Transforming Ideas into Opportunities

January 9, 2019

Via email: roi@nist.gov

AUTM Comments on the NIST Return on Investment Initiative Green Paper

AUTM, a nonprofit organization dedicated to bringing research to life by supporting and enhancing global technology transfer, represents more than 3,000 technology transfer professionals, mainly in the United States and in 50+ countries worldwide. Thank you for inviting comments on NIST's Return on Investment (ROI) Initiative Green Paper. AUTM supports this effort and believes that overall the recommendations will substantially improve the current technology transfer system. AUTM is in alignment with the higher education associations as evidenced in the letter dated Jan. 9, 2019, but wanted to separately provide more detailed comments on some of the Green Paper sections. Below we raise some concerns to your attention and as particular changes are considered and drafted, encourage NIST to continue seeking input as seemingly minor details could inadvertently negatively impact our finely-tuned technology transfer ecosystem. Our comments are included in the order in which the Intended Actions appear in the Green Paper. We hope they will help increase the impact of this important effort.

1) Defining the Scope of the Government Use License (Intended Action 1)

AUTM supports this recommendation. Having additional guidance to assure our licensees that this authority is limited and will not be abused would be very helpful as AUTM members and their organizations frequently hear incorrect interpretations from their private sector partners about the breadth and scope of the statutory language defining the government's right to use resulting inventions and practice them throughout the world.

One such abuse of this right is when a licensee refuses to pay agreed upon royalties to academic institutions when they sell resulting products to federal agencies without the agency's authorization to utilize the government's right to a royalty free license. As made clear in the Government Accounting Office's report "Agencies' Rights to Federally Sponsored Biomedical Inventions" (https://www.gao.gov/new.items/d03536.pdf) cited in the Green Paper:

> "*The government's right to practice an invention is limited to federal agencies* ***and their funding recipients specifically authorized to use the invention for federal purposes*** (emphasis added)."(GAO report p. 6)
>
> "*The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license.*" (GAO p.2)
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> "*The statute does not give the federal government the far broader right to purchase, 'off the shelf' and royalty free (i.e., at a discounted price), products that happen to incorporate a federally-funded invention when they are not produced under the government's license.*" (GAO p. 7)

Thus, it is clear the government's use license can only be invoked by the agencies or those they authorize to act on their behalf. It does not provide a pretext for those licensing federally-funded inventions to avoid paying agreed upon royalties.

> ***Recommendation 1:***
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> ***Clarify in Intended Action 1 that the government's license can only be invoked by an agency or those it officially authorizes to act on its behalf and does not automatically extend to private parties licensing federally-funded inventions who sell resulting products to a federal agency.***

2) Clarifying March-in Rights (Intended Action 2)

This may be the most significant Intended Action in the report. As noted by Secretary Ross, the Bayh-Dole Act has tremendously benefitted the public welfare both here and abroad. Resulting research partnerships between academic institutions and the private sector are important drivers of our economy and bring federally-funded inventions to market for the public benefit. Yet attempts to misapply the march-in provision of the Bayh-Dole Act to regulate the price of successfully commercialized products undermines the intent of the law as evidenced by the quote from Senators Bayh and Dole in the Green Paper.

AUTM strongly supports Intended Action 2 which proposes a clarification under the Bayh-Dole regulations "specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services." We also support the effort to: "Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace but not as terms (i.e. price control mechanism) for consumer use." Implementing the new regulation removes the burden from each agency to interpret the law which is why Congress designated the Department of Commerce as the lead agency. AUTM applauds this critical reinforcement of the system that has served us so well.

Recommendation 2:

AUTM strongly supports this Intended Action 2.

3) Strengthening Preference for U.S. Manufacturing (Intended Action 3)

AUTM appreciates NIST's intention to streamline the U.S. manufacturing waiver process which has been quite challenging and unnecessarily time-consuming to AUTM members and their licensees. The technology transfer process can already be complex, particularly with small or start-up businesses, and the cumbersome and confusing waiver process can easily and unintentionally eradicate a licensing deal, meaning the product is never deployed for use by the public. Making the waiver process uniform government-wide also allows agencies to trade best practices, thus making the process more efficient.

