

January 9, 2019

RE: NIST Special Publication 1234; ROI Draft Green Paper, December 2018

*Via email:* [roi@nist.gov](mailto:roi@nist.gov)

**Wisconsin Alumni Research Foundation Response to  
“Return on Investment Initiative for Unleashing American Innovation”**

The Wisconsin Alumni Research Foundation (“WARF”) appreciates the opportunity to respond to the Return on Investment Initiative (“ROI”) Green Paper issued by the National Institute of Standards and Technology (“NIST”) on December 6, 2018. WARF wishes to once again commend NIST for responding to the Lab-to-Market Cross-Agency Priority in the President’s Management Agenda by undertaking the ROI Initiative, and we thank NIST in particular for the thorough, thoughtful, and conscientious collection of feedback that informed the ROI Green Paper. Above and beyond its specific policy recommendations, the draft paper contains what might be the most comprehensive overview of the challenges facing federal technology transfer today and, indeed, perhaps the most accessible overview to date of technology transfer policies and regulatory practices. In that regard, the paper has already provided a worthwhile public service.

As stated in our response to NIST’s original Request for Information (“RFI,” Docket Number: 180220199-819-01) the Wisconsin Alumni Research Foundation—home to one of the oldest university patenting and licensing operations in the world—has an inherent, enduring interest in improving the transfer of technologies from the laboratory to the marketplace. For more than ninety years, we have pursued that goal in close partnership with the University of Wisconsin-Madison, whose scientific research our nonprofit mission pledges to support. Our work has also fostered strong, longstanding relationships with the state of Wisconsin and its citizens; fellow research institutions, universities, and businesses in Wisconsin; our colleagues at the Association of University Technology Managers (“AUTM”); and the various agencies and public servants of the federal government.



WARF's comments on the specific "Intended Actions" in the ROI Green Paper are driven by the same two principles stated in our RFI response: the freedom to invent and local empowerment. Researchers—the people best situated to understand the applications of their science—should be allowed the freedom to develop their technologies for the overall benefit of humankind, and universities and local businesses should be empowered to ensure the widespread, ethical distribution of the social benefits of those technologies. We find inspiration for these tenets of academic freedom and local empowerment in the Wisconsin Idea, the long tradition that the University of Wisconsin System, and by extension its supporting organizations like WARF, should strive to serve every family in our home state.

With those principles in mind, WARF appreciates and strongly concurs with NIST's stated goal of preserving the original intent of the Bayh-Dole Act, passed in 1980 and derived in part from the seminal contributions of WARF's late patent counsel Howard Bremer. We also concur with the Green Paper recommendations that would apply a regulatory framework similar to Bayh-Dole to the Stevenson-Wydler Act of 1980 and the Federal Technology Transfer Act of 1986. Such a change would allow federal laboratories and government employees to benefit from the same elegant solution that has served U.S. universities, nonprofit organizations, and small businesses so well for almost forty years. The results of Bayh-Dole have exceeded the hopes of the act's authors by providing significant social and economic benefits to the nation. Using the example of Bayh-Dole, all technology transfer can follow processes and policies that unleash innovation by trusting local experts, trusting the academic freedom of laboratory scientists, and ensuring that technology transfer professionals across the public, private, and nonprofit sectors have adequate resources to fulfill their mission.

WARF also recognizes, appreciates, and shares the goals enumerated in the Green Paper to "meet current and future economic and national security needs in a rapidly shifting technology marketplace" (p. 3) through such means as increasing industrial competitiveness, building an entrepreneurial workforce, and broadening the public accessibility of technology. We pursue those same goals in our home state in cooperation with UW-Madison, the state of Wisconsin, and industry partners, so WARF appreciates how legislation and regulation can—and should—address these pressing concerns of national interest.





