July 30, 2018

Re. RFI Response: Federal Technology Transfer Authorities and Processes
Docket Number: 180220199-819-01

Via email: roi@nist.gov

The Biotechnology Innovation Organization's Response to NIST Request for Information: Federal Technology Transfer Authorities and Processes, 83 Fed. Reg. 19052 (May 1, 2018)

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to offer our perspectives on the National Institute of Standards and Technology (NIST) review of current best practices in technology transfer and the request for insights on new ways to move innovative federally-funded research into the marketplace.

BIO is a trade association that represents over 1,000 companies, academic centers, and research institutions who are involved in the research and development of innovative biotechnology products and services. Our members are primarily small and medium enterprises working to develop and commercialize products in the areas of healthcare, agriculture, and the environment in the United States. BIO members work within a highly collaborative business environment, and rely on a web of relationships with different industry participants to shepherd the development of fundamental scientific discovery into tangible products and services. BIO members, accordingly, have a substantial interest in the laws governing ownership and licensing of inventions made with federal funding and ensuring that federal laws, such as the Bayh-Dole Act, will continue to provide an effective incentive for the biotechnology industry to continue its symbiotic relationships with universities and federal laboratories.

We have identified three areas of our industry's experience and interest related to the Return on Investment (ROI) Initiative and hope that the information provided will be useful in assisting NIST to enhance new strategies for success in Federal Intramural Technology Transfer efforts.

I. Healthcare Advances:

Entrepreneurial biotechnology companies are at the cutting edge of a new and revolutionary understanding of the genetic and biomolecular underpinnings of disease, and are committed to

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

developing the next generation of medicines to transform patient care. However, this goal can only be realized in a public policy environment that sustains scientific discovery and biomedical innovation.

Our industry has developed and commercialized more than 300 biotechnology drugs and hundreds of diagnostics, and another 400 or so products are in the pipeline. Science is galloping forward and we are on the cusp of the next generation of medical breakthroughs that will benefit patients and society for decades to come.

Biopharmaceutical companies have fundamentally transformed patient outcomes over the past decade. Diverse examples include the following:

- Hepatitis C – a once incurable disease that now has cure rates above 90%;
- HIV/AIDS – once a death sentence, it's now a chronic manageable condition;
- Cancer – 83% of children with cancer now survive, compared to 58% in 1970; and
- Vaccines – more than 730,000 children's lives have been saved in the last 20 years in the United States because of advances in vaccines.

Future medical breakthroughs rely on the promotion of smart public policy and rational public discourse. Innovators and advocates must all do their part to educate the public and elected officials about what we do, the risks and benefits involved and what is needed to bring the next generation of new cures and treatments to the people who need them most. Developing these new medical advancements involves lengthy development timelines and regulatory approval periods, significant financial investment, and substantial risk of failure. For example, the development of a new biopharmaceutical medicine requires about a decade of R&D, at an out of pocket cost exceeding $1.39 billion.[1] Innovative diagnostic products experience significant time-to-market periods, ranging from about seven to ten years.[2] New molecules entering human testing experience an approximately 90% failure rate on the path to regulatory approval.[3] Accordingly, any contemplated revisions to technology transfer practices must take into account

[1] J.A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, J. Health Econ. 47 (2016), 20-33.

[2] B.N. Roin, The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions, 61 UCLA L. Rev. 672 (2014).

[3] D. Thomas et al., Clinical Development Success Rates 2006-2015, (BIO Industry Analysis 2016), available at https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

the extensive challenges and risks innovators already face in attempting to bring new products to patients, and should not seek to introduce new obstacles.

II. Economic Impact Contributions:

Two recent studies provide evidence that the current U.S. technology transfer effort has been enormously successful in encouraging industry to partner with academic institutions, and turn basic research into new and valuable companies, jobs, and products that are driving America's innovation economy. As NIST considers changes to our overall federally-funded innovation system, conveners should keep in mind the value of commercialized academic research and the good, high-paying jobs it generates throughout the country.

The first report, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996- 2015," documents the sizeable return that US taxpayers receive on their investment in federally-funded research. It shows that, during a 20-year period, academic patents and the subsequent licensing to industry bolstered US industry gross output by

*Generating $1.33 trillion to the US economy while supporting 4.3 million jobs between 1996-2015. The impact on US gross domestic product and jobs supported increased 14% and 12% respectively since the previous study of 1996- 2013;

*Creating 2.75 new companies every day of the year while introducing 2.4 new products based on academic inventions;

*Filing 15,953 new US patent applications, a gain of nearly 15 percent, and 6,680 US patents were issued in fiscal year 2015, up 5 percent;

*7,942 new licenses and options on academic inventions were completed, up 15% from fiscal year 2014, with approximately 70% of licenses going to small companies.