We caution, however, that careful consideration of field-specific distinctions and the often global nature of corporate structures is essential to avoid inadvertently hampering technology development and product integration processes for certain products. For example, automobiles and mobile phones incorporate many inventions from various sources into a single product, and requiring the whole product to be substantially manufactured in the United States while a

minute portion of inventions are federally-funded may cause potential licensees to wholly decline development of such inventions made by academic institutions.

NIST plans to identify the pathways for expanding the U.S. manufacturing preference to non-exclusive licenses and to all contractors. As above, we have concerns that these seemingly noble efforts to support and enhance the U.S. manufacturing base may backfire and cause less technology transfer in the long run. Additionally, it is not clear what legal authority is being used to take the proposed action as Section 204 of the Bayh-Dole Act is explicitly limited to exclusive licenses. Congress apparently recognized that anyone wanting to manufacture a product in the U.S. from a non-exclusive license could simply apply for one.

Thus, the time, expense and complexity of requiring waivers for non-exclusive licenses does not appear to be justified and would be burdensome. This may interfere with Strategy 2, increasing engagement with the private sector, as companies find these processes slow and not "speed-of-business." Also, non-exclusive licenses tend to be just-in-time licenses, executed when technology development is already underway or a product close to launch. Withholding or delaying such a license may not result in a change of manufacturing location especially if the product is close to entering the marketplace. Lastly, if the non-exclusive licensing process includes publishing an intent to grant a non-exclusive license in the Federal Register, as it does when the license is exclusive, the publicity may further discourage potential licensees.

Subsequent proposed regulations for streamlining or making additional changes to the current process must be open for additional public input, be flexible enough to encourage consistent use of the outlined processes, foster dialogue with agencies on the nuances of specific circumstances, and contain a mechanism to appeal federal decisions that may not be sufficiently apprised of particular facts of the situation. Throughout this process, NIST should exercise caution to not create conditions discouraging the development of state-of-the-art advances in technology or hamper academic or governmental institution's ability to transfer technologies for the public good. We encourage NIST to seek additional public comment and input as it develops more concrete plans to implement such provisions.

Recommendation 3:

Create a uniform waiver process for federal agencies.

Recommendation 4:

As any company that wants to domestically manufacture a non-exclusively licensed federally-funded invention can apply for a license, there is no need to include a U.S. manufacturing requirement provision for non-exclusive licenses.

4) Streamline Partnership Mechanisms (Intended Action 8)

This section describes industry "concerns about consistency in licensing practices both within labs and across labs" and related problems caused by differing agency authorities and procedures. However, Intended Action 8(C) would have the government "establish consistent, transparent licensing policies and practices for federally-funded intellectual property..." Thus, the practices of academic institutions and private contractors under the Bayh-Dole Act would be swept in through this language. A better approach would be examining why industry is having problems working with specific agencies and laboratories.

A significant achievement of the Bayh-Dole Act is that it ended government micro-management of inventions made by grantees and contractors. Secretary Ross began this exercise by saying that the federal government had a lot to learn from the success of academic technology transfer. One reason for that success is that the Bayh-Dole Act cut through the red tape previously strangling the system, while allowing flexibility for contractors and their industry partners to mold license terms to match unique and varying circumstances. The law gives the government a limited oversight role. That does not include defining licensing practices beyond those listed in the statute. Even for the federal laboratories doing so could open a Pandora's Box of unintended problems.

One theme absent from the Green Paper is accountability. Some federal agencies appear to have made the process unnecessarily cumbersome and may not be fully utilizing their current authorities according to other studies of the problem. If federal agencies and their laboratories are not held accountable for their performance, effective oversight, rather than new regulations, is a better approach.

