



OFFICE OF THE VICE PRESIDENT - RESEARCH AND GRADUATE STUDIES

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[Submitted electronically to roi@nist.gov]

Dr. Courtney Silverthorn
Deputy Director, Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive, MS 2201
Gaithersburg, MD 20899

**Subject: Request for Information Regarding Federal Technology Transfer Authorities and Processes
(Docket Number 180220199-819-01, 83 FR 19052)**

Dear Dr. Silverthorn:

This letter is sent in response to the Request for Information issued by the National Institute of Standards and Technology (NIST) seeking feedback on the current state of Federal technology transfer and the public's ability to access federally funded research and development through collaborations, licensing, and other mechanisms. The University of California (UC) system is comprised of ten research-intensive campuses (including six academic medical centers) and is affiliated with three U.S. Department of Energy national laboratories. UC is the largest public research university system in the United States and receives substantial federal funding for cutting-edge research and for the training of the next generation of scientists, engineers and entrepreneurs. Federal funding has contributed to UC's development of new technologies and inventions, such as pioneering work in the field of recombinant DNA leading to the launch of the biotechnology industry, therapeutics for the treatment of prostate cancer, and a dynamic skin cooling device that revolutionized laser treatments for vascular birthmarks.

We appreciate NIST's inclusive and transparent process to obtain information through various open forums held throughout the country and to allow substantive time for written comments, enabling the public to provide thoughtful feedback on the important mechanisms to ensure that federally-funded inventions are moved from the research laboratory to the marketplace to benefit the general public.

UC strongly supports the extensive comments submitted by the five higher education associations on behalf of the larger U.S. university community: the Association of American Universities, Association of Public & Land-Grant Universities, Association of American Medical Colleges, Council on Governmental Relations, and American Council on Education. In our response, we highlight certain points and provide additional comments.

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

UC strongly supports the technology transfer principles as embodied in the Bayh-Dole Act of 1980 and implemented through 37 CFR Part 401. The remarkably successful Bayh-Dole Act, under which title to inventions developed with federal funding is retained by the inventing grantee organization, provides a fundamentally sound

framework that allows the inventing institution to further develop and commercialize inventions for the public benefit. Since not all inventions are best developed in the same manner, with a few suggested adjustments discussed below, the Bayh-Dole Act allows sufficient flexibility for the developer to navigate the risky, challenging path toward commercialization. The principles of the Bayh-Dole Act are of critical importance to the continued success of the federally-funded technology transfer enterprise and must be retained going forward. However, UC does believe that there is some room for improvement as discussed below.

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

Recognizing their connectivity, we have combined responses to the second and third questions posed by the RFI.

In the recent revisions to the Bayh-Dole regulations, the 60-day time limit for funding agencies to request title upon learning of a contractor's failure to disclose an invention or elect title was eliminated. The result is that, in effect, the government can elect to take title *at any point* during a patent's lifetime, even after it has been licensed and developed into a commercial product. This will result in a perpetual cloud of uncertainty that will negatively affect the ability to license the invention and promote its commercialization. ***UC therefore requests that the 60-day time limit be reinstated.***

The new requirement for a contractor to file a non-provisional patent application within ten months of filing a provisional application has raised concerns. A strict reading of this regulation (37 CFR 401.14(c)3) would require a provisional application always to be followed by a non-provisional application. However, provisional applications in practice are often filed as cost-effective placeholders to preserve priority in a first-to-file system for potential inventions while commercial and licensing viability is determined. A direct consequence of filing provisional applications is that there will inherently be some provisional applications that are subsequently determined not to be commercially viable and are appropriately left to expire without further investment of resources. This change in the regulations increases the burden on grantees, but does not appear to provide any benefits to the agency.

Many of the recent revisions to the Bayh-Dole regulations appear to introduce a 60-day notification period to facilitate a government agency's assuming prosecution for valuable technology where the contractor decides to discontinue prosecution. Having the contractor notify agencies at ten months from the provisional filing date of its desire to not claim priority to the provisional application would comport with this perceived underlying policy but that is not stated in the rules. Specifically, provisional applications were explicitly excluded from the 60-day notice for abandoning prosecution or defense of patents, implying the provisional application in fact cannot be left to expire. These perceived inconsistencies in the rules lead to potentially different interpretations which may have the unintended result of chilling commercialization and transfer of government-funded technologies. ***Consequently, UC requests that these inconsistencies be addressed, for example, by clarifying that provisional applications may be allowed to expire (with an appropriate notification of such an intent to the funding agency) without a requirement for a follow-on non-provisional application.***

UC supports the provisions of the Bayh-Dole Act, but the U.S. manufacturing requirement (37 CFR 401.14(i)) can make it difficult to find appropriate licensees to commercialize inventions in today's global economy. Furthermore, what constitutes "substantially manufactured" in the regulations is unclear, which can lead to the loss of potential licensees. The process for requesting a waiver to the requirement is also problematic, as the process and result of a waiver request are not transparent. ***UC suggests that technology transfer could be significantly enhanced if some***

reasonable flexibility was added to the U.S. manufacturing requirement, the waiver request process was made more transparent, and agencies were required to respond to such requests within a reasonable time period.

