



ACS
Chemistry for Life®

AMERICAN CHEMICAL SOCIETY
1155 Sixteenth Street, NW
Washington, DC 20036
T [202] 872 4534

Thomas M. Connelly, Jr., Ph.D.
Executive Director & Chief Executive Officer

July 27, 2018

National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Re: Docket ID No. 180220199-819-01

The American Chemical Society (ACS or “the Society”) is pleased to offer its insights and comments in response to NIST’s Request for Information seeking ways to improve the effectiveness and efficiency of federal technology transfer to generate a better return on the annual federal investment of \$150 billion in research and technology.

Since its founding in 1876, ACS has grown to become the world’s largest scientific society, comprised of more than 150,000 chemists, chemical engineers, and related professionals from across academia, government, and the private sector. ACS also has the distinction of having a national charter of incorporation passed by the U.S. Congress and signed into law by President Franklin Delano Roosevelt effective January 1, 1938.

Upon reviewing the docket listed above, ACS has several thoughts regarding increasing the commercialization of federally funded research and development.

Preserve the strong foundation of Bayh-Dole

The Bayh-Dole Act of 1980 (35 USC 200 et seq.) has proven to be one of the most effective pieces of federal innovation legislation enacted and its fundamental principles should be preserved. Bayh-Dole created incentives and authorities for universities and non-profit organizations to create best practices and models that enabled the United States to become the acknowledged leader for transferring government funded R&D to industry and new startups. 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. Since its passage, the United States has seen a huge impact on its economy from the many commercial developments of inventions created at

universities across the nation. It is estimated that well over \$1 trillion of economic impact has benefited the nation, creating with it thousands of new products and companies, and millions of jobs.

ACS would like to offer the following observations and suggestions for consideration in improving the current system.

Provide clarity for patent processes

One of the foundations that Bayh-Dole depends upon is a strong, reliable U.S. patent system. Uncertainties and inconsistencies in our current U.S. patent system create significant hurdles for the successful commercialization of federally supported R&D and must be addressed if the United States wants to continue its leadership in bringing new technologies to market.

Among the issues to be addressed are uncertainties in the scope of patent eligible subject matter and the Inter Partes Review (IPR) process, which creates asymmetries in claim construction standards, treats patent review as a hybrid form of continued examination and generally denies the due process patents were supplied in the courts.

Additionally, the grace period (35 USC sec. 102(b)(1)(B)), as interpreted by the U.S. Patent and Trademark Office (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 both 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 in the private sector. A strong grace period helps frustrate the theft of ideas by collaborators and thus encourages collaboration, as is the mission of Bayh-Dole. In order to do this, 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.

Build a common tech transfer language and culture

Universities, research institutions and federal labs all fill an important role in performing fundamental, federally funded R&D, but there remains a gap in bringing these projects to the point of commercial interest. Industry has very specific metrics and scorecards to evaluate technologies. These systems often have propriety aspects, but even the non-propriety aspects may not be used by academic and federal researchers when evaluating or describing their inventions. These include things like value chain analysis, net present value sensitivity analysis, voice of customer, and detailed manufacturing and capital cost estimates. This leads to misunderstandings by these groups as to the commercial value of their work.

In addition, the scorecards for industry revolve almost exclusively around commercial value of the work. Academic and federal researchers are valued on different metrics. This results in different work products between the groups. If there is a desire to move academic and federal researcher results to more commercially relevant topics, the systems will need to be adjusted to reflect this. For example, academic labs tend to focus on fundamental science outcomes such as journal publications and external reputation favors, which favors work at lower technology readiness levels (TRL). However, industry has difficulty valuing technology at these earlier stages. Incentives to push the TRL higher within academic and federal labs before exploring

transfer to industry would lower the risk to industry by clarifying the technology's value proposition in a commercial business model.

To make commercialization an agency priority, real rewards for programs and individuals who take the initiative to heart must be provided. 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. Of course, success of these efforts 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.

Address structural issues of working with federal labs

The commercialization of federal lab inventions can be unnecessarily difficult. Core federal technology transfer principles are followed differently by different participants. This creates problems for industry since it is hard to know the flexibility of the contract until a fair amount of effort has been invested in negotiating and defining the project. This uncertainty also dampens industry interest in working with new groups since it is hard to predict what a final agreement will look like.

Expanding 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—would enhance flexibility in licensing practices and mirror common commercial licensing practices. It would further be beneficial to 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.

Other structural obstacles impede industry – federal lab interactions. The large quantity of confidential information, the need for firm economic evaluations, avoidance of right to practice issues, and the need for broad and effective IP protection are barriers to federal labs working with industry. Industrial standards are well-established for business-to-business work, facilitating industry-industry collaborations all the time. However, the standard contracts, requirements, timelines, etc. provided at federal labs do not fit industry norms, which poses barriers to industry-federal laboratory collaborations. Allowing lab personnel to do proprietary work, allowing industry partners to secure reasonable cost exclusive intellectual property licenses, speeding up contracting process, and allowing for less defined projects could increase industry participation and thereby the relevancy of the work being done in federal lab facilities.

Increase interactions between federal labs and industry

Creating closer bonds between industrial and federal researchers will benefit of both groups. To ensure that federal lab scientists and industry scientists are able to work together more productively, sabbaticals, permitted consulting, and federal lab employees' attendance at industry, business, and scientific conferences that focus on applied research should be encouraged.

Industry has a lot to contribute to later stage gate decisions, but there is also value to their contribution during earlier project activities. Often small decisions made mid-project determine commercial viability. For example using a hazardous microbe instead of a nonhazardous microbe can dramatically change the range of suitability for bioengineered systems. When industry is involved, these decisions can be made with a broader perspective of the eventual commercial applications.

Maintain and expand I-Corps, CRADAs and GOALI programs

Government support of curiosity-driven research is essential to the decades-long process of providing American industry with the science to develop products to enable economic growth. Programs such as the National Science Foundation (NSF) I-Corps program, which help 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, are critical ingredients. Created at NSF in FY2011 by the American Innovation and Competitiveness Act, several other agencies have since funded I-Corps cohorts. Further expansion should be greatly encouraged to promote the technology transfer process. In addition, contractual methods like Cooperative Research & Development Agreements (CRADAs) and NSF's Grant Opportunities for Academic Liaison with Industry (GOALI) programs are valuable components of the U.S. innovation ecosystem, and should be maintained and strengthened.

Support grants 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.

Increase industrial opportunities to participate in federal R&D challenges

Due to the need to demonstrate the value of research activities, industry has detailed processes for evaluating commercial opportunities. These have been honed through many decades of experience in their markets. When it comes to setting the federal R&D agenda, industry is a minor voice in agency project selections and subject area workshops too often. Specifically inviting industry to participate in these activities may help to ensure that all voices are heard.

Create a R&D tax credit to encourage increased industry-university collaboration

To facilitate increased collaborative efforts between universities, industry, and federal laboratories, language in the basic research tax credit which narrowly defines basic research projects as “not having a specific commercial objective” should be broadened. Industry should receive an additional tax incentive to conduct collaborative research with universities and federal laboratories.

ACS appreciates the opportunity to provide comments on the federal technology transfer process. If there are any questions on the material provided herein, or if further information or clarification is needed, please contact Mr. Glenn Ruskin, Sr. Director, ACS External Affairs & Communications, Office of the Secretary and General Counsel at g_ruskin@acs.org.

Very truly yours,



Thomas M. Connelly, Jr., Ph.D.