

May 7, 2024

Submitted via Regulations.gov

The Honorable Kathi Vidal Director United States Patent and Trademark Office 600 Dulany Street Alexandria, VA 22314

AUTM's Comments in Response to the United States Patent and Trademark Office's Request for Comments Titled "Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace" (Docket No. PTO-C-2024-004)

Dear Director Vidal:

AUTM – the association of technology transfer professionals – is pleased to provide its thoughts to USPTO on this request for comment (RFC) on how best to improve the ability to move more inventions from the lab to the marketplace. Indeed, that process is what AUTM and its over 3,000 members strive to accomplish every day at universities and non-profit research institutions. We appreciate the opportunity to respond to the issues raised by the RFC.

In these comments, we attempt to answer the questions specifically raised within the RFC while providing additional insights. Some questions related to laws, others to policies and practices. Some relate to actions the USPTO alone can take; others are more open ended. We appreciate the opportunity to comment on the overall framework for our innovation ecosystem.

A stable framework:

While we understand that certain ongoing patent issues are outside the scope of this inquiry, we do feel obligated to at least mention one in particular.

While the USPTO is not directly involved in the current NIST discussions regarding the framework under which federal agencies ought to consider (or not consider) the use of the march-in provision, we believe 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. We urge you and others in leadership roles at the USPTO to strongly oppose the imposition of any new interpretations of the Bayh-Dole Act's march-in provisions based on pricing – an interpretation that the Act's authors explicitly rejected. As outlined in our direct comments on that NIST march-in guidance framework, we are convinced such a mistaken reinterpretation of law is not legal, will not be effective in reducing drug pricing, and will actually significantly inhibit the very goals this RFC raises. See <u>https://autm.net/AUTM/media/About-Tech-Transfer/Documents/AUTM-Comments_NIST-1-23-</u> <u>24_revised.pdf</u>.

That said, by far one of the biggest other challenges we face is seeking more stability and certainty about our ability to harvest the innovations we create on our campuses and in our institutions. We believe that more needs to be done to clarify what is patent-eligible, a position you yourself have espoused. We also believe that there needs to be changes in the adjudication of Patent Trial and Appeals Board (PTAB) cases. Too many challenges are used to block competing technologies or cripple small inventors. Analyses of who files PTAB cases show that many come from large corporate interests, when in fact PTAB was created to provide a cheaper alternative to going to court to protect one's patent rights.

Any efforts your office can undertake internally to provide a more level playing field for small inventors and other patentees would be most welcome as we await legislative action by Congress.

In terms of other potential actions PTO might take, we highlight the following for your consideration, some of which are discussed in more detail below.

- Better curation, analysis, and dissemination of patent office data. For example, PTO data could help identify areas where there is a lot of patenting activity. One such example could be quantum computing. Having such data would help provide universities with guidance about which discoveries they themselves might file on and help licensors and licensees find one another.
- Convening stakeholders with industry leaders, perhaps through local or regional conferences or podcasts, where industry could identify areas of particular commercial need.
- Supporting more innovators by developing additional new community outreach offices, similar to the office in Strafford County, New Hampshire, that is serving innovators in the New England region.

Clean and green, critical, and emerging IP-related challenges.

We express some reservation about application specific IP-related comments because virtually every scientific discipline is eagerly contributing to clean, green, critical, and emerging technologies! Our key business challenge is always finding and then engaging fully with committed implementer partners along a research, development, manufacturing, and distribution value chain.

Green and climate technologies come from every scientific discipline, are commercialized by a variety of industries, and are used in virtually every market, from agriculture and bioprocessing to energy generation and storage, from cement and steel production to transportation. A few examples of the interplay between technologies and the "green" markets they can serve are below:

