



University of Massachusetts

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

Via email: roi@nist.gov

The University of Massachusetts (UMass) welcomes the opportunity to respond to the NIST Request for Information (RFI) on Federal Technology Transfer Authorities and Processes Docket No. 18022019-819-01. On behalf of the five UMass campuses (Lowell, Amherst, Boston, Dartmouth and the Medical School in Worcester), we are pleased that NIST has initiated an evaluation of existing practices, policies and regulations to support and facilitate the transfer of innovations which have resulted from federal research funding.

For many years, the five UMass campuses have actively engaged in the assessment, protection and licensing of inventions and intellectual property (IP), partnering with the private sector to ensure the commercialization of new ideas results in societal benefits. Examples of products which have been licensed and commercialized as a result of UMass discoveries include:

- A portfolio of technologies from the Dartmouth campus covering a novel approach to impact-resistant fabrics that is being commercialized by a spin-off company for use in athletic headgear, with the goal of preventing or minimizing head injuries in youth and adult sports;
- Polyisobutylene-based biostable polyurethanes, which are used in coatings for pacemakers and defibrillators, licensed by UMass Lowell;
- Thermo Catalytic Biomass Conversion (Bio-TCat™), a clean technology platform for inexpensively producing petrochemicals from renewable, non-food biomass, has been licensed by UMass Amherst to start-up company, Anellotech;
- Several approved vaccines and drugs from the UMass Medical School, including Merck's ZINPLAVA which is prescribed to reduce recurrence of *Clostridium difficile* infection and Rabishield, a *rabies* monoclonal antibody developed in collaboration with the Serum Institute in India.

As you review current technology transfer policies and processes and consider making changes to enhance outcomes, we offer the following comments:

- 1- UMass is an APLU member university and we have reviewed the joint letter of response dated July 27, 2018 signed on behalf of APLU, AAU, COGR, AAMC and ACE (the "Associations' Letter") and agree with both the spirit and content of that letter. In particular, we want to ensure that the statutory framework of Bayh-Dole is maintained and that the public, and congress, are aware that the use of "march-in" is not an appropriate means of setting or controlling drug prices. In addition, we agree with all the points raised in the Associations' Letter regarding further adjustments that should be made to Bayh-Dole's implementing regulations which were released several months ago.
- 2- It is well known that academic technology transfer offices (TTOs) almost always operate at a loss and that inventions made at universities or teaching hospitals are very early stage. Having access to additional federal funding support for patents, including foreign filings when justified, and proof of concept or gap funding greatly increases the commercialization success rate and likelihood that the host institution will continue to maintain a licensing and startup program. With respect to gap financing, UMass recommends that NIST give serious consideration to creation of funding programs modeled after those which have proven effective and generated returns exceeding their cost. The UMass Technology Development Fund is a very small (\$200,000 in total) internally funded, annual grant fund that awards up to \$25,000 to faculty to show the commercial viability of their inventions. Results from the 12 years that we have been running this modest program have been impressive with the creation of several spin-off companies as well as licenses signed with established companies. In total this program has awarded \$2.7 million, which has resulted in ten new licenses and six new spin-off companies which have raised over \$22 million in follow-on funding. While these funds are well used and successful they are not adequate in many disciplines, especially in the life sciences, to show full commercial potential and secure additional development funding.
- 3- Conflict of interest regulations are necessary but often a hindrance in the context of faculty entrepreneurship and startups. The UMass Conflict of Interest Committee has been developing new practices to make disclosure and management of conflict of interest for faculty and student start-ups more streamlined. But the disclosure rules in place in the Public Health Service (PHS) Policy can still discourage such activity and that factor conflicts with Bayh-Dole's preference for licensing to small entities and the economic development mission of many schools.
- 4- The Associations' Letter mentions the challenge TTOs experience in complying with the U.S. Manufacturing Requirement in Bayh-Dole and we share that concern. Within the academic technology transfer community there is strong support for this requirement because it can lead to American job creation. However, both licensees and licensors often partner internationally and the requirement can undermine further development of a discovery, ultimately preventing the discovery from reaching the public. For example, the Dartmouth campus has recently licensed to a multinational company a patent covering one step in the preparation of dyed clothing. The licensee expects that the method would be used in a supply chain where manufacturing takes place in multiple countries, as is common for the clothing industry.

- 5- Academic TTOs are facing several patent challenges under the America Invents Act. The most serious of these relate to Section 101 eligibility, the substantial increase in IPR filings and the PTAB process in general. We support the initiatives and improvements suggested in the Association Letter.
- 6- With respect to measuring technology transfer success and the performance of TTOs, we agree with the concern raised in the Associations' Letter, namely, that too much emphasis has been placed on metrics such as revenue generation and number of patents. A better approach is to focus on impact and indirect effects even if they are harder to measure. UMass supports APLU's current initiative on metrics development and analysis of technology transfer which has proven to be a much broader activity than originally recognized.
- 7- The Associations' Letter cites the importance of the iCorps program. We view this program as one of the most successful efforts launched by government. Since its inception, iCorps has provided entrepreneurs, investigators and graduate students with an effective framework for outreach to prospective users of new technology or purchasers of new products, thereby confirming market need or, alternatively, the advisability of pivoting to another course of action. We urge NIST and the administration to continue supporting the iCorps program at NSF and expanding it to other agencies.

The University of Massachusetts endeavors to support the commercialization of technologies that are developed by our researchers, to ensure that the country and the world benefits from inventions made on our campuses. We hope that our input is helpful as you review the current technology transfer process and consider making changes which will enhance the outcomes of the Federal government's critical investments in basic research.

Sincerely,



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