July 11, 2018

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

*Via email: roi@nist.gov*

## AUTM's Response to NIST Request for Information: Federal Technology Transfer Authorities and Processes

AUTM, a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global technology transfer, represents more than 3,000 technology transfer professionals, mainly in the United States and in 50+ countries worldwide.
Since the passage of the Bayh-Dole Act in 1980, the United States has seen a huge impact on its economy from the many developments of inventions created at universities and research foundations across the nation. It is estimated that well over $1 trillion of economic impact has benefited the nation, creating with it hundreds of new drugs, thousands of new products and companies, and millions of jobs.

AUTM appreciates that NIST is seeking public input on the ROI Initiative, and is pleased to respond to the four core questions. Please note that we have combined our answers to questions two and three to provide a direct link between issues and proposed solutions.

AUTM supports the ROI initiative and looks forward to working with the NIST's leadership as it strengthens our national policies, implements best practices, refines metrics, develops effective training courses and ensures efficient reporting of discoveries to ensure that taxpayers receive the maximum benefit for their investment in federally-supported R&D.

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

   If there is any point that we want to stress the most, it is that the fundamental principles of the Bayh-Dole Act must be preserved.

   The Economist Technology Quarterly[1] aptly termed the Bayh-Dole Act:

   > "Possibly the most inspired piece of legislation to be enacted in America over the past half century... More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

The reason for this dramatic impact is that the law captured several fundamental principles critical for the commercialization of federally-funded research. They are the:

- Decentralization of technology ownership and management from Washington, D.C. to the creating organization;
- Establishment of clear rules that are uniformly implemented across all government agencies;
- Creation of strong incentives for university-industry partnerships for successful technology transfer; and
- Clarification of patent ownership and related benefits in the federal research and development (R&D) system.

The Bayh-Dole Act created the incentives and authorities for universities of all sizes to trade best practices and adopt appropriate models of technology management, which has made the United States the acknowledged leader in the commercialization of government funded R&D. The 2016 AUTM Licensing Survey underscores the resulting benefits to American taxpayers:

- 1,024 startups were formed around academic inventions (that's an average of 2.8 new companies created every day) and more than 70% of these companies remained in the creating institution's home state;

[1] https://media.economist.com/news/technology-quarterly/1476653-reforms-unleashed-american-innovation-1980s-and-were-emulated

- 16,487 U.S. patent applications were filed, up 3% from the previous year, and 7,021 U.S. patents were issued, up 5% from 2015;
- 800 new products were introduced, averaging more than 2 new products every day of the year; and
- Approximately 200 new drugs and vaccines are fighting disease here and around the world—yet not a single new drug had been developed when patent rights were taken by the government under the pre Bayh-Dole policies.

The foundation that Bayh-Dole relies upon is a strong, reliable U.S. patent system. It should be noted that the present uncertainties currently plaguing the U.S. patent system create significant hurdles for successful commercialization of federally-supported R&D and must be rectified if the United States wants to continue its leadership in bringing new technologies to market. Several of the most significant problems that are undermining a greater return on investment are addressed in Questions 2 and 3 below.

Because the clear, predictable rules of Bayh-Dole have been in place for almost 40 years, partnering companies have confidence that universities and other non-profit organizations can be reliable research partners. The Bayh-Dole Act is a recognized global, best practice because of the tremendous contributions it has made to our economy and the well-being of our citizens. Many countries have since modeled their national intellectual property policy on the Bayh-Dole Act. However, that does not mean that the U.S. system is working as intended. Lax oversight threatens to allow the Bayh-Dole Act to unravel and NIST should do everything within its power to promote and sustain this crucial Act.

***Recommendation 1: An oversight office within the Department of Commerce should be reinforced to ensure proper and consistent application of the law and regulations – particularly related to the use of "exceptional circumstances" and "march-in rights."***

When the Bayh-Dole Act was enacted, its fundamental principle was that contractors, including non-profit grantees, would be allowed to own and manage inventions made from federally-supported R&D in exchange for granting the government a royalty-free license and complying

with obligations such as diligently pursuing commercialization, reporting inventions to the funding agency, giving a preference in licensing to small companies, etc. Congress made two exceptions to this general rule as discussed below. Recognizing that misuse of these exceptions would undermine the law, a careful balance was struck within the laws and regulations to prevent abuse under the oversight of a lead agency and to ensure the law would be implemented as intended.

