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

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Questions

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

Protected:
A) The large majority of provisions of the Bayh-Dole Act should be protected.
B) The allocation of rights to employers in federally-funded inventions should remain protected. Any model whereby the inventors of federally-funded inventions can choose who to assign their rights to and/or who to work with in commercializing their inventions should be avoided.

Adapted or Changed:
A) 37 CFR 401.14(i) requires substantial manufacturing in the U.S. of products produced from federally-funded inventions, which often poses a problem for companies without a location in the U.S. and thereby inventions do not get commercially developed. Reccomended Adaptions: (i) Define substantial" and provide quantitative means for universities and their licensees to know whether or not they're meeting the criteria; (ii) in cases where "substantial US manufacturing" is not satisfied, define and streamline the process for securing a manufacturing waiver.
B) Make invention reporting obligations on federally-funded inventions uniform and consistent across the various US Government agencies like NIH, NSF, DOD, DOE, etc. as currently there are various forms of invention reporting requirements for some of these agencies.
C) Under 35 USC Section 202(d) and 37 CFR 401.9, the process for assignment of invention rights to the inventor following non-election of title by the grantee/contractor should be improved and streamlined. Too often it takes inventors several months to obtain assignment of such rights from the US Government.
D) The invention reporting requirements and processes recently released by NIST, especially through iEdison, need improvement. With the recent changes to 37 CFR, iEdison is not setup to capture the changes made by the US Government. Also, many more inventions now being reported through iEdison are being rejected as not containing sufficient information although they meet the requirements stipulated in 37 CFR 401. Furthermore, some of the changes to reporting timelines recently adopted by NIST on May 14, 2018 are going to make technology transfer practices in protecting inventions more difficult.

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?

A) The Food and Drug Administration moves too slowly and often creates unnecessary burdens and hurdles that halts the development and commercialization of federally-funded inventions. For one current ongoing example, a particular startup company out of one of our universities has been awaiting a necessary decision from the FDA for over 2 years when the FDA had promised a response by summer of 2017…it is now a year later and the company (and technology) are about to be closed down due almost entirely to the lack of action and responsiveness by the FDA.
B) Filing and prosecution of patents in the US covering inventions assigned (in part) to the US Department of Veterans Affairs (or perhaps any agency of the US Government) should not require Large Entity fees to be paid to the USPTO. In many cases where these subject inventions are co-owned with an affiliated university who frequently takes on the burden of financially supporting patenting expenses, these Large Entity fees are often prohibitive to continued patent prosecution and maintenance, and technologies are abandoned as a result.
C) A number of new funding programs, for example DOE's ARPA-E program, require participation of a commercialization partner at the proposal stage of the project. The partners are usually required to cost-share and/or provide in-kind support. However, given the terms and conditions of federal funding and the relative inability for any university to offer upfront rights to project IP, the value proposition for any potential commercialization partner is incredibly weak.
D) Graduate students and post-docs who are inventors funded by federal grants are often the best individual to commercialize the research via a startup company; however, their foreign national status often prevents them from forming a startup because they must seek employment sponsorship immediately or return to their home country.

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.

A) The FDA should be provided more resources and held to very firm timelines on decisions. As an alternative, if a therapeutic/diagnostic/medical device/etc. is approved in another jurisdiction like the EMA (European Medicines Agency) then such product should receive expedited review in the US, thereby eliminating unnecessary burdens and getting more technologies commercially developed.
B) Allow Small Entity fees to be the applicable fees on any patents covering subject inventions co-owned by any agency of the US Government and small entities (such as universities, small businesses or individuals).
C) Allow a university to grant an exclusive time-limited option to the commercialization partner.
D) Create a "startup-to-greencard" program to enable graduates funded by federal R&D to remain and pursue startups based on their rearch after their student visas have expired. Expand access to SBIR funding for startups based on federal R&D that are founded by inventors in this program.

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?

A) Increase financial support for commercialization-focused and/or translational research grants for universities and other non-profits. Too often early-stage inventions are not licensed and the technology transferred because of lack of funding prior to the stage the invention may be ready for such funding as SBIR and STTR support. There is a real gap in the funding continuum between basic research funding and more commercially-focused research funding. Increased funding at this critical gap of applied research/translational research would go a long ways in seeing more inventions benefit the US economy.
B) The US Government should support the administration of technology/knowledge transfer in each grant it awards. For example, in each grant the Government awards, 1% of the funds should go to the recipient to directly support technology transfer.
C) Provide US companies incentives to in-license and/or develop inventions stemming from US Government funding. For example, provide US companies a tax break in years when they license a federally-funded invention from another party in order to further develop such invention. This will incentivize more US companies to look more closely at federally-funded inventions.
D) Require commercialization plans at the stage of Phase I SBIRs/STTRs, not only at the stage of Phase II grants. This will require these small businesses to be thinking more strategically at an earlier stage and may likely improve outcomes and the return on the US Government's investment.
E) Ambiguity in patent law is a major systemic challenge. Congress needs to take meaningful legislative action to clarify the law and the USPTO will need additonal resources to deploy these legislative changes.
F) For large Center/Institute awards, require that the proposal include entrepreneurial training (I-Corps or similar) for PIs and students involved in the scope of work to increase the likelihood that valuable innovations will be identivied and that the inventors will be better able to appreciate and communicate the business aspect of innovation commercialization.

Thank you for your time and participation.