

Request for Information

Federal Technology Transfer Authorities and Processes

Last day to submit the responses: July 30, 2018

Introduction

In order to advance the President's Management Agenda to modernize government for the 21st century, including the associated Lab-to-Market CAP Goal in coordination with the White House's OSTP, NIST is initiating a Return on Investment (ROI) Initiative [4] with the intent of conducting a comprehensive assessment of the Federal technology transfer system that will identify opportunities to improve Federal technology transfer efforts, policies, and practices. The goal of this effort is to, where appropriate, streamline and accelerate transfer of technology from Federal R&D investments to attract greater private-sector investment for innovative products, processes, and services, as well as new businesses and industries that will create jobs, grow the economy, and enhance national security.

NIST is seeking broad input and participation from stakeholders in Federal R&D, intellectual property, and technology transfer to assist in identifying and prioritizing issues and proposed solutions. This assessment will address: (a) Core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed; (b) approaches to improve efficiency and reduce regulatory burdens for technology transfer to attract private sector investment in later-stage R&D, commercialization, and advanced manufacturing; (c) new partnering models and technology transfer mechanisms with the private sector, academia, other Federal agencies, state, and other public-sector entities to support technology development and maturation; (d) new approaches that will reduce or remove barriers, and enable accelerated technology transfer, with a focus on areas of strategic national importance; (e) better metrics and methods to evaluate the ROI outcomes and impacts arising from Federal R&D investment; and (f) new approaches to motivate significantly increased technology transfer outcomes from the Federal sector, universities, and research organizations.

This information will only be used as input to the Return on Investment initiative. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Instructions

This template is designed to facilitate responses to the RFI. Use of this form is optional.

It is not required to fill out all of the sections, for example a participant may elect to only provide input on one question.

Save and email it to roi@nist.gov.

Contact Information

Full Name	<u>Carl P. B. Mahler, II</u>
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Organization Name	<u>The University of North Carolina at Charlotte</u>
Organization Type	<u>Academic (State university)</u>

Questions

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

The Bayh-Dole Act works very well and should be protected, although its implementation by the Federal agencies can be improved. The Internal Revenue Service's Revenue Procedure 2007-047 is an unnecessary impediment to technology transfer and should be eliminated; if it cannot be eliminated, then the IRS should provide much clearer guidance as to how academic institutions can work within the constraints that it imposes. Finally, the Federal agencies should institute a very small increase (0.5% of awarded funding) to enable awardees to conduct critical experiments and create prototypes so that their research results are more attractive to potential investors and users.

2. What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider those identified in the RFI as well as others that may have inhibited collaborations with Federal laboratories, access to other federally funded R&D, or commercialization of technologies resulting from Federal R&D?

The Federal agencies do not all use a common portal to enable awardees to meet their obligations under the Bayh-Dole Act, nor do they enable awardees to easily find people within the agencies who are empowered to grant exceptions to the Standard Clauses found at 37 CFR 401.14. IRS Rev. Proc. 2007-047 needlessly and senselessly hamstrings adoption of inventions by prohibiting universities from entering into research agreements that include grants of licenses - or even setting the economic terms of licenses - to industrial sponsors who desire to turn research results into products. Federal agencies also generally will not provide the often small amounts of funding that would enable awardees to build prototypes or conduct critical experiments that demonstrate the industrial and commercial utility of research results.

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? Please consider the approaches identified in the RFI.

(1) Require all Federal funding agencies to use the iEdison system to allow awardees to meet their obligations under the Bayh-Dole Act. Currently a number of Federal agencies, including NASA and the Department of Energy, do not use the iEdison portal.
(2) Mandate that all Federal funding agencies designate individuals who are empowered to grant exceptions to the Standard Clauses found at 37 CFR 401.14, and provide contact information for these individuals in the iEdison portal.
(3) Repeal IRS Rev. Proc. 2007-047. Failing full repeal, provide much clearer guidance as to how owners of facilities financed with tax exempt bonds can meet the obligations of this Revenue Procedure.
(4) For awardees who invest in patenting results of Federally funded research, provide supplemental funding in the amount of 0.5% (one half of one percent) of the funded amount in order to enable the awardees to construct prototypes and conduct critical experiments that demonstrate the industrial and commercial utility of the research results.

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? What changes would these proposed improvements require to Federal technology transfer practices, policies, regulations, and legislation?

See attached letter.

Thank you for your time and participation.



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July 20, 2018

Dear Sirs,

These comments are in response to the National Institute of Standards and Technology's Request for Information (RFI) published in the Federal Register, Volume 83, No. 84, page 19052 on May 1, 2018 and more specifically to address "systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D."

As background, I have been a patent attorney in the U.S. (Patent Office Registration Number 35265) for nearly 25 years. I have spent most of that time working in the technology transfer offices of various American research universities (seven years at Case Western Reserve University in Cleveland, OH; five years at Carnegie Mellon University in Pittsburgh, PA; and eleven years at the University of North Carolina at Charlotte). I have maintained active memberships in the Association of University Technology Managers (AUTM) and the Licensing Executive Society (LES) for virtually all of this time. I believe that this experience provides me with a certain depth of experience in how technology transfer occurs from American universities and opportunities for improvement in this area. I am writing in my capacity as the Executive Director of the Office of Technology Transfer at the University of North Carolina at Charlotte.

I would first note that the Bayh-Dole Act of 1980 has served the nation extremely well and continues to do so. You have doubtless heard from AUTM already about the many benefits to the United States, to the economy, and to academia that result from this Act and so I will not go into further detail here other than to say that the Act functions extremely well and needs no significant modifications. This does not mean that improvements cannot be made in how it has been implemented by the Federal funding agencies.

