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RE: RFI Response: Federal Technology Transfer Authorities and Processes
Docket Number: 180220199-819-01

Northeastern University is writing in response to the NIST Request for Information Regarding Federal Technology Transfer Authorities and Processes, Docket Number 180220199-819-01. We appreciate that NIST is seeking public input to review and evaluate technology transfer practices and processes and believe that this initiative will enable us to better fulfill our mission of pairing solution-oriented research with real-world needs for the enrichment of society through the protection, acceleration, and commercialization of technology. We are pleased to respond to the four core questions below.

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

   Northeastern acknowledges that some challenges related to the Bayh-Dole Act exist, but firmly believes that the fundamental principles of the Act must be preserved. The Act is recognized globally because of its contribution to the economy. It promotes investment by the private sector in commercialization of federally funded research discoveries for the public good and promotes entrepreneurship at its earliest stages.

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) Inadequate funding for patent expenses, technology development and technology transfer

Although Bayh-Dole provided a much needed mandate to commercialize technology arising from federal funding for public good, no funding is provided to universities and labs to facilitate this effort. This lack of funding has left potentially valuable technologies on the shelf and poses a fundamental challenge to the transfer of technology. Funding is needed for a variety of reasons, patent costs, proof of concept work to further technology development and general programmatic expense to increase efficiency and effectiveness. Patent costs in particular have proved burdensome due to rising costs in recent years.

B) Inconsistency of Invention/Patent reporting requirements

Invention and patent reporting is an important part of tracking and measuring the viability of technology transfer under the Bayh-Dole Act, however, inconsistency between and within federal agencies regarding the interpretation of requirements adds to compliance burdens without increasing effectiveness of reporting. Any particular issue with a federally-funded invention may be handled differently by various funding agencies, and even by different employees within the same agency. This creates uncertainty regarding a contractor's obligations and increases the time cost of handling routine administrative tasks.

C) Lack of flexibility in the application of requirements

One example is the strict requirements regarding the inclusion of a government support clause in all U.S. patent applications. In order to comply with federal regulations, it is expected that applications which do not contain this clause be amended. It is not possible, however, to amend abandoned or lapsed applications, resulting in irreversible non-compliance.

D) Conflict of Interest Rules

Although some Conflicts of Interest may be inevitable, regulations imposed in recent years by the Public Health Services (PHS) to expand the disclosure and review of researchers' financial interests as well as reduce the financial threshold to be disclosed by a faculty member have made it more difficult for some faculty to work with industry to commercialize their ideas.

E) Waiver of Rights to Inventors

Although Bayh-Dole allows agencies to grant rights to university researchers upon the university waiving its rights, there is limited information and guidance provided for this process. Additionally, there is a lack of consistency between agencies. Timing of requests is often important to the continuation of patent prosecution and a seamless commercialization effort.

F) Inconsistency of patent prosecution deadlines between government policy and USPTO

The current version of 37 CFR § 401.14(c)(3) requires contractors to file non-provisional U.S., PCT and/or foreign patent applications within 10 months of an initial U.S. provisional application. This early-filing requirement places an additional hurdle

for the commercialization of technologies by universities. This represents a significant reduction in the period of time available for universities to reach a decision on conversion and/or foreign filing, both of which incur significant expenses. This requirement disproportionally affects early-stage technologies, since they are most likely to benefit from the full 12 months provided by national and international statutes for filing non-provisional applications.

G) University Commercialization Culture

Partly due of traditional thinking and partly because of imposed Conflict of Interest policies, researchers often don't prioritize commercialization efforts. Emphasis is placed on research instead of commercialization and incentives have been shaped accordingly.

H) Measurements of Success

Measures of success are not clearly defined and, at this time, too narrow in scope.

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) Inadequate funding for patent expenses, technology development and technology transfer

Federal funding agencies should consider allowing a larger percentage of SBIR/STTR funds to be used towards patent expenses so that start-up companies can better focus on prototyping of early stage technology while ensuring adequate patent protection. Additionally, institutional grants which promote proof-of-concept funding would help universities to work with their faculty to successfully commercialize their discoveries. SBIR/STTR funding directed to patent costs accrued during the term of the research grant while the start-up is driving towards a commercially marketable application of the subject technology will lessen the debt burden on the company while seeking early stage seed/venture funding.

We propose that NIST/Commerce consider the expansion of federal funding to be used as accelerator funds in order to de-risk technology which in turn will cultivate and deepen relationships with industry partners and investors. This can be done through a number of approaches. One example would be to consider establishing a separate pool of funds specifically for this purpose. Another possible approach would be to support or match commercialization efforts funded by universities, such as gap funding or even industry sponsored research, to further develop technology and bridge the "valley of death".

Furthermore, there are many successful university programs to support entrepreneurial endeavors such as entrepreneurial education, accelerator and mentoring programs, industry partnering forums that if funded properly could substantially increase the success of start-up companies ultimately creating greater

economic impact. University resources are often limited for these types of programs and could benefit and be scaled with additional external funding. Programmatic expenses would enhance commercialization efforts, increase efficiency and allow universities to share best practices and leverage regional economic programs. As a consideration of such funding, the university could model a successful program to be replicated by other universities and labs.

B) Inconsistency of Invention/Patent reporting requirements

Streamline current technology transfer reporting requirements by adopting best practices across all federal agencies. One clear and definite process and interpretation of requirements across all agencies is necessary. If possible, direct all incoming inquiries to a single body (as opposed to each agency handling the cases funded by that agency). Provide ongoing training of personnel to ensure consistent application of regulations within an agency.

C) Lack of flexibility in the application of requirements

Increase flexibility in the application of requirements, especially in regards to older patent applications. Extend the NIH U.S. Patent and Trademark Electronic Patent Assignment System (EPAS) process for the government support clause on abandoned and previously waived patents to all federal funding agencies.

D) Conflict of Interest Rules

We propose that the agency review and address the Conflicts of Interest challenge, balancing the importance of research integrity with the importance of industry partnerships. This realignment will remove barriers for federally-funded investigators to participate in commercialization and start-up activities.

E) Waiver of Rights to Inventors

We suggest adopting cross agency best practices and developing detailed guidelines to help facilitate and streamline the process for waiving rights to inventors.

F) Inconsistency of deadlines between government policy and USPTO

Align filing requirements with federal patent law, Patent Cooperation Treaty and Paris Convention, i.e., grant contractors the full 12 months provided by national and international statutes to decide on the filing of a non-provisional or foreign application. It is not clear the reason for this early-filing requirement; in case it stems from the desire of establishing a de facto march-in provision (since the federal agency may retain title in case a non-provisional application is not filed within 10 months), its appropriateness or usefulness can be questioned, since the absence of patent protection is unlikely to meet any of the four criteria that would trigger 35 U.S.C. 203.

G) University Commercialization Culture

Develop programs to incentivize behavior for research individuals contributing to the successful commercialization of inventions, whether it is in the form of a successful industry partnership or interest in entrepreneurship via the formation of a start-up company. Promote the change of culture within the academic setting. Make it easier for entrepreneurial faculty by revising Conflict of Interest rules.

H) Measurements of Success

While there are continued directives to increase the rate of technology transfer, there have been published few actual goals and metrics. Goals such as economic and societal impact are very broad and revenue should not be the only indicator of success. New methods and definitions should be developed to better capture impacts and effectiveness of technology transfer efforts.

Northeastern appreciates the efforts of NIST to evaluate and refocus Federal technology transfer in a way that increases effectiveness and promotes commercialization with the private sector. We thank NIST for the opportunity to address these important issues and welcome any questions regarding recommendations contained in this response.

Sincerely,

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