

National Laboratory Directors Council (NLDC) White Paper on Technology Commercialization Return on Investment (ROI) (National Institute of Standards and Technology [NIST])

The Department of Energy (DOE) National Laboratories are mission-driven organizations. The mission of the DOE is to ensure America's security and prosperity by addressing its national security, energy, environmental, and nuclear challenges through transformative science and technology solutions. Our National Laboratories conduct cutting-edge science and technology research and development in multiple domains in support of the DOE mission. Our focus is typically on longer term, multidisciplinary challenges and transformational science, as well as technology development that links basic science and practical applications, rather than focusing on near-term solutions to commercial issues. Moreover, the National Laboratories conduct research and development at a scale where we can bring several scientific and engineering disciplines to the solution of particularly difficult problems. We leverage investments from DOE and other federal and non-federal sponsors to develop science and technology expertise and infrastructure to execute on the mission.

Agency emphasis on, and support for, technology transfer is a significant driver of success at the DOE National Laboratories. We define technology transfer in the broad sense as the process of transferring scientific discoveries, technologies and authored works from our laboratories to other organizations for the purposes of furthering research, development and/or for commercialization to benefit the U.S. The DOE National Laboratories use many pathways to carry out this responsibility, including: (a) publication of our research efforts; (b) hosting scientific users at our cutting-edge user facilities; (c) conducting research and development activities with industry, academia, and others; (d) exchange of personnel via joint appointments with academia or industry exchange; (e) licensing of patents and copyrights secured through our research efforts; (f) creation or support of start-up businesses that help to move our early stage science and technology into commercial applications; and (g) novel commercialization mechanisms sponsored by the DOE that leverage the use of laboratory expertise such as the Small Business Voucher Program, the Lab Embedded Entrepreneurship Program, and the Technology Commercialization Fund.

Past legislation, including Bayh-Dole and Stevenson-Wydler, has been instrumental in enabling the transition of research conducted at the National Laboratories to commercial use. Given that it has been about four decades since the passage of these laws and given that the global economic landscape is very different today than it was then, this is a good time to re-visit core Federal technology transfer principles and ask the question as to whether they should be adapted or changed in some way.

Recognizing that other organizations such as the DOE Technology Transfer Working Group (TTWG), individual National Laboratories, and various university groups have provided comments, we

support many of these ideas. We would like to emphasize the following key focal areas for enhancing commercialization impacts from federally-funded research:

- a) **Software:** The role of software in research and development has grown significantly over the years since the initial technology transfer legislation. There is an opportunity to create clear and uniform policy and procedures for asserting software copyright ownership, and in enabling transfer and licensing of federal-funded software. We believe that the absence of such clear policies has created confusion and served as an obstacle to commercialization success.
- b) **U.S. Competitiveness:** We recommend clarification of U.S. competitiveness provisions such as 'substantial manufacture in the U.S.' in relation to sponsored research and licensing activities conducted by the National Laboratories. Given multinational firms and global supply chains, even U.S. companies balk at this provision which is an obstacle to greater commercialization activities.
- c) **Stage of Development:** We recommend a mechanism to allow the use of federal funds to support technology proof-of-concept/demonstration/prototyping to partially bridge the gap between early stage technology and commercial application.
- d) **Cost Share:** We recommend offering flexibility in cost share expectations when industry collaborates with the National Laboratories (e.g., as opposed to more stringently requiring 1:1 matching funds).
- e) **Conflict of Interest:** Although it is imperative to identify and manage conflicts of interest that could affect research integrity or the safety of human subjects, the regulations addressing conflicts of interest have become more burdensome without demonstrating greater positive effect. In many cases, inventions made with federal funding represent early stage technologies that need both the intellectual property and the know-how of the scientist(s) who made the discoveries to be successful in the marketplace. To enable this, clear guidelines for addressing the potential for conflict of interest – in particular with respect to licensing inventions – should be available.
- f) **Cooperative Research and Development Agreement (CRADAs):** Industry engagement with our researchers through CRADAs may be our most impactful vehicle for technology based economic development and should be expanded. It is imperative that we improve the approval turn around for all (domestic and foreign) CRADAs.
- g) **March-in Rights:** The legislative record of Bayh-Dole makes it clear that Congress intended the march-in provision to apply only in narrow circumstances, such as when a licensee fails to make a good faith effort to bring an invention to market or if health or other emergencies arise and the licensee is unable to make enough of a product to meet public needs. We believe it would be helpful for NIST to provide clarification on the intended purpose, scope and appropriate uses of march-in rights to alleviate the uncertainty around march-in rights that can have a chilling effect on laboratory technology transfer.

Thank you for the opportunity to comment.