One is the use of "exceptional circumstances" {35 U.S.C. Section 202 (a)} when Bayh-Dole rights are denied to contractors because "it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives" of the law. The first item listed under the policy and objective of the Bayh-Dole Act is "to use the patent system to promote the utilization of inventions arising from federally supported research or development." Thus, any agency seeking to invoke this provision because it wants to prevent the patenting of resulting technologies would have a very difficult case to make.

Agencies seeking to invoke the exceptional circumstances clause must file a notice with the Secretary of Commerce (charged by statute with overseeing the law) within 30 days after issuance of the federal award, along with an analysis justifying the proposed action.

The law then states:

If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter (the Bayh-Dole Act), the Secretary shall so advise the head of the agency concerned and the Secretary and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

Bayh-Dole provides that such corrective actions can include using Commerce's regulatory authority to list "classes of situations in which agencies may not exercise the authority of those clauses."

Unfortunately, enforcement of this requirement appears to have fallen by the wayside. Some agencies no longer bother to inform Commerce when they decide to issue "determinations of exceptional circumstances."

Other agencies don't appear to know they are bound by the Bayh-Dole Act as evidenced last year when the Department of Education (DoEd) decided that educational software created under its funding must be made freely available[2]. While software often is not patented, in cases where it is, in fact, patentable, the Bayh-Dole Act allows federal award recipients to choose whether or not to pursue patent protection. If they choose to exercise that right, the invention cannot simply be taken away by the funding agency without complying with the requirements of the Bayh-Dole Act. There is no indication that the DoEd sought an exceptional circumstances determination, as required, to comply with the law, but it issued a final regulation without being challenged by the Department of Commerce.

Another issue concerns the march-in provisions of the law {35 U.S.C. Section 203}. The most serious threat to the Bayh-Dole Act are the frequent attempts by a small band of critics to misinterpret the march-in provisions in ways that were never intended by Congress. The law provides that in cases where a contractor's invention is not being developed in good faith, the funding agency can "march in" under certain specific circumstances to require additional licenses be granted. This can only be done after completing the prescribed rigorous process to determine the facts of the case. Agencies can also march in if the licensee is unable to meet the production requirements needed to meet a national emergency or if they failed to honor their pledge to manufacture the technology substantially in the U.S.

Twenty years after enactment, opponents of the law sought to reinterpret the march-in provision, alleging that agencies can force the licensing of competitors if the price of a successfully commercialized product isn't "reasonable" according to their determined standards. When this theory first arose, Senators Bayh and Dole immediately rejected it as completely contrary to their law[3]. Numerous attempts to petition agencies to march in as a means of price control have all

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[2] https://www.federalregister.gov/documents/2017/01/19/2017-00910/open-licensing-requirement-for-competitive-grant-programs

[3] http://www.washingtonpost.com/wp-dyn/articles/A29626-2002Apr11.html

been correctly rejected by funding agencies. However, the challenge is that individual agencies are being petitioned to interpret the meaning of the statute separately, which threatens the uniform application of Bayh-Dole. Through an oversight office, the Department of Commerce should ensure that the statute continues to work as intended by clarifying that agencies have no authority under the Bayh-Dole Act to question the price of a successfully commercialized product. The current uncertainty is a major concern of the life science industry, which is responsible for many of the most significant benefits generated under the law. Erosion of this principle would almost certainly result in companies being reluctant to invest in the development of federally-funded inventions.

In summary, the Bayh-Dole Act continues to function as intended and should not be modified. While AUTM sincerely appreciates the efforts of NIST to oversee proper implementation of Bayh-Dole, NIST has many other responsibilities as a science agency. Bayh-Dole depends on its provisions being properly enforced and protected by the lead agency, and that duty needs to be reinforced and consistently performed as intended by Congress either through a dedicated office at the Department of Commerce or additional resources to NIST to add the expertise required to properly oversee Bayh-Dole.