- i. <u>Agriculture: Robotics + AI/ML + image curation and processing enable reduced pesticide use</u>. A tractor mounted camera, image processing, and AI determine which plants in a field need pesticide, thus reducing pesticide use by about 75%. See <u>http://extension.msstate.edu/publications/see-spray-technology</u>.
- ii. <u>Personal care: Biotechnology + bioprocessing enable cold water laundry detergent</u> Energy use is reduced by 90% if cold water replaces hot water, and by 70% if cold water replaces warm water. See <u>https://cen.acs.org/business/consumer-products/chemistry-cold-water-washing/102/i3</u>.
- iii. <u>Magnets for green energy: Physics + materials science + AI:</u> Making high performance magnets for green energy generation using only earth abundant minerals. <u>See DOI:</u> <u>10.1021/acs.chemmater.3c00892.</u>

AUTM believes that green and climate technologies need reliable intellectual property protection, motivated innovators and fully committed implementers as much as other technologies do. However, in view of the inherent global nature of green and climate technologies, and the role data plays in the development and deployment of these technologies, AUTM takes this opportunity to i) comment on international patent harmonization initiatives, and ii) reference and expand upon our prior AI and data comments.

Harmonization of patent prosecution: The majority of AUTM's members come from academia, where the grace period between publication and filing a patent application is particularly valued. AUTM supports restoring the full twelve-month grace period worldwide, preferably with few other requirements. However, if the alternative is no international grace period at all, then trade-offs on the i) required statements identifying the "graced" publication(s), ii) possibility of earlier publication of the patent application, and iii) AIPLA proposals on conflicting applications, prior user rights, and prior art are generally acceptable to AUTM.

Data and AI Systems: Worldwide remote sensing and analysis of the data gathered is an overarching need of green and climate technology. Remote sensing depends on data, image processing, and AI/ML. See the EPO report on Space Borne Sensing and Green Applications. See <u>https://link.epo.org/web/Spaceborne%20sensing%20and%20green%20applications%20report.pdf</u>.

See AUTM response to the USPTO's Request for Comments Regarding Artificial Intelligence and Inventorship" Docket # PTO-P-2022-0045, <u>https://autm.net/getattachment/About-Tech-Transfer/Advocacy/AUTM-Speaks-Out/AUTM-Comments-for-Docket-ID-Number-PTO-P-2022-0045.pdf?lang=en-US</u>, especially paragraph 7: *"Incentives are needed to invest in the creation of more robust, tested, transparent datasets that are capable of more readily, and reliably, validating the trustworthiness of AI Systems."*

Intellectual property rights, whether patents, copyright, a *sui generis* right for data, or defined via contract, are an important tool for overall data use and management. See AUTM response to the United States Copyright Office's Notice of Inquiry and Request for Comments Regarding Artificial Intelligence and Copyright (Docket No. 2023-6; Document No. 2023-18624), <u>https://autm.net/AUTM/media/About-Tech-Transfer/Documents/AUTM-Comments-for-COLC-2023-0006-0002.pdf</u>, excerpted below:

"Data is a vital asset for AI systems in a myriad of forms. While certain compilations of data have traditionally been afforded copyright protection, there are too many legal uncertainties for how other aspects are protected and treated. As detailed in AUTM's response to the USPTO's Request for Comments Regarding Artificial Intelligence and Inventorship (Docket ID Number: PTO-P-2022-0045), AUTM supports (i) the rights of the creators and owners of datasets and (ii) laws and rules that value and respect such rights. Uses of data for AI system training, development, or new improvement must be authorized and properly licensed, as well as compensated and/or acknowledged, where necessary."

The USPTO can play a role by creating a secure data storage resource, analogous to its sequence listing resource (<u>https://www.uspto.gov/patents/apply/sequence-listing-resource-center</u>).

The U.S. Office of Copyright can play a role by signaling its ability to host copyrightable AI training sets, including those of chemical or materials compositions.

The USPTO and U.S. Office of Copyright could offer hosting resources which possibly i) allow view only and/or ii) allow downloads upon registration and agreeing to terms of use, as is the case with <u>https://nyu.databrary.org/.</u>

The USPTO can indicate whether it will accept synthetic databases to satisfy applicable enablement requirements.

AI-assisted Patents: We appreciate the USPTO's RFC on its recent guidelines for determining inventorship of AI-assisted patents. We look forward to additional guidance on how AI assistance will change criteria for obviousness and enablement. We are keenly interested in how, if and when entirely in silico enablement will be acceptable in an unpredictable art.