However, technology transfer policy must remain dedicated to two over-arching, inter-related missions: encouraging scientific research and promoting the development of that research into world-changing innovations. The rarity of true breakthrough discoveries in science and technology, and the density of resources needed to bring ideas from the laboratory to the market, means that technology transfer professionals—and the regulations that guide them—must remain laser-focused on transforming basic research into practical applications. Between the inherent unpredictability of the scientific endeavor, the costs required for commercial development of innovative products, and the inevitable happenstance of any human enterprise, the chances that the technology transfer of any particular product might be derailed are so high that deviation from our core mission can only lead to less innovation and fewer benefits delivered to humankind. The price of a product, the location of its manufacture, or the jobs it creates will be irrelevant if that product is never developed in the first place.

In the spirit of the above statements, WARF wishes to make the following specific comments on the intended actions enumerated in the ROI Green Paper:

#### **Intended Action 1 – Government Use License.**

WARF concurs with the Green Paper recommendation to define “government use” under Bayh-Dole as “use directly by the government purpose only and not for use by a third party” (p. 29). This intended action aligns with our stated principle that policy should empower inventors to make the best decisions for licensing their intellectual property, and we thank NIST for recognizing the importance of clarifying the purpose of a government use license. We also wish to reiterate those comments from RFI respondents, as summarized in the Green Paper (p. 27-8), who argued that government use licensing for the purchase of discounted products or to otherwise intervene in the post-commercialization consumer market would have a negative effect on return on investment. The possibility that a government agency might use its license for distribution to a third party has had a chilling effect on the willingness of private companies to invest in and develop federally funded intellectual property, and applying the government use license to such purposes would have other unanticipated complications and cancel out any benefits.



In terms of implementation, we ask that regulations specify that the royalty-free government use license be initiated by a government agency. Consider, as an example, a licensee that refuses to pay a full royalty to a patent-holder on the basis that they intend to sell the licensed product to the government but then charges the government a standard, non-reduced rate. Situations like this have been known to happen and they leave the patent-holder little recourse but to pursue litigation to recoup lost revenue. NIST can guard against potential abuses by clarifying that only a government agency may implement their royalty-free license.

### **Intended Action 2 – March-In Rights.**

WARF concurs with the Green Paper recommendation to clarify the proper use of March-In Rights and reduce the ambiguity of “reasonable terms” and “practical application” in regulatory language. The Bayh-Dole Act presumes that contractors retain the rights to their intellectual property and assumes that intellectual property can best be commercialized by giving inventors broad leeway to develop and license inventions. Commercial partners need to be certain of their position under such licenses, and these partners are reluctant to invest in development with a looming threat of government intervention. March-In Rights exist as a safeguard to ensure that contractors fulfill their responsibility to bring patents to market—not as a means for government agencies to assume that responsibility themselves. The fact that March-In Rights have never been exercised should not be a source of criticism but instead seen as primary evidence for the success that grantees and contractors have had in fulfilling the goals of the Bayh-Dole Act and implementing its provisions. As stated in the Green Paper, “march-in rights should not be used as a mechanism to control or regulate the market price of goods and services” (p. 33).

On that last point, extending March-In Rights for these purposes would demand that patent-holders fulfill obligations that are not only outside their purview as inventors but that could bring separate sets of government regulations into conflict. Under the Bayh-Dole Act, federally funded inventors must fulfill four specific obligations (as enumerated on p. 30 of the Green Paper) or else a government agency will march in to ensure those obligations are met. By marching in for the purpose of controlling prices, therefore, the government would be indicating that patent-holders have an obligation to control prices. While a licensing agreement that dictates or attempts to influence a product’s price may not, in and of itself, constitute price fixing under the law,





requiring a patent-holder to pursue lower prices would open the door to antitrust scrutiny. In other words, federal contractors would be put in a position to choose between compromising their intellectual property rights or engaging in anti-competitive practices. Such an outcome would not serve the interests of patent-holders, licensees, the government, or the public, and could upend the proven success of Bayh-Dole. For these reasons, WARF emphasizes its appreciation to NIST for recognizing the importance of clarifying March-In Rights.

### **Intended Action 3 – Preference for U.S. Manufacturing.**

WARF welcomes the recommendation to streamline and implement a uniform, government-wide process for regulating the U.S. manufacturing preference mandated by Bayh-Dole. We strongly urge NIST not to expand the U.S. manufacturing preference to non-exclusive licensing. To consider the problem that either a complicated waiver process or an expanded preference would cause, consider the central challenge that patent-holders face when commercializing their technology. Universities and federal laboratories—by their design—lack the capacity to manufacture products.