***Recommendation 2: Commerce should explore streamlining procedures and adopt best practices across all federal agencies.***

Individual agencies may have certain practices that provide clarity on implementation of the Bayh-Dole Act and encourage commercialization of the technology that should be applicable across agencies. For example, in 1996 NIH put into place a procedure to handle the non-election of title to patentable biological materials.[4] This was to allow universities to pursue commercialization, consistent with the intent of the Bayh-Dole Act, by providing clarity that universities can retain title to such inventions without having to expend significant funds to secure patent protection. In many cases, such protection is not critical to the successful commercialization of the material. Best practices and efficient, useful procedures such as this,

[4] https://grants.nih.gov/grants/guide/notice-files/not96-131.html

which provide greater clarity and encourage technology transfer, should be implemented across federal agencies. In addition, a similar approach could be adopted for software that may or may not still be patentable in this evolving patent landscape, allowing commercialization without the need to invest in an unnecessary patent application. In fact, Section 1 (b)(6) of Executive Order 12591 states that the head of each agency shall work toward a uniform policy to allow federal contractors to retain rights to software, engineering drawings, and other technical data generated under federal grants and contracts.

Another idea regarding the streamlining of commercialization would be to set-up a more defined and expedient process for waivers of U.S. manufacturing in certain circumstances. With guidance from AUTM and other stakeholders on developing a defined process and timeline, Commerce could set up a mechanism to streamline the waiver process with a public posting of the technology for a certain period of time to satisfy a reasonable public marketing effort before allowing the licensor to self-certify the public marketing effort, automatically securing the waiver, and moving forward with licensing with the waiver in hand.

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.**

   **AND**

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?**

***Issue 1: Uncertainty about the scope of patent-eligible subject matter as well as the degradation of the status of patent rights to nothing more than "public franchises"[5] have created significant challenges for AUTM members and others seeking to transfer federally funded technology.*** Patents are a unique tool in the innovation ecosystem, as they simultaneously disclose and protect, enabling spillover benefits and lowering the perceived risk of investing. The spillovers result several ways: when licensees license the patents and benefit from technology they did not themselves invent, when companies and people are inspired by the technical disclosure in the patent application to invent around the idea while the patent is in effect, and after patent expiration. Patents lower the perceived risk of investing and help attract private investment dollars to developing early-stage technology by mitigating competition during the life of the patent. Patents are also a form of marketing and one way of making the for-profit sector aware of activities within universities and other nonprofits.

***Proposed Solution 1A: Fix the IPR process to require a) a party using it to have standing, b) permit the patent owner to amend the claims during the process, c) limit the number of times it can be used before ex parte reexam or litigation are the only options.***

***Proposed Solution 1B: Issue a USPTO guidance on the use of the first step of the Mayo-Alice test***: "Determine if the claim at hand is directed to a law of nature, a natural phenomenon, or an abstract idea," requiring the examiner to support that finding with evidence. The examiner should be required to identify the natural law, natural phenomenon, or abstract idea, and show that it is highly predictive and not merely sometimes observed in association with a particular outcome. This clarification would restore a class of meritorious insights into use of naturally occurring molecules with otherwise unpredictable effects unless used, prepared, purified, or administered according to the claimed invention. It would restore the breadth of Section 101, and rely on the existing enablement and written description requirements, as well as the existing novelty and non-obviousness standards

[5] See *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 584 US ___ (2018).

***Issue no. 2: Uncertainty about policies and practices of federally-funded licensors can also impede technology transfer and fruitful partnering with the private sector.***

> ***Proposed Solution 2A: Expand the toolkit and expertise of the federal labs and other federally funded licensors to license intellectual property other than patents, including copyrights, materials, and data. This enhances flexibility in licensing practices and mirrors common commercial licensing practices.***
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> ***Proposed Solution 2B: Encourage federally-funded licensors to provide greater transparency on their licensing processes, such as the need for a business plan from licensees and consider sharing their template forms.***

***Issue 3: Incomplete knowledge about commercially significant technical challenges faced by industry can limit productive technology transfer.***

> ***Proposed Solution 3: Encourage industry, under appropriate confidentiality agreements, to share with federally-funded academic scientists technical specifications that would be commercially compelling to them in order to accelerate moving technologies from lab to market***.

