



July 27, 2018

Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive MS 2201
Gaithersburg, MD 20899

RE: RFI Response: Federal Technology Transfer Authorities and Processes, Docket No. 180220199-819-01

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing tens of thousands of Americans, writes in response to the National Institute of Standards and Technology's (NIST) request for information regarding federal technology transfer authorities and processes.

CPR supports NIST's taking a close look at federal policies, practices, and processes concerning the transfer of technology to private-sector and other partners. This important practice serves the national interest by facilitating the commercialization of inventions and discoveries for which taxpayers contributed funding, by providing certainty to encourage the follow-on investment needed to bring these discoveries to market so that society, consumers, and the nation practically benefit from the investment of their money in federal research and development.

The key to successful technology transfer is transferring secure, enforceable private intellectual property (IP) rights. Streamlining processes, procedures, and rules across federal agencies for the transfer of technology to U.S. private-sector firms, especially of secure private IP rights, helps ensure the greatest bang for the taxpayer buck. Further, efficient, property rights-based tech transfer terms will maximize the contribution toward America's having a strong domestic industrial base that achieves competitiveness, provides jobs, and creates wealth due to our innovative edge.

Bayh-Dole: The Right Model

The nearly four-decade track record of the Bayh-Dole Act, founded on transferring not only technology but the exclusive IP rights to federally funded research discoveries, provides the model for federal departments, agencies, and laboratories to emulate. The Congressional Research Service reports, "One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."¹

¹ Wendy H. Schacht, "The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology," Congressional Research Service Report RL32076 (Dec. 3, 2012), p. 10. Available at: <https://www.fas.org/sgp/crs/misc/RL32076.pdf>. ("Schacht B-D")

However, technology transfer from federal laboratories and agencies has varied depending upon the federal entity and over time. Whereas Bayh-Dole bestows dependable, exclusive private property rights and decentralizes licensing and commercialization decisions to university, small business, and nonprofit grantees, the uneven oversight and accountability of federal government technology transfer has resulted in greater variation and uncertainty for private-sector entities.

Before Bayh-Dole, the U.S. government owned 28,000 patents; however, only 5 percent of those patents were commercialized. Twenty-six different sets of rules controlled commercial use of federally owned IP across agencies. Grantees obtained title on a case-by-case basis, having to negotiate a waiver to take title to a discovery. The government normally only gave nonexclusive patent licenses.² In short, private-sector commercializers and investors could not assume the tremendous risks under such tenuous property rights to the IP.

Since Bayh-Dole, which transfers clear private title to any discoveries made from federally funded research, became law in 1980, the private IP rights have led to practical benefit from the taxpayer dollars that fund university and similar research. Clear, exclusive IP rights have translated into new products, new businesses, new jobs, newly created wealth, and more. In the past 20 years, this commercialization has contributed \$1.3 trillion to U.S. gross industrial output, \$591 billion to U.S. gross domestic product, 11,000 startup businesses, 4.3 million jobs, and development of more than 200 FDA-approved drugs and vaccines.³

Bayh-Dole contains a “march-in” provision allowing the government, in certain narrow, extraordinary circumstances, to require the patent owner or exclusive licensee to issue a license to the patented invention. Examples would be failure to achieve practical application of the invention or failure to reasonably satisfy public health and safety needs. In addition, Bayh-Dole provides the federal government the right to “a nonexclusive, nontransferable, irrevocable, paid-up license” to practice a federally funded invention if the government needs to for a particular government use. 35 U.S.C. § 202(c)(4). These clauses represent “takings” of private property during the arduous, uncertain applied research, product development, or market development stage, well after the property has been enhanced, expanded, and had value added using private investment. No federal agency has exercised march-in rights, though a number of petitions have requested it over the years.

The Congressional Research Service notes, “Observers generally agree that the Bayh-Dole Act has successfully met its objectives. . . . The government receives a significant payback through taxes on profits and society benefits from new jobs created and expanded productivity. The importance of patent ownership has been reinforced by the positive effects

² U.S. Government Accountability Office, “Information on the Government’s Right to Assert Ownership Control Over Federally Funded Inventions,” July 2009, available at: www.gao.gov/products/GAO-09-742.

³ Biotechnology Innovation Organization and Association of University Technology Managers, “The Economic Contribution of University/Nonprofit Inventions in the United States, 1996-2015,” June 2017, available at: https://www.autm.net/AUTMMain/media/Partner-Events/Documents/Economic-Contribution-University-Nonprofit-Inventions_US_1996-2015_BIO_AUTM.pdf.

[that] studies have demonstrated P.L. 96-517 [has had] on the emergence of new technologies and new techniques generated by American companies.”⁴

The Bayh-Dole Act establishes a social contract built on the property-rights foundation of our U.S. patent system. This makes for a win-win for taxpayers, academia, small businesses, inventors, investors, established companies engaged in commercialization, the government, and American society at large.