Foundational innovations—by their very nature—have yet to be manufactured at all. If someone already knew how to make an innovative product, it would not be a true innovation. Technology transfer offices, therefore, must either find a way to develop a new manufacturing capacity through a partnership with a startup company, or convince an existing company that developing a new manufacturing process would be a profitable endeavor to undertake. Choosing the most effective manufacturing partner can be a crucial factor in determining the success or failure of a licensed product, and today's interconnected global economy increases the options for finding an optimal relationship. Having more options leads to higher odds of success and a higher return on investment.

In the case of startups, new companies formed to develop federally funded inventions will most often be founded in close proximity to the inventor. Local connections increase the odds of success and both the inventors and the communities in which they live have strong incentives to develop their local economies. In these circumstances, having to complete a waiver process can only hinder commercial development that will benefit the government's return on investment as well as benefiting domestic production. For a variety of reasons, impediments against startup creation can become insurmountable, whether because of insufficient capital, the burdens of regulation,



limitations in necessary infrastructure or workforce skills, or any of a number of other well-documented hurdles that a new business must overcome.

If a startup company proves not to be a viable alternative, then inventors must license their patents to an existing company, in which case the struggle to find a willing partner can be long and difficult. This is the process that extends across the gap so often called the “valley of death” between federal funding and private investment. When traversing the valley, technology transfer offices do not necessarily seek out exclusive licensing agreements, but we recognize the importance of exclusivity as an incentive to attract private investors. Many companies will only justify the risk of commercial development if they have an assurance of exclusivity for at least some period of time.

In those circumstances where a non-exclusive agreement can be reached, technology transfer offices can use multiple licenses to achieve, as described by the Green Paper, “a balance between encouraging other countries to open their markets for American businesses and protecting American taxpayers’ interests in United States Government-funded technologies” (p. 36). A technology transfer office could license a foreign company while leaving open the opportunity for one (or more) domestic companies to step up, or vice versa. Exclusivity should also not be understood as static. Without a strict U.S. manufacturing requirement, companies could take advantage of an initially non-exclusive license to test a new product in existing facilities overseas. If successful, they could then convert their agreement to an exclusive license, build a new facility, and bring the jobs home to the U.S. for a net increase in domestic productivity. In any event, the potential for failure in the commercialization process means that patent-holders must seize the opportunities presented to them or risk losing the chance to bring their intellectual property to market. More flexibility means more opportunities.

In sum, federally funded inventors have every incentive to choose a local opportunity to commercialize their intellectual property. When they chose an exclusive license, or a license to a foreign company, they do so out of careful consideration over how to maximize the chances of success—to maximize their own return on investment as well as that of their government funding agency. Further, individual non-exclusive licenses cannot be evaluated in isolation because by definition a non-exclusive license represents a single, incomplete portion of a non-exclusive strategy. To fulfill the goal of strengthening the American manufacturing base, we encourage the government to





focus on ways to drive the creation of new companies and not on restricting the flexibility of inventors doing all they can to further the success of federally funded inventions.

For these reasons, we propose that the government establish a regulatory framework similar to the one that has been so successful in the exercise of March-In Rights. Rather than requiring contractors to navigate a waiver process, the government should presume that patent-holders have chosen their licensees for well-considered reasons based on in-depth knowledge about the challenges of commercial development, the potential market for their products, and their responsibility to fulfill statutory requirements. As with the march-in petitions reviewed by the National Institutes of Health over the years, a similar process for the preference for U.S. manufacturing would not prevent U.S. companies from filing complaints or prevent the government from evaluating potential abuses. We have reason to believe that such abuses would be rare. WARF understands the national interest to protect and promote domestic manufacturing, but placing the burden on patent-holders to demonstrate substantial domestic production on every one of their licenses sets a high bar, one that will hinder, rather than advance, return on investment.