***Issue 4: A lack of familiarity with a business culture on the part of nonprofit licensors, and an analogous lack of familiarity with university culture on the part of the business community can also impede technology transfer.*** Academics, via sabbaticals and permitted consulting, and their students have more opportunity to move back and forth between academia and industry than scientists and engineers at federal laboratories.

***Proposed Solution 4A: Expand programs for personnel exchanges between the for-profit and not-for-profit sector.*** Encourage faculty and researchers to attend conferences focused more on applied research than those they typically attend, or to attend business conferences, such as Licensing Executive Society (LES) or Biotechnology Innovation Organization (BIO) meetings. Encourage the for-profit community to attend AUTM conferences to understand the university environment and culture.

***Proposed Solution 4B: Expand federal funding for accelerator funds.*** For a variety of reasons, including current trends in available and enforceable patent protection, nonprofit licensors are being asked to de-risk technology more before it is transferred to the business community. This can be done in a variety of ways that increase interaction with the business community generally, such as grant review committees with members both from nonprofit and from the for-profit sector.

***Issue 5: The grace period (35 USC sec. 102(b)(1)(B)), as interpreted by the USPTO, is weak and ineffective in excluding as prior art anything other than the inventor's own public disclosure.*** Strengthening the grace period will benefit universities and federal laboratories, and consequently the commercialization of federally-funded inventions. Universities and -federal - laboratories are open environments where there is less reliance on trade secrets than the private sector. A strong grace period helps frustrate theft of ideas by collaborators and thus encourages collaboration which is one of the objectives of the Bayh-Dole Act.

***Proposed Solution 5:*** The USPTO should broaden its interpretation of 35 USC sec. 102(b)(1)(B) to exclude as prior art third party disclosures that are substantially identical or obvious variations of the subject matter previously disclosed by the inventor. This reinterpretation will strengthen the grace period encouraging more collaboration among universities, federal laboratories and the private sector.

4. **What 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?**

***Suggested Improvement 1: Simplify and streamline current technology transfer reporting requirements.***

It is critical to advancing technology transfer efforts of federal contractors that current reporting requirements are simplified and improved. NIST provided encouraging comments in the preamble to the recent final rule updating the Bayh Dole regulations indicating that they are collaborating with the National Institute of Health (NIH) on improvements and training related to iEdison. Most, *but not all*, federal agencies use the iEdison system housed at NIH for reporting federally funded inventions. iEdison is a legacy system that has never been properly resourced. It is characterized by an obsolete architecture and multiple required gateways that are extremely burdensome for users. In addition, NIH requires literal compliance with prescribed government support statements on reported patents and has insisted that faulty statements, even on abandoned or expired patents, must be corrected. Moreover, use of iEdison is not mandatory, and several agencies have their own burdensome reporting requirements (e.g. NASA). A uniform, simplified invention reporting system utilizing current information technology standards across all federal agencies should be implemented in place of the current system, with oversight provided by the reestablished Commerce office (recommended in response to the first question). Furthermore, use of this system should be mandatory for all federal funding agencies.

***Suggested Improvement 2: Support institutional grants to create new funding for institutional proof of concept/translational research awards.***

Existing SBIR/STTR funding presumes there is already evidence that specific research or technology has enough value to attract further investment. However, in many cases there still exists a dearth of funding needed to push technologies across the "Valley of Death." This often prevents universities from moving new research discoveries and technologies

quickly into the marketplace and sometimes prevents such transfer entirely. The high-level of risk associated with these early stage technologies has left companies, angel investors, and venture capitalists even less willing to invest in the proof-of-concept, scaling-up, and modeling required to explore the commercial value of such advances. The current SBIR program begins to address this issue, but it falls short of providing the necessary early stage support for "proof-of-concept" research. The proposed TRANSFER ACT, previously passed by the U.S. House of Representatives, builds on the NIH's Research Evaluation and Commercialization Hub (REACH) program, an early-stage, "phase zero" proof-of-concept pilot program, previously authorized under Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81). Institutional grants such as these would help more universities and federal laboratories develop the required infrastructure to work with their faculty to successfully commercialize their research discoveries.