Room for Improvement in the Government

Federal agency and laboratory technology transfer can improve, namely by adopting features that have given rise to the Bayh-Dole Act’s successful tech transfer record and associated returns. There must be renewed commitment to conveying exclusive, reliable private property rights; restored oversight and accountability to ensure uniform rules and practices, along with their consistent application across the government; and lessons learned from what sows uncertainty and unnecessary transactional costs for private-sector partners.

Secure IP Rights. The Bayh-Dole Act says, “It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research or development.” 35 U.S.C. § 200. Distinguishing Bayh-Dole technology transfer is exclusive rights, clear title to the IP, enforceability of private property rights, and rare federal intervention. Certainty over the IP rights transferred is imperative, or else the ability to attract investment and expertise becomes all the more difficult. Thus, every effort should be made on the federal side to assure and ensure transferees of the certainty that exclusive IP rights convey.

The federal government should promote broad agency incorporation of existing frameworks for successful university, private sector, and government initiatives to enhance research partnerships. The government-use license and narrow, exceptional march-in rights of Bayh-Dole should continue to be consistently, narrowly construed by officials involved in technology transfer from federal research labs.

Oversight and Accountability. The Reagan administration’s implementation of the Bayh-Dole Act, the Federal Technology Transfer Act, and similar statutory authorities featured a high-level office answering to the Secretary of Commerce, closely coordinated with the White House. It ensured that federal agencies followed the statutes and partnered with the private sector. This office’s vigilant oversight of and authority to hold agencies accountable for seeking to end-run the law achieved success, including preventing several attempted giveaways of U.S. IP to foreign competitors, overcoming bureaucratic gamesmanship holding up appropriate tech transfer, and countering intransigence by certain federal officials.

The eventual disappearance of this office and its muscle that brought obstreperous officials and agencies into line has resulted in lack of oversight, lack of accountability, and thus lack of taxpayers’ benefit from much of the government research they underwrite. Today, federal agencies and labs do not place sufficiently high priority on commercialization.

An example of missing oversight and unaccountability comes from the prior administration. The U.S. Department of Education apparently ignored technology transfer statutes for protecting IP and outlicensing. Education adopted a compulsory open-source rule

⁴ Schacht B-D, pp. 1, 24.

regarding certain software (Docket ID ED-2015-OS-0105), even software whose functionality may be patentable and, thus, constitute transferrable technology — statutorily protected IP.⁵

Lessons to Be Learned. The death knell to transferring technology from federal laboratories to others, especially private-sector partners, is the combination of uncertainty, bureaucratic pace and processes, and high transaction costs. Government must apply the lessons of how agencies can cut red tape and streamline technology transfer. It is wholly appropriate to safeguard against transferring technology whose transfer would jeopardize our national security. And it is true that the variety of federally invented technology complicates the specifics of the terms of transfer from case to case. Nevertheless, broadly applicable guiding principles, effective practices, and an attitude of customer service to American businesses seeking the transfer of technology for commercialization would advance practical uses of federal research.

Tying federal research agencies' and laboratories' budget requests to their real-world performance in technology transfer would incentivize agencies to get efficient and streamline these processes. Technology transfer expert Joe Allen highlights the problem: "Commercialization remains a neglected step child in many agencies. Government technology managers are often hamstrung from effectively making deals by bureaucratic procedures and second guessing from agency lawyers. Many lab directors and middle managers see tech transfer as an unfunded mandate, taking time and resources away from their mission." Mr. Allen suggests an evidence-based, budget-conditioned solution: "[R]equire that research agencies submit five years of data on their patents licensed and royalties received . . . calculate how their licensing contributed to GDP, jobs supported, etc. — in other words, a tangible ROI [return on investment] to the American people."⁶

At the individual transaction level, training and performance standards should inculcate a professional business-like ethic among those federal officials involved in technology transfer negotiations and approvals. The Congressional Research Service explains, "[T]here are still significant added costs of commercialization after the transfer of technology has occurred." Beyond such R&D costs, "industry unfamiliarity with these technologies, the 'not invented here' syndrome, and ambiguities associated with obtaining title to or exclusive license for federally owned patents also contribute to a limited level of commercialization. Complicating the issue is the fact that the transfer of technology is a complex process that involves many stages and variables. Often the participants do not know or understand each other's work environment, procedures, terminology, rewards, and constraints."⁷ Requiring government employees to make the effort to understand and meet customers' needs and streamlining policies, procedures, and practices should improve federal technology transfer and its ROI.

Expanding federal workers' cognizance of — and accountability for being responsive to — private-sector constraints and pressures due to inane government red tape in tech transfer

⁵ Joe Allen, "Want a greater ROI for taxpayers? Restore the patent system, protect Bayh-Dole and cut the red tape strangling federal labs," IPWatchdog, July 9, 2018. Available at <http://www.ipwatchdog.com/2018/07/09/roi-taxpayers-restore-the-patent-system/id=99136/>.