Critical technologies need speedy translation. Emerging technologies may present unpredictable challenges. As for green and clean technologies, these innovations also come from virtually every scientific discipline, are commercialized by a diverse group of organizations, and can be used in a wide variety of markets.

AUTM believes that critical and emerging technologies need reliable intellectual property protection, motivated innovators and fully committed implementers as much as other technologies do. However, we take this opportunity to comment on exclusive licenses, motivation, and transparency, all of which contribute to speedy translation, committed public-private partnerships, and thoughtful approaches to emerging technologies. **Competitive wedges and exclusive licenses:** Early technologies are often commercialized via start-up companies. These start-ups rely on what the business community calls "a competitive wedge" or unique advantage, to attract funding. The Bayh-Dole Act enables discretionary exclusive licensing and licensing judgment calls on the part of the research performer's organization. Patent-based exclusivity is a business tool that is consistent with the academic ethos – it both discloses and provides a time limited protection to the innovation that can then attract committed implementer partners and investors. AUTM members play a substantial role in start-up creation. In 2022 alone, AUTM members negotiated approximately 1,000 start-up licenses.

To illustrate the importance of exclusivity to start-ups, see AUTM's February 8, 2013 letter to George Elliott (responsive to the USPTO's Roundtable on Genetic Diagnostic Testing held January 10, 2013) showing that from 2004-2006 (the most recent years these data were gathered) over ninety percent of start-ups had an exclusive license (either fully exclusive or exclusive in a particular field of use). See https://www.uspto.gov/sites/default/files/aia_implementation/gen_a_autm_20130208.pdf.

Motivation: Critical technologies benefit from highly motivated innovator-implementer partnerships. Young academic innovators are highly motivated to transfer themselves along with the technology, streamlining the development path from lab to market. This level of commitment, combined with exclusive grants to IP rights, helps attract equally committed implementers.

Transparency: New and unfamiliar technologies, such as blockchain, carbon capture via ocean sequestration, gene drives or AI present almost by definition not fully anticipatable questions and concerns. Some emerging technologies may be relevant to patent prosecution itself, such as AI, which the USPTO is thoughtfully addressing. See https://www.uspto.gov/initiatives/artificial-intelligence.

Concerns about privacy and safety benefit from a well-informed discussion of risks, benefits, and tradeoffs. Patents themselves, because they require disclosure, facilitate transparency about the technology itself and the organizations and people working on it. The USPTO can contribute to, and potentially help organize, knowledge about emerging technologies, including via curation and analysis of patent filings.

Stable patents are good for the innovation ecosystem.

Patents are weakened, along with AUTM Members' ability to license them to implementer partners, when the eligibility guidelines are so open to interpretation as to be unpredictable. AUTM strongly supports fact-based and skilled artisan informed patent examination and enforcement.

AUTM agrees with the perspectives expressed in the Bilski blogs, that a law of nature is a universallyobserved-to-be-true set of rules and predictions that has not yet been falsified, and that a product of nature exists absent human intervention. See <u>https://www.fenwick.com/bilski-blog/bad-science-makesbad-patent-law</u> and <u>https://www.fenwick.com/bilski-blog/bad-science-makes-bad-patent-law-noscience-makes-it-worse-part-ii.</u> Associations useful enough to be helpful in the real world, for example, an observation that a certain genetic sequence is associated with a certain medical condition, are <u>not</u> laws of nature. In fact, virtually all such associations are imperfect. They become good enough to be useful when their sensitivity (not too many false negatives) and specificity (not too many false positives) for a particular use are deemed acceptable.

A product of nature exists absent human intervention. DNA, for example, is highly regulated in a living cell, by other molecules that control what it does in a complex network of on and off switches and feedback loops. Outside a living cell, it is a molecule that scientists can put to use as they devise, and such innovative uses should be patent-eligible.

AUTM strongly supports the Patent Eligibility Restoration Act (PERA), S. 2140.