***Suggested Improvement 3: Expand I-Corps program at the National Science Foundation (NSF) and other federal agencies.***

The NSF I-Corps program helps train and prepare scientists, engineers, and graduate students to extend their focus beyond the university laboratory and to accelerate the economic and societal benefits of basic research projects that have commercialization potential. The American Innovation and Competitiveness Act authorized the I-Corps at NSF, and encouraged its expansion. Since its creation in FY2011, several other federal agencies have funded I-Corps cohorts and we feel the efforts could still be expanded.

***Suggested Improvement 4: Develop new methods to measure and report on effectiveness.***

Agencies have received numerous presidential and departmental directives on increasing the rate of technology transfer and economic and societal impact from Federal R&D investments. Each time the directives came with a goal of improving the results of technology transfer and commercialization activities. While agencies were tasked to develop goals and metrics, consistent and universal definitions have not been developed. Success should not be measured primarily by revenue, but by contributions to broader economic prosperity and societal impact. New methods and metrics with universal

definitions should be developed to effectively capture impacts and improve measurements of effectiveness across the various recipients of federal funding.

***Suggested Improvement 5: Consistent interpretation and development of Conflict of Interest Rules***

Ease barriers for federally-funded investigators to participate in commercialization and start-up activities. If any federal agencies other than NIH plan to promulgate conflict of interest rules, they should be consistent with the standard conflict of interest policies of NSF for a consistent application of conflict of interest rules across agencies. In addition, individual programs, such as the NSF SBIR program, should not add more restrictions beyond the standard agency policy.

***Suggested Improvement 6: Create reward and incentive programs to encourage individuals to participate in commercialization activities and create a change in culture.***

Make commercialization an agency priority by developing and providing real rewards for programs and individuals who take the initiative to heart. In any organization, employees are not going to adopt new behavior when it is apparent that incentives and rewards do not match administrative directives. If technology transfer does not factor into performance reviews, promotions or funding allocations, this leads to cultural barriers in the federal system, from top management to bench scientists. A number of universities have successfully reversed this culture by incorporating technology transfer activities as a factor for gaining tenure and promotion, and bringing on new hires.

***Suggested Improvement 7: Remove barriers for universities to work with industry.***

Amend current tax law to allow for increased public-private use of bond financed facilities. For example: H.R. 1819 of the 114$^{th}$ Congress would amend the Internal Revenue Code to create more flexible standards under which public-private research activities at tax-exempt bond financed research facilities can occur.

***Suggested Improvement 8: Remove uncertainty of title under the Bayh-Dole Act.***

The new final rule updating the Bayh-Dole regulations went into effect on May 14, 2018. A contractor must (i) disclose a subject invention to the Government within two months after the inventor discloses it to the contractor's personnel responsible for patent matters, and (ii) elect to retain title within two years after disclosure of the invention to the Government. Under the prior regulations, if the contractor failed to comply with either of these obligations, the agencies could request title within 60 days after learning of the contractor's action or forgo the election. A recent amendment to the regulations at 37 CFR 401.14 (d)(1) removes the time limitation which creates a perpetual cloud on the title or other inadvertent transfers of title which will have a chilling effect that is inconsistent with efforts to commercialize federally funded technologies.

***Suggested Improvement 9: Create a collaborative R&D tax credit to encourage increased industry-university collaboration.***

To facilitate increased collaborative efforts between universities and industry, language in the basic research tax credit which narrowly defines basic research projects as "not having a specific commercial objective" should be broadened. At a minimum, Congress should delete such language from current law and allow any research expenditures at universities to qualify for the basic research credit. Additionally, industry should receive an additional tax incentive to conduct collaborative research with universities and federal laboratories. This could easily be done by doubling the existing credit from a 20% flat credit to a 40 % flat tax credit.

In short, AUTM thanks NIST for the opportunity to address these important issues, and we look forward to working with the agency to make narrow changes that do not disturb the value that the Bayh-Dole Act has brought to our nation.

Sincerely,

Stephen J. Susalka, PhD, RTTP, CLP
AUTM CEO