⁶ Allen.

⁷ Wendy H. Schacht, "Technology Transfer: Use of Federally Funded Research and Development," Congressional Research Service Report RL33527 (Dec. 3, 2012), p. 2. Available at: https://www.nist.gov/sites/default/files/documents/2017/05/09/Technology_Transfer_Use_of_federally_funded_research_-_development.pdf. ("Schacht TT")

arrangements could help alleviate unnecessary delays, costs, barriers, etc. University faculty and student inventors frequently assume key roles in and derive benefits from their inventions' commercialization — hence, bringing deep familiarity with the technology, as well as energy, enthusiasm, and personal commitment that motivate driving through challenges along the way to commercialization. Government inventors should be given similar opportunities, bringing some of the same strengths as their university counterparts to the commercialization enterprise.

Further insight into how individual-level tech transfer best operates comes from the Congressional Research Service. “The transfer of technology appears to be most successful when it involves one-to-one interaction between committed individuals in the laboratory and in industry or state and local government. ‘Champions’ are generally necessary to see a transfer through to completion because it is so often a time- and energy-consuming process. Given this, technology transfer is best approached on a case-by-case basis that can take into account the needs, operating methods, and constraints of the involved parties.”⁸ Foster federal “champions” within federal research agencies through tangible professional recognition and credit.

Federal requirements, dictating strict terms having nothing to do with facilitating commercialization of federal R&D, can have a chilling effect on private firms that otherwise want to pursue commercialization agreements concerning federal discoveries and inventions. For example, consider the National Institutes of Health’s (NIH) CRADA experience in the 1990s. In 1989, NIH started requiring a “reasonable pricing” provision in its Cooperative Research and Development Agreement (CRADA) federal contracting vehicle in order to obtain an exclusive license to NIH-funded technologies. This requirement caused a significant drop in NIH CRADAs, from 42 in 1989 to an average of 32 the next six years. The uncertainty, diminished IP value, micromanaging of market-related matters, and undermined property rights rising from this CRADA clause led NIH to drop the provision. CRADAs with NIH immediately shot up to 87 agreements in 1996 and 153 in 1997.⁹

A successful approach to streamlining federal technology transfer across agencies could involve instituting the customer-friendly approach Dr. Scott Gottlieb, commissioner of the U.S. Food and Drug Administration (FDA), has instituted for advancing regulatory efficiency. Dr. Gottlieb has established new FDA guidance designed to promote certainty, faster regulatory review times, reduced backlogs, and greater responsiveness by FDA staff to pharmaceutical, medical device, and other stakeholders under FDA’s authority. The new standards are having a positive effect and spurring approvals and clearances of innovative medical technology.¹⁰

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⁸ Schacht TT, p. 2.

⁹ How the Bayh-Dole Act Propelled U.S. Global Leadership in Life Sciences, Pharmaceutical Research & Manufacturers of America, (July 12, 2016), pp. 23-24. Available at: <http://phrma-docs.phrma.org/sites/default/files/pdf/bayh-dole-act-white-paper-summary.pdf>

¹⁰ Scott Gottlieb, “Reflections on a Landmark Year for Medical Product Innovation and Public Health Advances and Looking Ahead to Policy in 2018,” FDA Voice blog (January 9, 2018). Available at <https://blogs.fda.gov/fdavoic/index.php/2018/01/reflections-on-a-landmark-year-for-medical-product-innovation-and-public-health-advances-and-looking-ahead-to-policy-in-2018/>; and Scott Gottlieb and Jeffrey Shuren, “New Steps to Facilitate Beneficial Medical Device Innovation,” FDA Voice blog (December 14, 2017). Available at <https://blogs.fda.gov/fdavoic/index.php/tag/least-burdensome-provisions/>.

In conclusion, Conservatives for Property Rights appreciates NIST's initiative to make federal tech transfer great again, just as Bayh-Dole is achieving on the university side. Done right, this will help restore quiet title in private-sector commercializers' federally transferred intellectual property.

American businesses invest substantial time, effort, and money into commercializing a patent licensed from the U.S. government. Every federal research agency must be a good, reliable partner in handing off to those in the private sector who can take an invention or discovery and run with it in order to bring about its commercially viable use. This is in the best interests of the U.S. government and, more importantly, the taxpayers whose hard-earned money pays government employees and underwrites the costs of their federal research.

CPR encourages NIST to aim for exclusive licenses, secure IP rights for licensees, efficient and effective policies and processes for entering technology transfer agreements, oversight and accountability measures to guard against rogue agency or agent conduct, and both preaching and practicing a rededication to the kind of professionalism and standards exhibited by IP licensing professionals in the private sector and universities. This is in the best interest of the American people.

Respectfully,

James Edwards
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Conservatives for Property Rights