Another concern is Intended Action 8(E). The purpose of royalties ***are not*** "primarily to promote compliance by the licensee to the terms of development and achieve practical application of the technology." That's the purpose of diligence milestones that academic institutions use to monitor development of the technology. One reason why march-in rights have not been utilized is that academic institutions will terminate a license if it appears that good faith efforts toward commercialization are not being made. Royalties, on the other hand, are a cost to the licensee, not an incentive toward development. But they are important incentives for public sector institutions to share in the success of a product they helped to discover.

It is not by accident that both the Bayh-Dole Act and the Federal Technology Transfer Act include receiving royalties for academia and federal laboratories as critical parts of their formula. Generating appropriate royalties provides an incentive for public institutions to undergo the rigors and expense of technology transfer. Under both statutes, royalties fund

additional research, reward public sector inventors and researchers for participation in the process while helping to pay technology transfer expenses.

As noted by Secretary Ross, federal agencies significantly trail academic institutions in generating royalties. One reason why technology transfer may be lagging in some federal laboratories is that the rewards are minimal while the costs drain their budgets. Artificially limiting royalties exacerbates this problem and undermines Goal 3 on building a more entrepreneurial workforce in the public sector.

It is important that reasonable royalty rates be charged but that can only be determined by the nature of the invention and other factors specific to each deal, not through regulation. While doubtlessly well meaning, Intended Actions 8(C) and 8(E) as currently described raise serious concerns.

Recommendation 5:

While AUTM supports the sharing of general licensing best practices, we do not recommend implementing specific "one size fits all" approaches through regulation due to the vast diversity and complexity of license agreements.

5) New/Expanded Partnerships Mechanisms (Intended Action 9)

While AUTM supports in principle new mechanisms that make technology transfer more effective, there should be clear, compelling reasons for such actions. We have significant concerns about the idea of expanding the use of the "Other Transaction Authority" (OTA) through the proposed "Research Transaction Authority" (RTA) under Intended Action 9. We are also concerned that a proliferation of mechanisms, rather than holding agencies accountable for how they are utilizing existing authorities, only adds to industry's confusion with how to effectively partner with federal laboratories.

It is not clear from the description in the Green Paper why adding yet another authority allows agencies to be more efficient in completing partnering agreements with industry. It appears that one reason in the delay in processing CRADAs is due to the agencies' own procedures rather than a lack of authority. Regardless, creating a new OTA type program raises serious concerns.

Because OTA's are neither contracts, cooperative agreements, nor grants, Bayh-Dole Act rights do not apply. Intended Action 9 would spread the use of this program government-wide through the RTA. The Green Paper says that "appropriate conveyance of intellectual rights consistent with Bayh-Dole" would be done through the implementing regulations. If the purpose of the new RTA authority is as described, Bayh-Dole Act rights should be guaranteed in the legislation. Leaving such fundamental rights to the vagaries of regulation, which could be reversed in future Administrations, is a very serious concern. The history of the OTA at the Department of Defense, where it originated, proves this is not an idle fear.

Here's how a December 14, 2018 article (https://www.jdsupra.com/legalnews/dod-issues-new-other-transactions-guide-74710/) describes the new OTA guidance from the Department:

> *While both the new and old guides confirm that the Bayh-Dole Act, 35 U.S.C. §201-204 for patents and 10 U.S.C. §2320-21 for technical data, do not apply to OTs, the new guide encourages more latitude in negotiating appropriate IP clauses. Specifically, the prior guide stated:*
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> > *The Agreements Officer should seek to obtain intellectual property rights consistent with the Bayh-Dole Act (35 U.S.C. §201-204) for patents and 10 U.S.C. §2320-21 for technical data and computer software. Negotiation of rights of a different scope is permitted when necessary to accomplish program objectives and foster Government interests, and to balance the interests of the awardee.*
>
> *The new OT Guide instructs that "these statutes do not apply to OTs and* **negotiation of rights of a different scope is permissible and encouraged***" (emphasis in original). Where the language of the prior guide appeared to reflect a grudging admission that deviation from standard IP clauses was permitted, the new guide provides, in bold type, that different terms are encouraged.*

An express purpose of Congress in passing the successful Bayh-Dole Act was to create a uniform patent policy across all government agencies. The existing OTA undermines that goal, and a new RTA could further harm that objective. As Secretary Ross stated, the success of academic technology transfer under the Bayh-Dole Act is the centerpiece of our technology transfer system. It has yielded significant returns on investment for the American taxpayer. It is hard to see how denying Bayh-Dole Act rights to academic institutions and small businesses so inventions can be given to prime contractors serves the public interest.

