can be extremely challenging. Moreover, the uncertainly associated with whether or not a waiver will be granted, and in what timeframe, can be prohibitive to non-US based entities consideration of exclusively licensing rights associated with such inventions. Moreover, the challenges associated with securing a waiver can be problematic for U.S.

based licensees that may wish to leverage the expertise of foreign companies in the manufacture of products embodying subject inventions or produced through the use thereof.

We have found that obtaining a response from a federal agency for a request to waive its rights to inventors in subject inventions is often challenging. The timeframe for receiving responses to such requests is highly variable, and in our experience, can range from anywhere from two months to nearly two years. Penn has the ability to release its rights to inventor(s) for those inventions where we don't find that a commercial opportunity exists. Unfortunately, for subject inventions, we often do not get approval from the federal government to transfer title to the inventor(s) in a timely fashion. These delays negatively impact the willingness of our faculty to go through the release process. Furthermore, uncertainly associated with the timeline for receiving a response from the federal agency can stifle the inventor's efforts to commercialize such subject inventions independently of Penn.

We strongly endorse the AAU/APLU/COGR/AAMC comments regarding March-In-Rights. The private sector is rarely concerned with these March-In-Right because they are a generally well understood and accepted as part of the package associated with licensing federally-funded inventions from academic institutions. With that said, it would be highly problematic if Congress exercised March-In-Rights more expansively than what was the original intent, which would likely result in an unwillingness of the private sector to license federally funded inventions

3. What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?

We echo the proposed solutions articulated by the AAU/APLU/AAMC. In addition, we would strongly advocate for a reinstatement of the 60 day time period for federal agencies to request title upon learning of a contractor's failure to disclose or elect title to a subject invention.

Furthermore, we strongly suggest that time limits be imposed on agencies to respond to a request for a waiver of rights to inventors in subject inventions.

Finally, we emphasize the need for a time limit to be imposed on agencies for responding to requests for a waiver from the substantial US manufacturing requirement.

Conclusion:

We greatly appreciate being able to provide comments and recommendations on the NIST ROI initiative. We also support the objectives of identifying improvements and new initiatives to enhance the transfer of federally funded inventions to the private-sector to develop new products, processes, and services, to benefit the public and to increase economic growth.

Sincerely yours,

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