#### **Intended Action 7 – Presumption of Government Rights to Employee Inventions.**

As a university supporting organization, not a government agency, WARF defers to the federal government in determining the assignment of rights to its employees. That said, WARF continues to be unique among U.S. universities in presuming individual inventors own their intellectual property, and we stand by the record of that policy. Our nine decades of history have shown that empowering individuals provides the highest level of adaptability and expertise to promote commercialization. We believe that offering the same rights to government inventors would do much to accomplish the entrepreneurial goals of the ROI initiative.

#### **Intended Action 9 – New/Expanded Partnership Mechanisms.**

WARF shares the concerns expressed by AUTM and COGR regarding the expansion of Other Transaction Authority agreements through the establishment of a Research Transaction Authority. The Office of the Vice Chancellor for Research and Graduate Education at UW-Madison has expressed similar concerns and, as indicated



in our addendum to their Green Paper response, WARF associates itself with our university's statement and, in particular, to their comments on this Intended Action.

#### **Intended Action 10 – Technology Maturation Funding.**

WARF appreciates NIST highlighting the importance of earmarked federal funding specifically for technology transfer services. While we understand the need for the ROI initiative to assume a revenue neutral stance, we hope that Congress and federal agencies will see fit to allocate more resources to federal laboratories and contractors for patenting and licensing. Technology transfer deserves a dedicated revenue stream. Allowing grantees the flexibility to use some R&D funds for patenting, and communicating with the Small Business Administration about improving SBIR/STTR funds, can only be a step in the right direction.

#### **Intended Action 11 – Technology Entrepreneurship Programs.**

WARF welcomes the continued expansion of entrepreneurial programs and a review of best practices to build on the success of NSF's I-Corps program. As a supporting organization for a university, we have firsthand knowledge of the importance of education and training success—whether academic, technical, or professional.

#### **Intended Action 13 – Federal IP Data Reporting System(s).**

#### **Intended Action 14 – Access to Federal R&D Assets.**

WARF eagerly anticipates the arrival of “a modern, secure, interoperable platform for reporting data” that can implement “consistent and streamlined government-wide regulatory requirements and practices” (p. 122). As the Green Paper rightly notes, the existing platforms—most notably iEdison—have long been outdated and do not offer a universal solution for cross-agency data collection. A modernized, user-friendly system with fewer glitches and partitions will be welcomed by all technology transfer offices and their staff members. We would still emphasize that building an effective reporting system is not just a matter of technology but about the reporting requirements themselves. On a number of occasions WARF staff have attempted to enter data into iEdison only to find that the system requires a field that cannot be applied to the license or patent at hand, thus making the electronic form impossible to submit. The replacement for iEdison should therefore be built on simple reporting





categories that fulfill the statutory requirements in a straightforward, intuitive, and universally applicable way.

We offer similar feedback for the proposed “federated data portal” to provide access to R&D assets. Such a portal could be a valuable resource for technology transfer, but usability and accessibility should be simplified for those who will be asked to supply the data. WARF, like most technology transfer offices, already compiles technology summaries and other documents on our patenting and licensing activities. We design these resources with specific business purposes in mind and for distribution to researchers, inventors, industry connections and other partners. Providing this information in our existing formats can be accomplished without too much effort, while a portal that required reformatting or re-entry would be burdensome and perhaps prohibitive. For requirement reporting and the asset portal, WARF asks that new functionalities not lead to new or more complicated requirements for reporting or data collection.

#### **Intended Action 15 – Benchmarking and Metrics.**

The MIT RFI response on benchmarking resonated with WARF. “There is no single, obvious way to measure the success of tech transfer that everyone has somehow been missing,” and “at the same time, metrics should not be altered lightly because stability is needed to make comparisons over time” (p. 113). In an information age awash with a seemingly infinite supply of daily information, the challenge of metrics is not to reinvent the wheel but to devise new ways of understanding the resources that we, as an industry, already produce. WARF recommends that NIST work closely with our colleagues at AUTM to determine best practices in this area. AUTM has been tracking the technology transfer industry for decades now and has more experience than any other organization in wrestling with how to measure what we do in ways that are accurate, insightful, useful, and consistent all at the same time. We also appreciate the Green Paper’s emphasis on “broad-based R&D outcome and impact metrics,” which we read within the context of defining ROI in a way that “emphasizes the underlying social and public mission inherent in the development of Federal research into products and services benefiting American taxpayers” (p. 21). Benchmarking and metrics can be essential tools in helping our industry serve its social and public mission, but we hope that a focus on measurement will not become an end itself that detracts from our core purpose in technology transfer. WARF looks



forward to collaborating with NIST and AUTM in developing a mission-driven formulation of metrics.

