



The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property
Director of the U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

COGR & AAU Comments in Response to *Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace* (Docket No. PTO-C-2024-004)

May 14, 2024

Dear Director Vidal,

On behalf of the member institutions of our respective organizations, we appreciate the opportunity to provide comments in response to the above-referenced Request for Comments (RFC) on potential efforts to increase translation of innovation to commercialization.

COGR is an association with over 200 research universities and affiliated academic medical centers and research institutes. COGR focuses on the impact of federal research regulations, policies, and practices and advocates for sound, efficient and effective regulation that safeguards research and minimizes administrative and cost burden. The Association of American Universities (AAU) is an organization of 69 leading U.S. public and private research universities on the leading edge of innovation, scholarship, and solutions that contribute to scientific progress, economic development, security, and well-being.

Our associations generally concur with the [comments](#) submitted by AUTM – the association of technology transfer professionals – in response to this RFC. We would like to focus on suggestions of particular importance to our members.

1. March-In Framework

In comments submitted by both [COGR](#) and [AAU](#) to NIST in February 2024, as well as [joint higher education association](#) comments, we expressed the belief that that the draft framework recently proposed by NIST for the exercise of march-in rights by federal funding agencies will cause irrevocable damage to the 40+ year success story of the Bayh-Dole Act, and our nation's longstanding and successful technology transfer practices will be undermined. As stated by AUTM, this framework will have a crippling impact on the ability of universities and others to find licensees and investors willing to invest in high-risk, early-stage technologies. The framework will harm the ability of research institutions to license patents vital to new products,

processes, and technologies that start-up companies and others rely on to commercialize products and services that benefit our nation's health, security, and economy.

We realize that USPTO does not have direct responsibility for the draft framework. The RFC suggests that this topic is beyond the scope for comment. However, according to the RFC its focus is on "opportunities for positive public impact by bringing innovation to market through commercialization, for example via the licensing of IP rights." The draft march-in framework if implemented would constitute a difficult if not impossible barrier to achievement of this goal.

We understand from recent public comments made by NIST Director Dr. Lori Locascio that, following the review and assessment of the more than 50,000 comments received in response to the draft NIST framework guidance, the Interagency Working Group for Bayh-Dole (IAWBD) will be re-convened to determine whether to amend, finalize, or rescind the framework. To inform those future conversations, we wish to provide feedback on the impact the draft guidance is already beginning to have and the need for rescission.

From conversations and convenings throughout our membership and the wider innovation ecosystem, it is apparent that the draft guidance will have a chilling effect on technology transfer. Current licensees and their funders are evaluating and assessing their potential exposure and risk to their current licensing agreements on university technologies, which is affecting the current commercialization process. Additionally, many funders, including venture capitalists, are flatly stating that they will not even consider licensing Bayh-Dole affiliated innovations while the draft framework is still lurking and could be finalized at any time. Neither of these two conditions will change without rescission of the draft framework itself.

It is our fervent hope that the stakeholder feedback being received by federal agencies and the Biden administration will be insightful for continued efforts by the IAWBD and provide a positive resolution for the future of U.S. innovation.

2. Patent Eligibility, Exclusivity, and the PTAB

We fully agree with AUTM's comments on the need to clarify patent eligibility as an avenue to foster greater translation of innovative discoveries to patentability. In tandem, patent-based exclusivity is crucial for start-ups, which is the mechanism frequently used to commercialize early-stage university technologies. This is especially true for critical and emerging technologies at the very cutting edge of global innovation. Both eligibility and exclusivity are crucial for the ability to commercialize university innovations and translate the groundbreaking research performed by our member institutions.

We also agree that the Patent Trial and Appeal Board (PTAB) has not functioned as originally intended to the detriment of small and university inventors. Significant changes need to be made in PTAB practices. We are hopeful that the feedback and insights your office will receive in response to the Notice of Proposed Rulemaking on Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement (Docket No. PTO-P-2023-0048) will assist your agency in promulgating regulations that will course correct current PTAB practices back to the original intention of the America Invents Act for

PTAB to function as an administrative tribunal to provide judicial efficiency in patent proceedings for the federal Article III courts.

It is also an important agency policy which supports accessibility that patent fees for micro entities and universities to continue to remain affordable. We urge your agency to make further reductions to PTAB fees for such entities wherever possible.

3. Harmonization of Patent Prosecution

We have recommended in the past and fully concur with AUTM's recommendation to restore the full twelve-month grace period (under which inventors' own disclosures do not constitute barring prior art) worldwide, preferably with few other requirements, as well as the suggested alternatives to the lack of an international grace period. International harmonization of intellectual property law, while a significant governmental undertaking, is a key component to creating a supportive environment for innovation globally. We commend the work of the U.S. PTO Patent Public Advisory Committee (PPAC) with bodies such as the American Intellectual Property Law Association (AIPLA) and others to bring such harmonization to fruition.

4. Speed and Quality of Patent Examination

Patents that issue in a timely manner after thorough patent examination are more readily licensable and more valuable to licensees than patent applications that linger in prosecution, or issued patents that are vulnerable to post-grant challenge. As suggested by AUTM, we recommend conferring with patent examiners to find out what resources would help them expedite their work and providing ongoing training to examiners.

5. Upgraded Patent Databases

We agree with AUTM about the value of making patent application data more easily searchable and usable. User-friendly patent search interfaces; quality control of patent data (inventor and assignee names, corporate information); and forward and backward citation searches, ideally by reference type (102/103) would all be useful tools for universities and other research institutions seeking commercialization partners (licensees, collaborators, sponsors), and for university licensees seeking to understand the competitive landscape and identify potential suppliers and customers.

6. Licensing Biological Materials and Data

Licensing of biological materials and data, which may or may not be protectable under the current patent system, has become increasingly important in university tech transfer activities. USPTO should consider convening working groups to discuss and develop best practices for the storage, sharing, protection, and licensing of biological materials and data. Your agency could convene the

community in a transformative way and provide the necessary leadership towards community standards that will foster accessibility and homogeneity in the treatment of such resources.

7. Assisting Historically Black Colleges and Universities (HBCUs)

We agree on the importance of USPTO leadership to promote and support patenting and technology transfer at HBCUs. This requires outreach to and education of university administrators at these institutions. USPTO could play a critical role in this process, providing a supportive convening space to identify strategic initiatives to foster these goals, as suggested in the AUTM comments. We also commend the recent release of the USPTO National Strategy for Inclusive Innovation and look forward to its implementation.

Conclusion

We applaud and support USPTO's efforts to identify challenges and opportunities to commercialize innovations through the use and strengthening of the U.S. intellectual property system. University innovations typically involve early-stage technologies, and their successful commercialization presents many obstacles. Our organizations continue to stand ready to serve as resources to your agency and encourage USPTO to continue to consider appropriate initiatives in this very important space.

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