Patents are similarly destabilized when the PTAB and the courts apply different standards for considering patent challenges, and when the PTAB permits serial and duplicative challenges. AUTM strongly supports PREVAIL (Promoting and Respecting Economically Vital American Innovation Leadership Act), S. 2220, as a remedy for these PTAB problems.

Operational suggestions and finding licensees.

Faster higher quality patent examination is desirable. Reach out to patent examiners to learn what resources they would find most helpful. Consider providing or even requiring continuing technical professional education for patent examiners to help them stay abreast of new developments in their art unit.

Consider further reducing PTAB fees for small and micro entities, as is currently the case for prosecution. This would be a welcome step toward a more level playing field for smaller innovators.

Published patents and patent applications help licensors and licensees find one another. Searchable databases or catalogs of other IP resources, such as biological materials, databases, or copyrighted works may similarly increase technology transfer and make it more efficient.

Published patents contain a wealth of business development information which the USPTO could leverage. The European Patent Office does an excellent job of making a business and social impact case for patents, in particular for emerging technologies via its Patent Insight Reports: <u>https://www.epo.org/en/searching-for-patents/business/patent-insight-reports.</u>

For example, pages 23, 24, and 25 of "<u>Quantum Computing</u>", shows co-applicant patterns by country and sector, including patents jointly invented by and among inventors from universities, companies, and nonprofits. These data and diagrams support the importance of international collaborations, patent harmonization to help facilitate such collaborations, and of public-private partnerships.

Upgrade public patent databases so they have more of the features of private subscription based databases. Business development professionals use patents, as they do other publications, to help identify potential suppliers, licensees, partners, customers, and competitors. Forward and backward citations are valuable indicators and conversation starters.

One challenge of analyzing USPTO data is simply the variety of spellings, including abbreviations (and typographical errors) of assignee names and inventor names. The USPTO could assign a stable reference ID to each assignee, and offer additional corporate tree functionality, which provides a history of the name changes of the assignee, including when patents or entire companies are bought and sold.

Another seemingly small change with a potentially large impact would be to enable citation searches by the type of reference, whether it was cited by the examiner or not, and if so, as what type of reference (e.g, as an anticipating/102 reference or as support for an obviousness/103 rejection). Analysis of such citation data is helpful in making both business and policy decisions.

Convening stakeholders to foster consensus best practices.

<u>Managing data and biological material:</u> A challenge for our time is defining and using additional classes of protectable subject matter, which can still be managed and protected so as to foster public-private commercial partnerships as needed, and also prudently disclosed and fairly shared for other purposes. AUTM has previously commented on certain similarities between biological materials and data. See paragraph III c of <u>https://autm.net/AUTM/media/About-Tech-Transfer/Documents/AUTM-Comments-on-Intellectual-Property-Protections-for-Artificial-Intelligence-Innovations_1-10-20.pdf</u>.

AUTM noted that each resource requires time and commitment to produce and maintain, and there is a desire to share it with others, typically with some conditions, such as receiving appropriate credit. As data becomes an increasingly important research resource, it is timely for stakeholders to share their experience managing such resources, both commercially, and for research purposes.

The USPTO could convene working groups to discuss experiences and evolving consensus-based practices for licensing data and biological materials as well as patents and software. Examples of approaches to licensing software, biological materials, patent rights, and for storing, securing, and sharing data are listed below.

- i. <u>Software:</u> The Carnegie Mellon University open source license grid has a variety of options with respect to permissions, limitations and conditions. See <u>https://www.cmu.edu/cttec/forms/opensourcelicensegridv1.pdf</u>.
- ii. <u>Biological materials and patents</u>, for commercial use and for internal use: The NIH OTT has a variety of templates and approaches for nuanced sharing and licensing of biological materials and patent rights. See https://www.techtransfer.nih.gov/resources#LAP.
- iii. <u>Patents and biological materials for CRISPR</u>: The Broad Institute approach to sharing and licensing CRISPR resources, where the tools are made available at no cost to the research community, and commercial licensing is tailored to the intended use. See <u>https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edi</u>.
- iv. <u>Data:</u> See the NYU hosted <u>https://nyu.databrary.org/</u>, which enables data downloads upon registration and agreeing to terms of use.