A more general concern is with the potential application of the government's march-in rights under Bayh-Dole. While the intent was that march-in rights provisions would be used only in very narrowly defined circumstances (e.g., in public health emergencies), UC has noted that there has been considerable recent pressure from both advocacy groups and Congress to use the march-in rights for price control purposes, which was not the original intent of the provision, as confirmed by the authors¹. Nor is it the most effective means of addressing the much larger issue of drug pricing. The possibility that the march-in provisions might be used in such a way is understandably concerning for potential licensees, especially in the biomedical fields, and thus a potential roadblock on the path to successful technology transfer. ***Therefore, UC urges NIST to provide clarification on the intent and scope of the appropriate use of the march-in provisions of the Bayh-Dole Act based on the original intent of the authors, particularly with regard to use of these provisions as a mechanism for influencing drug pricing.***

The cost of operating a technology transfer office has increased substantially, particularly as patenting costs have risen, and universities have to carefully decide on which technologies to invest their limited funding. While facilities and administrative (F&A) costs could conceivably be used for technology transfer, the opportunity to do so is limited by the fact that recovery of administrative costs is capped by the federal government and in most cases is already less than the actual costs incurred by universities in the conduct of sponsored research. Therefore, the current lack of direct funding for technology transfer costs is an impediment to the most effective transfer of new technologies from universities to the commercial sector and a barrier to the associated economic development opportunities. ***This could be ameliorated by additional government funding, in the form of direct costs, specifically earmarked for technology transfer expenses.***

Apart from requirements of the Bayh-Dole Act, the current IRS restrictions on private use of facilities financed by tax-exempt bonds sometimes impede partnerships and technology transfer between universities and industry (particularly industry research funding and small start-ups). UC, like most public universities, has many buildings constructed with the aid of tax-free bonds. Since private use regulations currently restrict UC's ability to engage in certain research partnerships with for-profit entities in these buildings - and indeed, this is an issue that is often raised in contract negotiations between UC and companies - there may be considerable opportunities for valuable technology transfer and continued collaboration that are being missed under the current regulations. Further, companies may be encouraged to take their research to locations overseas where there may be fewer and less restrictive regulations on private use of such facilities. ***UC recommends that the tax code be modified to ease such restrictions and therefore allow more innovative relationships between academia and industry, taking full advantage of all of the available facilities – including those financed with tax-free bonds.***

UC, like many universities, has experienced issues surrounding the process of required invention reporting under iEdison, an outdated system that could be more user-friendly. The fact that not all agencies use the same system is in itself problematic and inefficient. Inconsistencies in reporting requirements from one agency to the next (and even within agencies) lead to confusion and unnecessary time and effort that could better be spent engaged in the substance of technology transfer activities. ***UC strongly supports a single, consistent government-wide reporting process using a state-of-the-art, easy-to-use portal that is adequately funded and maintained. Agency requirements for invention reporting should be harmonized.***

¹ See, e.g., Statement of Senator Birch Bayh to the National Institutes of Health (2004), available at <http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf>. See also, CRS Report, "March-In Rights Under the Bayh-Dole Act" (August 2016), available at <https://fas.org/sgp/crs/misc/R44597.pdf>

Finally, because the government has inconsistent approaches toward the handling of federally-funded software inventions, it would be useful for NIST to issue clarifying guidance that would enable universities to more effectively make these inventions available to the public.

4. What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy?

UC supports the expansion of the successful NSF I-Corps program into other agencies. This program helps train academics in entrepreneurship by giving them the tools to effectively commercialize the results of their research.

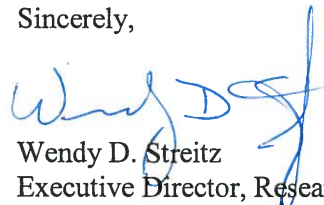
Universities create early stage inventions under their basic research programs, but often there are insufficient funds to bring the technology to a stage of development where prospective industry partners are willing to license the invention and pursue further development and commercialization. Federal funding to assist the development of a prototype or reduce the invention to practice would enable more technologies to move from the research laboratory to the marketplace.

Summary

In conclusion, the continuation of the current Bayh-Dole framework is the single most important requirement for the ongoing success of the federally-funded technology transfer enterprise. However, as mentioned above, there is room for improvement, even within the Bayh-Dole regulations. Lack of funding, problems with the reporting process, and issues with the tax code as it pertains to private use of tax-exempt, bond-financed buildings also present obstacles to the transfer of technology between academia and industry. Further, innovative programs such as I-Corps, may present a model for increased success in this area.

Thank you for this opportunity to comment. We greatly appreciate your efforts to seek stakeholder input regarding the future of federal technology transfer. Please feel free to contact us if you have any questions about the points we note above.

Sincerely,



Wendy D. Streitz
Executive Director, Research Policy
Analysis and Coordination