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April 5, 2021

Submitted through the Federal eRulemaking Portal

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

Re: Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327)

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. We are witnessing this success now as we become vaccinated against COVID 19 from vaccines resulting from this partnership. 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. While we believe that the statutory framework of the Act should remain unchanged, we agree that it is important to continually review and update processes covered under the Act.

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 400 invention disclosures a year from our faculty. Over the past ten years, over 150 Duke startups have raised more than $5B in public and private financing; a number of these companies are in the public market or soon will be, others have been acquired, and others have entered into partnerships with industry. Products from Duke research impacting health and well-being include Myozyme® for treatment of Pompei disease and Kystexxa® for treatment of refractory gout, along with a vibrant pipeline of new therapeutics ranging from vaccines, antibodies, mRNA and gene and cell therapy treatments all in various stages of the clinical trial process to further benefit public health.

Our industry partners are very important to Duke – in addition to funding basic research across campus, they provide resources for many of the clinical trials underway in our Clinical Research Institute (DCRI) and also provide the mechanism by which our technologies are commercialized. Industry investors provide the funding for our nascent startups such that they can move early stage technologies forward and they provide internship and job opportunities for our students. Some of the proposed changes to the Act, in particular uncertainty related to broadening the scope of applicability of march-in rights (§ 401.6) beyond Congress's original intent, could significantly reduce interest in federally funded research at universities driving these investors to fund research overseas and to not pursue early stage technologies at our universities. We believe concerns over drug pricing are better suited for the legislative process and not through amendments to the Act.

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I commend my professional association, AUTM, in its detailed and thorough review, comments and suggestions provided to NIST March 28, 2021 as well as comments from COGR. In addition, we would like to highlight and provide additional comments:

§ 401.6 Exercise of march-in rights.

The added section (e) below indicates a lack of understanding of the licensing process between contractors (universities in our case) and the licensee. University licenses rarely, if ever, set prices for products sold under the license. Instead, universities focus on ensuring that the technology is diligently developed such that we share in the upside when the technology moves to commercialization.

> (e) *March-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.*

We would suggest removing this addition entirely or consider AUTM's suggestion that this section be revised by removing (i) the word "exclusively" and (ii) the phrase "of the contractor" so there is absolute clarity that end-user pricing may not be used as a factor in determining whether to exercise march-in rights and further reflecting that pricing is not, nor should be, a component of university licenses.

§ 401.14 Standard patent rights clauses.

We are disappointed that NIST did not take the opportunity to address Subject Inventions that, while commercializable, may not be patentable or should not be protected by patents – namely those inventions that result in copyrightable technology such as software, databases and content. Many universities, including Duke, receive a significant portion of disclosures that fall under this category and for which we license to existing companies and new startups. Artificial intelligence and machine learning technologies in particular are resulting in considerable success in digital health and other digital technologies, many of which have no need for patents to reach the market. A contractor should not be required to file for patent protection in order to claim title to a subject invention:

> *(3)(i) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use.*

(c) Invention Disclosure, Election of Title and Filing of Patent Application by Contractor

By their nature, university technologies are often quite early and it is not uncommon for tech transfer offices to receive incomplete disclosures, disclosures that are only at the idea stage, and disclosures that lack data or true proof of concept. Every tech transfer officer would love to have all disclosures be "sufficiently complete" as described below, but that unfortunately is an unrealistic expection. Section (c)(1) continues to be an issue for universities resulting in disclosures being "rejected" by the iEdison system. It is the job of our offices to work with our inventors to further develop and translate those early inventions. We believe that the best

description of a disclosure should be at the time of patent filing, not at the initial disclosure stage.

> (1) The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). *It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.* The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

We also agree with AUTM that the requirement in § 401.14 (c)(3)(i) that requires a non-provisional application be filed within 10 months of the filing of the provisional application should be removed. Duke routinely utilizes the full 12-months before "converting" the provisional application as set forth in the patent statute. As stated above, academic technologies by nature are quite early stage and our inventors require the full 12 month period to obtain the necessary data needed for a complete patent application that can satisfy the 35 USC §112 requirements for written description and enablement. Needing to file unnecessarily early will result in incomplete patent applications and thereby jeopardize the ability to obtain strong and meaningful patents, hence undermining the entire purpose of this statute. Duke asks NIST to consider changing the time period back to 12 months.

Duke also does not support the newly proposed § 401.14 (c)(3)(ii) which states:

> *(ii) Each provisional application filed following the initial patent application must contain additional written description of the subject invention not previously disclosed in a patent application. The contractor shall file or notify the government that they do not intend to file a non-provisional application within 10 months of the last filed provisional application that is consistent with this section.*

To avoid losing their rights in a technology to the government, contractors will often use the tactic of refiling the initial provisional application instead of converting, thereby forfeiting the original priority date for a new one. Duke sometimes uses this practice in situations where the the subject invention has not been disclosed in a publication, is not ripe for conversion (e.g., enabling data is still needed), and/or if there is not yet any commercial interest.

There is also concern that § 401.14 (c)(3)(ii) may also require a contractor to secure agency approval before filing a follow-on provisional patent applicaton (i.e., filing of a new provisional patent application that contains new subject matter). With the ever increasing utilization of the provisional patent process by contractors since the implementation of the first-to-file rule, requiring agency approval for all follow-on provisionals would result in an overwhelming burden for most, if not all, university technology transfer offices, not to mention on the agencies themselves who would need to review and approve such requests.

Additionally, the intent of § 401.14 (c)(3)(iii) is unclear:

> *(iii) The contractor will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.*

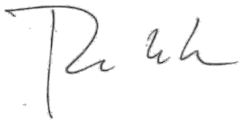
Does this include PCT applications? As written, it appears that the statute is requiring a contractor to file directly in a foreign country 10 months after the filing of the first filed patent application. In the case of a contractor that routinely filed provisional patent applications as the first filed patent application, it would require the filing of foreign patent applications at the ten month date. It is rare for Universities to file foreign applications unless there is a licensee who can help pay the patent costs. Further, in the event that a University does elect to file internationally, it will generally do so by filing a Patent Cooperation Treaty (PCT) application first and then electing to enter the desired foreign juridictions at the required time during national phase. An exception to the rule would be for filing in a country that is not part of the PCT (e.g., Taiwan).

§ 401.16 Federal agency reporting requirements.

Duke strongly supports NIST taking the necessary steps to require all federal agencies to use iEdison. This step along with the ongoing changes to the currently outdated database will be a benefit to both the government in terms of more accurate and efficient reporting and in ensuring better compliance with the reporting system overall.

Thank you for providing us the opportunity to comment on the proposed revisions; we look forward to working with NIST on the continued improvement of the iEdison system.

Sincerely,



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