**In addition to the specific comments enumerated above,** WARF extends its appreciation for the strategy NIST has outlined in the Green Paper. Taken as a whole, the intended actions have the potential to ease regulatory burdens for our colleagues at federal laboratories, simplify processes, and bring the implementation of Stevenson-Wydler more in line with Bayh-Dole regulations. Attempts to streamline, modernize, and use university technology transfer as a model for federal laboratories can only have a positive effect on the government's return on investment.

**In conclusion,** WARF congratulates NIST on the insights reflected in the Green Paper, the time and care put into its creation, and for the overall effort to collect the lessons learned since the passage of Bayh-Dole to build a better technology transfer future. At WARF, we believe the future must be built on history. We were founded in 1925 when UW Professor Harry Steenbock, looking to ensure that science developed in his lab would benefit Wisconsin industry and Wisconsin's university, discovered that university administrators were reluctant to take on the financial and political risks of commercializing research. Instead, Steenbock collaborated with two of his deans and a handful of UW alumni to form the Wisconsin Alumni Research Foundation as an independent nonprofit corporation. WARF's statutory purpose, still in effect today, is not to manage intellectual property but "to promote, encourage and aid scientific investigation and research at and within the University of Wisconsin-Madison" and "to provide or assist in providing means and machinery by which their scientific discoveries, inventions and processes may be developed for the overall benefit of humankind." In 2018, we believe that mission, and the national mission of federal technology transfer, can still be served with Steenbock's combination of academic freedom, the removal of bureaucratic roadblocks, and an investment in the future of scientific discovery.

Sincerely,

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Office of the Vice Chancellor for  
Research and Graduate Education  
UNIVERSITY OF WISCONSIN-MADISON

January 9, 2019

RE: [NIST Special Publication 1234](#): Return on Investment Initiative for Unleashing American Innovation, Draft Green Paper, December 2018

*Submitted via e-mail to [roi@nist.gov](mailto:roi@nist.gov)*

The University of Wisconsin-Madison (UW-Madison) appreciates the opportunity to respond to the Return on Investment Initiative Green Paper issued by the National Institute of Standards and Technology on December 6, 2018.

UW-Madison is aware of the comments filed by the Wisconsin Alumni Research Foundation (WARF) in response to the Green Paper and wishes to associate itself with these comments.

**Background about UW-Madison and its relationship with the Wisconsin Alumni Research Foundation**

UW-Madison was founded in 1848 and was among the first group of land-grant universities in 1862. As Wisconsin's flagship university, UW-Madison prides itself on its "firsts." Among our "firsts" was the discovery in 1924, by Professor Harry Steenbock, of methods to enrich food with vitamin D. It was this "first" that precipitated the creation of the Wisconsin Alumni Research Foundation (WARF). Since 1925, WARF has managed UW-Madison's patents and the resulting revenue, helping the University become a top-tier research institution.

UW-Madison's achievements are inextricably linked to WARF's support. WARF has sponsored several dozen WARF Named Professorships, providing research funding to faculty from a variety of disciplines. WARF has contributed to UW2020, an effort to stimulate highly innovative and groundbreaking research. WARF and UW-Madison have partnered on Discovery to Product, an initiative focused on entrepreneurship and providing faculty, staff, and students with mentorship and resources to translate their ideas into commercial products and services. These, and other, efforts have enabled WARF and UW-Madison to make vital contributions to the Wisconsin economy and to ensure that federally-supported inventions find their way to the marketplace. WARF plays an integral role in assisting UW-Madison in fulfilling the Wisconsin Idea – that the work of the University goes beyond the boundaries of the classroom and impacts the world.

Sincerely,

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and Graduate Education  
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