Additional opportunities for international harmonization:

Harmonized approaches, or at least standard approaches to managing jointly owned IP assets, including each of patents, copyright, and data will streamline IP commercialization. See this IPWatchdog post on the patchwork of international default laws on joint ownership at

https://ipwatchdog.com/2016/02/18/the-default-law-of-joint-ip-ownership/id=66154/, underscoring the need to pre-agree on how such joint IP will be managed before it is created.

Comments related to Patents 4 Partnerships and WIPO Green Initiative:

AUTM has our AUTM Innovation Marketplace (AIM) Database (<u>www.aim.autm.net</u>) which provides 30,000+ licensing opportunities across all fields. AUTM would welcome the opportunity to work with the USPTO on this critical tool.

AUTM has also been a partner in the WIPO GREEN initiative for over a decade and exports green technology opportunities from the aforementioned AIM database into the WIPO Green database. We encourage the USPTO to continue to partner with this important initiative.

Outreach across America.

We applaud the efforts of the USPTO to reach out to help provide more opportunities for women and other underrepresented groups to participate in the patent process. One excellent way to help track this progress would be for Congress to adopt the IDEA Act, which would provide more data to analyze and track patent holders in key demographic groupings.

We also support USPTO in its efforts to ensure that patent fees for small entities remain more affordable. There are many inventors – and many institutions – who simply do not have the resources to file for as many patents as they might otherwise.

As for underrepresented groups, AUTM does a lot of outreach to those innovators. We have worked with USPTO on these issues and look forward to continuing to collaborate.

Another idea is to engage historians to write about interesting historical patents focusing in compelling human interest examples, such as the Coston Flare (see <u>https://en.wikipedia.org/wiki/Martha_Coston</u>) and Precision resistor (see <u>https://www.invent.org/blog/inventors/otis-boykin-electrical-resistor-pacemaker).</u>

How to assist Historically Black Colleges and Universities:

The integration of patenting processes into research and innovation at HBCUs will take a system level approach. HBCU leaders, starting with their presidents, should be part of Roundtable discussions with the USPTO where they will gain a clearer understanding of tech transfer, the patenting process, and how all this fits into the research and innovation agenda at their institutions.

The key is to educate the administrators (presidents, deans, chairs, vice presidents for research, etc.) on the resources available, the best practices, and the value of engaging in the patenting process. This will encourage them to add innovation, entrepreneurship, and tech transfer into the strategic plan and vision for the university. If there is no leadership buy-in, it is difficult for tech transfer to be promoted and/or supported on the campus of HBCUs. USPTO can have "Campus Champions" at the HBCUs -- especially individuals who have spent a day or two at the USPTO understanding how the USPTO works, the patent examiner process (sort of a Day in the Life of a Patent Examiner program) and use examples of how great innovation and patents have solved societal issues that impact the communities that HBCUs serve. As anchors of these communities, it would be insightful and relatable. The experience can be for faculty, students, and administrators.

An HBCU Application Assistance Program could also be helpful to those HBCUs that are not located close to Patent Pro Bono Offices or who do not have the TTO expertise on their campus. Essentially, draft applications can be reviewed prior to filing and feedback provided, especially on the claims. Additionally, the program can be designed as a cohort model or pilot program, inviting HBCU faculty, staff, and graduate students to spend two/three days at the USPTO, learning to conduct patent landscape searches, drafting claims, and perhaps completing provisional patent applications. The hands-on learning experience will be critical to developing capacity and increasing the diversity of people engaged in the patenting process.

In addition, similar policies and procedures can be applied to other Minority Serving Institutions (MSI) such as Tribal Colleges and Universities.

CLOSING

In summary, AUTM very much appreciates the close working relationship that it has with the USPTO. University-based inventions are by their very nature early and tenuous. Any uncertainty and unpredictability of their patent rights makes them even less able to withstand the rigor needed to move from the lab to the marketplace. We once again call on Congress to act to strengthen patent rights, and we continue to urge you and your colleagues at USPTO to make patenting a more powerful and inclusive tool in America's technology arsenal.

Thank you for the opportunity to provide comments to this Request for Comments.

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