The need for creating any new authority should be seriously weighed and documented. If there is ample reason for doing so, Bayh-Dole Act rights should be protected in the statute to secure the greatest return on investment from federal research and development (R&D).

> ***Recommendation 6:***
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> ***Do not create any new partnering mechanisms built upon the OTA model that denies Bayh-Dole Act rights to grantees and contractors.***

6) Establish a modern platform for reporting data on intellectual property resulting from federal R&D (Intended Action 13)

Information about the fruits of research expenditures, such as how often research succeeds, and the results produced, change what we as a society are willing to fund, and the entities willing to fund it. We strongly support Intended Action 13, on modernizing a platform for reporting data on intellectual property resulting from federal R&D. We caution against an overly narrow or literal interpretation of recommendation 10.2 in the 2016 National Academies of Sciences report cited in the Green Paper at footnote 271:

> *10.2 The Department of Commerce, in consultation with the proposed Research Policy Board, should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act.*

Applying a "do not exceed the statute" approach to reporting under the Stevenson-Wydler Act could interfere with Goal 5, and thus the initiative on enhancing the national return on research investment overall.

We suggest that some of the requirements currently in the statute may be less helpful, for example, on reporting the skew in the license income:

> *the total earned royalty income including such statistical information as the total earned royalty income, of the top 1 percent, 5 percent, and 20 percent of the licenses, the range of royalty income, and the median, except where disclosure of such information would reveal the amount of royalty income associated with an individual license or licensee;*

It may be more useful to report the fraction of licenses to small business and start-up businesses, or the fraction to domestic licensees.

> ***<u>Recommendation 7A:</u>***
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> ***Engage with a working group of compliance and reporting stakeholder users of such a platform, including AUTM members, to develop user interface and performance specifications.***
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> ***<u>Recommendation 7B:</u>***
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> ***Create a modernized, secure, inter-organizational system for reporting to all federal agencies on intellectual property resulting from federal R&D, leveraging off of iEdison if possible.***
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> ***<u>Recommendation 7C:</u>***
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> ***Manage the project to interim deliverables.***

Recommendation 7D:

Engage with a working group of Goal 5 users, namely the stakeholders who want to use the information to better understand global science and technology trends and benchmarks, and take their requests into account.

7) Establish a federated data portal that is easy for the public to access, use and analyze (Intended Action 14)

We strongly support Intended Action 14, on establishing a curated data portal on intellectual property and federal R&D programs for public benefit, mindful of the need to build in an approach to documenting and moderating access to such a portal so it is consistent with an overall goal of supporting U.S. manufacturing.

Use of such a portal may provide a valuable opportunity to contribute to Goal 2. Simple web analytics on the number of sessions, users, page views, pages/session, average session duration, bounce rate, and others may provide insight into the interest in and demand for technologies. If users are required to register, it will also further contribute to Goal 2, leading to an increase in corporate engagement, as it would potentially enable more targeted marketing.

AUTM has developed a robust technology transfer portal called the "AUTM Innovation Marketplace" or "AIM" (https://aim.autm.net/) which currently lists almost 20,000 technologies available for licensing from over 170 institutions. AIM provides many of the features listed above, along with the ability to sign up for customized alerts based on keywords.

Recommendation 8A:

Engage with a working group of federal laboratory technology transfer practitioners and their potential customers to i) develop content and operational specifications for the portal and ii) monitor results and refine the content and specifications as needed.

Recommendation 8B:

Develop a prototype portal, or join AUTM's interactive AIM portal.

Recommendation 8C:

Improve the portal and marketing processes based on user experience, customer feedback and data.