I believe that the Bayh-Dole Act can be made more effective by implementing two changes at the level of the Federal funding agencies. The first such change pertains to the iEdison reporting portal that was created in 1994 by the National Institutes of Health and is now used by over thirty Federal agencies. iEdison works well and provides an excellent way for universities to fulfill their obligations of reporting inventions that result from federal funding, electing or formally notifying the funding agencies of decisions not to elect title to those inventions, and informing the funding agencies of patent prosecution. However, not all federal funding agencies participate in iEdison – for example, neither NASA nor the Department of Energy use iEdison. Universities therefore have increased burdens in meeting their obligations under Bayh-Dole for inventions that result from funding received from those

agencies that do not participate in iEdison. I therefore recommend that all federal funding agencies be mandated to use iEdison as a way for recipients of funding from those agencies to meet their Bayh-Dole reporting requirements. This should, if anything, result in a net financial savings for the government by avoiding needless duplication of the functions performed by iEdison.

The second change would be a requirement that each Federal funding agency publicly identify an office housing employees who are authorized to grant exceptions to the standard clauses specified in 37 CFR 401.14 (part of the regulations implementing the Bayh-Dole Act). The standard clauses anticipate situations in which variations may be necessary; for example, 37 CFR 401.14(k)(1) prohibits awardees from assigning their rights in inventions to third parties (for example, to the inventors) “without the approval of the Federal agency.” Situations arise frequently in which inventors ask universities to disclaim inventions to them personally. Similarly, 37 CFR 401.14(i) prevents awardees from granting exclusive rights in inventions that are subject to the Bayh-Dole Act to any party that does not “substantially” manufacture the subject invention within the United States unless Federal agency waives this requirement. There are situations in which the only realistic licensees of some inventions only manufacture their goods in foreign countries. When confronted with these situations it can be difficult and time consuming for the awardees to find individuals within the Federal agencies who have the authority to grant these approvals and waivers. Even when such individuals can be identified they frequently have little experience to guide them as to whether those approvals and waivers are appropriate. If the Federal agencies can publicly identify these individuals then these individuals can build up their knowledge and experience base so that these decisions can be made more quickly and more accurately. In the interest of ease of identifying these individuals, I recommend that this contact information be made available through the iEdison portal.

A third area of improvement that would enhance the Nation’s return on investment in Federally funded research would be to clarify – or better yet, to eliminate –the Internal Revenue Service’s Revenue Procedure 2007-047 (the “Private Activity Bond” ruling). That ruling creates needless obstacles to commercializing research and accomplishes virtually nothing positive. It basically says that if industry-sponsored research is conducted by an awardee in facilities financed through outstanding tax-exempt bonds then the awardee is prohibited from granting the sponsor rights to use the results of that research – or even from specifying the financial terms of a subsequent license within the sponsored research agreement. Most inventions that result from Federally sponsored research require substantial follow-on work before they can be successfully commercialized and the Private Activity Bond ruling creates a huge disincentive for industry to support that follow-on work. Many U.S. universities currently interpret this ruling very narrowly because of the enormous exposure they would incur if it were violated. If the Federal government desires to increase the return on its investment in research, there are few things it could do that would be more effective than removing this onerous and needless impediment.

Finally I would like to propose something that I believe is highly likely to generate a large return on the Nation’s investment in research at a relatively small cost or, as requested in the RFI, a way to “significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy.” The most recent data available from AUTM indicate that in FY2016 16,487 new U.S. patent applications were filed as a result of \$66.9 billion in research expenditures. As noted earlier, significant investment is required to transform a laboratory finding into an actual product that benefits society. Universities try to be good stewards of these inventions by filing patent applications on those inventions. (It is worth noting that a Brookings Institute review of academic technology transfer offices published in 2013 found that 87% of university technology transfer offices

never reach break-even, i.e., they fail to produce sufficient revenue to pay for their own costs. Patenting by universities is thus best seen as a contribution for the good of society, not a revenue enhancement for the universities. The Brookings report can be downloaded from <https://www.brookings.edu/research/university-start-ups-critical-for-improving-technology-transfer/>.)

A reasonably accurate estimate of the cost to a university for obtaining each U.S. patent is \$20,000. Based on the numbers cited from AUTM, universities spend approximately \$330 million on patents annually, and many of these patents are never licensed. My experience is that providing a relatively small amount of additional funding to enable the researchers to conduct critical experiments of interest to industry or to create prototypes of products embodying the patented technology would induce significant follow-on funding and industry interest in those inventions. I therefore propose that for those inventions that result from Federal agency funding and for which the universities choose to expend their own money to obtain patent protection the funding agencies provide an additional amount equal to 0.5% (one half of one percent) of the previously awarded funding. This money would be used for the purpose of creating prototypes and conducting industrially-relevant follow-on experiments using the patented technology. The 0.5% figure for additional funding is not arbitrary; it represents the proportion of the original funding noted in the AUTM report (\$66 billion) that is expended on estimated patent costs (\$330 million). In other words, it provides roughly a 1-to-1 match of Federal dollars for each dollar invested by the universities in applying for patents, and this funding would greatly enhance the universities' opportunities to license the inventions to industry.

I hope that you find these proposals worth considering.

Sincerely,

A handwritten signature in dark ink, reading "Carl P. B. Mahler, II". The signature is fluid and cursive, with a small mark at the end that looks like a stylized "I" or a flourish.

Carl P. B. Mahler, II
Executive Director, Office of Technology Transfer