Duke UNIVERSITY | OFFICE of LICENSING & VENTURES

July 30, 2018

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

Duke University commends NIST for requesting input as it reviews federal technology transfer processes. The public-private partnership among the federal government, research universities and industry remains unparalleled and has resulted in the United States being the premier country for innovation and entrepreneurship. For over forty years, the Bayh-Dole Act (the "Act") has provided support for this partnership by authorizing U.S. universities, nonprofit organizations, and small businesses to retain title to their federally funded intellectual property. There is no question that the Act is working. Just recently, Cleary et al., tracked new drug approvals from 2010-2016 and concluded that NIH funding contributed to ALL of the 210 drugs approved in this time frame[1]. While we believe that the statutory framework of the Act should remain unchanged, we agree that it is important to continually review our processes in light of changes in research and technologies required for the future of our country and the world.

Duke University is one of the country's leading undergraduate and graduate universities. Duke's schools of medicine and engineering are consistently ranked in the top 10 of research intensive schools and in the top 10 of NIH funding. Our research and clinical expenditures top $1B resulting in over 300 invention disclosures a year from our faculty. Over the past ten years, over 100 Duke startups have raised close to $3B in public and private financing; 8 are in the public market. Products impacting health and well-being include:

- Myozyme® for treatment of Pompei disease
- Kystexxa® for treatment of refractory gout
- EvolvEdge™ for automated passenger visitor screening
- mTenna™ software enabled metamaterials for satellites
- Variety of imaging and brain stimulation technologies including 3D Human Anatomical Models for simulation, dosimetry technologies for CT imaging and electrical stimulation technologies for deep brain stimulation and treatment of chronic pain

In addition to these products, Duke technologies ranging from treatments for cancer and rare brain disorders to quantum computing and machine learning for next generation computers and data analysis are in the pipeline for future commercialization.

It is important to note that Duke faculty are not our only innovators -- Duke students also participate widely in the innovative and entrepreneurship process. Last year over 200 undergraduate students obtained innovation and entrepreneurship certificates with many more participating in a myriad of startup showcases and business internships. Our students come here ready to be innovative and expect education and resources to support these endeavors.

[1] Cleary, EG., et al. (2018). Contribution of NIH funding to new drug approvals 2010-2016. *PNAS, 115* (10): 2329-2334.

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As members and participants of various associations, we have reviewed the responses to the RFI submitted by other organizations including:

- The joint response from the Association of American Universities (AAU), Association of Public and Land Grant Universities (APLU), Council on Governmental Relations (COGR), and the Association of American Medical Colleges (AAMC) ("Association Joint Response");
- The response from AUTM, a non-profit organization representing more than 3000 technology transfer professionals

Duke largely agrees that the detailed recommendations presented in these responses merit serious consideration by NIST. We would like to highlight a number of these recommendations:

Overall, we strongly recommend that the *Bayh-Dole Act remain unchanged as the statutory framework for promoting the transfer of federally funded research to the public*. That said, there are a number of improvements that could be made to processes recognizing the changes in technology since the Bayh-Dole Act was first written:

1. Improve and standardize the iEdison database. We understand the importance of reporting federally funded inventions and their status, but the different reporting requirements and legacy databases for various funding agencies is an extra burden on our already understaffed offices. *A single unified database combined with consistent and well-defined definitions for reporting across the various governmental agencies would be a significant improvement and could improve overall compliance*.

2. Reconsider recent Act implementing regulations. We agree with the Association Joint Response related to the removal of the 60-day time period for funding agencies to request title upon learning of a contractor's failure to disclose an invention or elect title. The possibility that a cloud of title could be cast indefinitely over the invention should the university not correctly report an invention is problematic. This could inject a very plausible point of breach for Duke in our licenses and/or make federally funded inventions less appealing to potential licensees.

In addition, we are unclear as to the need for the requirement for the contractor (in our case the University) to file a non-provisional patent application ten months after filing a provisional patent application. It is not uncommon if there are no public disclosures for universities to refile provisionals for very early stage technologies to enable the inventors another year to gather needed data and results. How is NIST planning to handle the refiling of a provisional patent application under this requirement? Would a refiling reset the clock, or once we a file the first provisional, are we unable to refile?

3. U.S. manufacturing requirement compliance challenges. As with our comments on iEdison above, we believe that a standardized system or a single waiver for all federal agencies would reduce costly time delays and confusion. We recently had a licensed invention that had funding from multiple agencies -- the response time varied considerably among the agencies, one never responded, and we ultimately had to hire outside counsel to navigate the process resulting in extra time and costs to the university. While we agree with the intent of the manufacturing

requirement, not all technologies can be easily manufactured in one country resulting in the loss of some valuable products as potential licensees look elsewhere for new technologies if the difficulty of licensing federally funded technologies is too cumbersome.

4. Clarify process and government rights for copyrighted technologies: When the Act was written, software, databases, artificial intelligence and other similar technologies were mostly on the horizon. At some universities these technologies are a significant portion of the invention portfolio but in most cases patent protection is not appropriate for them. There is considerable inconsistency and confusion as to not only how to report these types of inventions through iEdison, as well as government rights to various copyrighted materials resulting under various federal contracts. Improvement of the iEdison database as recommended above may solve some of these issues, but *one consistent standard, as for patented technologies, would serve to further advance these types of technologies into the marketplace*.

5. Patenting Costs and Challenges: U.S. Universities continue to place considerable resources into technology transfer processes because support of innovation and entrepreneurship is an important service to our faculty and students. However, these activities do not always result in commercial products resulting in some university tech transfer offices operating in the red. Escalating patent costs contribute significantly to the required increases in resources. Universities with jointly owned inventions with the federal government, including those medical schools like Duke with associated Veterans Hospitals, must pay large entity fees, doubling our costs for fees. Micro-entity status granted in the AIA (35 USC 123(d)) was thought to be one solution for increased patent costs, however, the lack of clarity of when a university can claim this status has resulted in the majority of universities not using micro-entity and having to pay the higher small entity costs. *Revisiting small entity (or micro-entity) status for the government and the micro-entity rules would alleviate some of the patent expenses burden.*

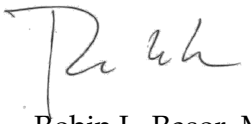
In parallel with the challenges of escalating patent costs, broad interpretations of Section 101 of the patent code has resulted in significant challenges for universities in protecting technologies such as medical diagnostics, genetic based inventions and software. In some cases, universities must choose only to file for patent protection outside of the United States or not at all. In particular, medical innovations that require considerable investment prior to regulatory approval may never make it to the market due to lack of patent protection and therefore industry investment. *We recommend NIST review the proposals developed by the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO) and the American Bar Association (ABA), which address these areas of concern.*

6. Public-Private Use of Tax-Exempt Bond Financed Facilities. As mentioned above, the partnership among the federal government, universities and industries is a strong contributor to our economy. Industry increasingly depends on university research for new product inventions and universities depend on industry investment to further develop federally financed basic research to enable these technologies to reach the public. Universities dependent on tax exempt bonds for continuing to improve and develop world class laboratories and research facilities face a lack of clarity over activities that may be deemed private business use such as licensing agreements, sponsored research, support for licensed technologies, and other activities. Linking tax status of a specific research facility to negotiations with industry results in

lost opportunities not only for the university, but for the local community and the U.S. as industry may choose to fund such research overseas at institutions without such regulation.

Thank you again for soliciting viewpoints from various stakeholders.

Sincerely,



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