8) Establish metrics to better capture, assess, and improve federal R&D outcomes, impacts, and operational process (Intended Action 15)

AUTM cautions against *de novo* reframing and instead supports continuous improvement of current approaches to understanding short term, long term, local, diffuse, societal, and economic impacts of federal research. These impacts are intertwined and not readily separable.

AUTM commends the recognition in the Green Paper (page 110) that a number often criticized as leading to an overemphasis on economic returns -earned royalties- is the same number which is the basis of a jobs estimate - a societal return.

> *"For example, government metrics that include a monetary return on investment in the form of royalties for patents licensed are used to understand the more valuable metrics for government performance in job creation, economic competitiveness, and national security capabilities."*

Key science and engineering indicators and macroeconomic concepts, such as gross domestic product (GDP), have been developed and refined over decades and generations, technology transfer indicators will similarly be developed over decades and generations. We appreciate the mention of the data in figure 3 of the AUTM/BIO report on page 108 which would not have been possible without two decades of standardized academic technology transfer data. The data provide quantitative support for the importance of new products to prosperity. Such a result would not be possible without standard and routine data collection with well-established definitions for the data collected, including data on royalty payments.

The authors of the AUTM/BIO report were unable to generate an analogous figure for the federal laboratories because of a lack of consistently defined data elements over time. Just as overly or prematurely standardized approaches risk missing key insights, overly unique approaches do not lead to actionable insights and are not conducive to continuous improvement.

AUTM both welcomes federal laboratories to submit to our Annual Licensing Activity Survey as well as the opportunity to help develop additional appropriate and meaningful measures of success. Management consultant Peter Drucker once said "If you can't measure it, you can't improve it."

Technology transfer at its core is about sharing risks and rewards among transferors and transferees. Sharing, or trading, occurs more easily with experience, and with the trust in the process built by such experience. Neither insurance, nor investments in early technology would exist if we did not understand, and have documented experiences with patterns of success and failure.

Recommendation 9:

Rename Intended Action 15 to "Continuously improve our approaches to and metrics for understanding and improving federal R&D outcomes, impacts, and operational processes."

Recommendation 10A:

Form and support a working group, which includes a cross section of federal laboratory technology transfer practitioners from the agencies with federal laboratories; representative laboratory types: GOCO's, GOGO's and FFRDC's; and expert advisors, such as economists, historians, and AUTM members who have grappled with analogous issues.

Recommendation 10B:

Task the group with defining data elements to count, measure, observe and document.

Recommendation 10C:

Implement their recommendations, leveraging off of AUTM Survey infrastructure if it is possible and efficient to do so, and improve measures based on experience and feedback from the working group.

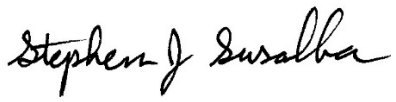
Additional Recommendation

In addition to the 15 Intended Actions identified by NIST, AUTM recommends another crucial safeguard for our technology transfer system. Congress enacted the Bayh-Dole Act to create a uniform patent policy across all agencies. In doing so, it recognized that this goal would unravel over time without oversight. That is why the law designated this critical role to the Secretary of Commerce. For too many years, this function has been neglected and some agencies began denying Bayh-Dole rights inappropriately for grants, cooperative agreements, and contracts by misapplying the exceptional circumstances provision of the law or promoting alternative mechanisms like the previously discussed OTA. AUTM applauds the renewed attention that the Department is now giving to its statutory duties. Effective oversight is critical to the continued success of the Bayh-Dole Act which was appropriately lauded by Secretary Ross when launching the ROI Initiative.

Recommendation 11:

AUTM sees it as critically important for maximizing the return on investment from extramural research & development that the Department of Commerce effectively oversees the Bayh-Dole Act to ensure that all agencies are in compliance.

Thank you for providing this opportunity to comment on the Green Paper. AUTM looks forward to working with NIST in creating the greatest possible return on investment from the taxpayer's investment in federally-funded R&D. Please do not hesitate to contact us if there are any questions regarding the above comments.



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

About AUTM

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.