In addition, a June 2018 TEConomy Partners/BIO economic analysis report re-affirms that academic/industry partnerships, including technology transfer, are a key factor for the US lead in biotechnology and the life sciences:

*The bioscience industry employs 1.74 million people in the US and creates another 5.5 million in the overall economy;

*The industry pays an average salary of $96,000, with more and more states creating programs to encourage biotech development. That figure is more than the average salary for all jobs in the US;

*The industry is active in all 50 states, Puerto Rico, and the District of Columbia in both R&D and manufacturing or distribution of biotechnology products.

These and other studies provide further evidence that vital intra and extramural NIH funding and the Bayh-Dole Act allow inventions arising from federally-funded research to be patented and licensed by the research institution, which has been enormously successful in encouraging industry to partner with academic institutions to turn basic research into new and valuable companies, jobs, and products that are driving America's innovation economy.

III. Strong Patent Protection and Licensing Rights:

Intellectual property is the lifeblood of the biotechnology industry. Strong patents, and an efficient, predictable, and objective patent system, are critical to ensuring a steady stream of capital to biotechnology companies developing innovative medicines, alternative energy sources, insect- and drought-resistant crops, and a wide range of other innovative biotechnologies that are helping to feed, fuel, and heal our planet. This quintessentially-American industry leads the world in innovation, providing the United States with a global competitive advantage and spurring economic growth and the creation of high-paying jobs here at home.

The ability of universities, small business, and federal laboratories receiving federal funding to flexibly license their patented (or patent-pending) inventions is important to continue incentivizing industry relationships and investment. The success of the Bayh-Dole Act in promoting the transfer and development of biopharmaceutical innovations to marketed products is illustrative. Before Bayh-Dole, the government took ownership of all federally-funded inventions and offered only non-exclusive licenses to any and all interested third-party commercial developers.[4] Among the changes brought about by this landmark legislation was to allow federally-funded grantees and contractors to take ownership of inventions they develop with such funding, and to license such inventions on an exclusive or non-exclusive basis. Since the passage of Bayh-Dole in 1980, more than 200 federally-funded inventions have been developed into marketed new drugs and vaccines through public-private partnerships and technology licensing.[5] Amendments to federal technology transfer regulations and policies that would add burdens to companies seeking patent licensing opportunities would threaten the continued success of these programs.

[4] PhRMA, How the Bayh-Dole Act Propelled U.S. Global Leadership in Life Sciences (whitepaper), available at http://phrma-docs.phrma.org/sites/default/files/pdf/bayh-dole-act-white-paper-summary.pdf.

[5] J. Allen, Academic Patent Licensing Helps Drive the U.S. Economy, IPWatchdog (June 20, 2017), available at http://www.ipwatchdog.com/2017/06/20/academic-patent-licensing-helps-drive-u-s-economy/id=84778/.

Recommendations:

*The Bayh-Dole Act continues to be a vital tool in moving research into potential commercialization activity. Alternative actions that would impair the ability of research communities and the biotechnology industry to continue these partnerships would have a negative impact on the overall health of the industry, in particular those companies that require venture funding to move technology development forward.

*The US patent system, upon which technology transfer is based, should not be taken for granted. Preserving technology transfer and the US patent system is critical to ensuring US economic sustainability and spurring the next wave of American innovation in the life sciences. As illustrated by the over 60 countries represented at the BIO International Convention in 2018, the US is competing for partnerships between government, academic researchers, and industry.

*While many new discoveries and advances in science occur in universities and federal laboratories, the application of this new knowledge to commercial and useful public purposes depends largely upon actions by business.

*While our industry does receive early-stage federal research support, the vast majority of funding necessary to develop new products comes from the private sector. But private sector investors will not invest in the development of research that they do not believe will yield a return on their investment. As such, the exercise of march-in powers, for example, to set price controls would defeat the overarching goal of the Act-which is to facilitate commercialization of government funded research.

*Cooperation among academia, federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened.

Conclusion:

BIO continues to be an interested party to the NIST ROI Initiative conversation and looks forward to receiving the initial findings of the effort and identifying ways to provide the biotechnology industry input vital to the process of “bench-to-bedside” benefits.

Please contact us at (202) 962-9200 if you have any questions regarding our comments. Thank you for the opportunity to provide input on this important matter.