September 16, 2024

Submitted via Regulations.gov

Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property
Director, United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

AUTM's Comments on the 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence (Docket No. PTO-P-2024-0026)

Dear Director Vidal:

Thank you for the opportunity to provide comments on the 024 Guidance Update on Patent Subject Matter Eligibility Including on Artificial Intelligence (Docket No. PTO-P-2024-0026).

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development and distribution of innovations arising from academic research. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses, and government organizations around the globe.

AUTM's membership has traditionally stemmed—and continues to draw primarily—from academic settings (67%). AUTM members in such academic settings are focused on advancing early-stage inventions and other technologies to the marketplace, primarily through licensing and further development with partners (i.e., implementers). Between 2013 and 2022 (the most recent decade for which we have data), our skilled professionals filed over 160,000 patents for academic inventors and negotiated over 70,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions. Our innovators are active contributors to and users of computer science and AI Tools.

On behalf of our innovators, AUTM members seek, foster, and negotiate the public-private partnerships that move academic innovations from lab to market. These activities lead to the creation and distribution of new products that care for our citizens and our planet, create jobs, and strengthen U.S. global competitiveness. From 1996-2022, products resulting from these AUTM member associated public-private partnerships contributed nearly two trillion dollars to U.S. gross industry output and supported six and a half million jobs.[1]

AUTM has responded to previous RFCs on artificial intelligence (AI) from the USPTO and from the U.S. Copyright Office[2] and appreciates this opportunity to comment on additional AI-related matters.

Introduction and General Comments

AUTM supports legislative action on subject matter eligibility. AUTM has publicly supported PERA.[3] Our strong preference is for a return to broad subject matter eligibility. The current situation—where the first step in determining whether an invention is worthy of patent protection involves a difficult and time-intensive analysis that often improperly imports elements of novelty, nonobviousness, and enablement—is untenable. The fact that the USPTO must continually issue new guidance to try to help its examiners understand and apply the inconsistent caselaw on subject matter eligibility underscores the problem.

As previously stated, AUTM supports guidance that reenforces patentability of AI-enabled inventions, as well as inventions on novel AI architectures. AUTM also supports improved protection of the datasets that are necessary to further AI innovation.[4]

We neither support nor endorse "adjusting to *Alice*," though we appreciate the collection and presentation of data in the 2020 USPTO Report named "Adjusting to Alice." The report showed that after *Alice* and for patent applications in "*Alice*-affected areas,"[5] there was a significant

[1] See https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-EconomiContributions-of-University-Nonprofit-Inventions_14JUN2022.pdf.

[2] See July 29, 2024 AUTM's Comments on the Impact of the Proliferation of AI and Determinations of Patentability (Docket No. PTO-P-2023-0044); May 7, 2024 AUTM's Comments on the USPTO's Inventorship Guidance for AI-Assisted Inventions (Docket No. PTO-P-2023-0043); October 30, 2023 AUTM's comments in Response to the US Copyright Office Notice of Inquiry and Request for Comments Regarding Artificial Intelligence and Copyright (Docket No. 2023-6; Document No. 2023-18624); May 15, 2023 AUTM's Comments in Response to the USPTO's Request for Comments Regarding Artificial Intelligence and Inventorship (Docket ID Number PTO-P-2-22-0045); January 10, 2020 AUTM's Comments on Intellectual Property Protections for Artificial Intelligence Innovation (Docket No. PTO-C-2019-0038); November 8, 2019 AUTM Comments on Patenting Artificial Intelligence Inventions (Docket No. PTO-C-2019-0029).

[3] See AUTM's August 16,2023 Letter to Senators Coons and Tillis.

[4] See note 2.

[5] Patent applications having the same classification as those in litigations involving subject matter eligibility. See www.uspto.gov/sites/default/files/documents/ieg-sme_crt_dec.xlsx.

increase in both first office action Section 101 rejections and inter-examiner variability in issuing such rejections. After the 2018 Berkheimer[6] memorandum and the 2019 Revised Patent Eligibility Guidance, the data show improvement—i.e., fewer first office action Section 101 rejections and decreased inter-examiner variability. So, the guidance is informing practitioners who file applications in the "*Alice*-affected areas" and improving consistency in examination, but nonetheless, such applications are still many times more likely to receive a first office action Section 101 rejection than in other technology areas. That alone is enough to make patent applicants question whether it is worth the time, effort, and expense to file such applications. This is especially true for university tech transfer offices, who must consider budget and personnel limitations when making decisions about how to protect intellectual property. And often, lack of patent protection makes it harder for universities to find industry partners to test and develop their technologies for potential public use.

We agree with Judge Plager's dissent in *Interval Licensing, LLC v. AOL*, in which he characterized the courts' *Alice* jurisprudence as "useless," "an abstract (and indefinable) doctrine," "unworkable," an "intellectual morass," and "incoherent."[7] This ambiguity harms AUTM members and the U.S. innovation ecosystem.

We note that the motive to limit subject matter eligibility was initially driven by the concept of preemption—such as when courts explained that one should not be allowed to patent a newly-discovered natural law because such patent claims would unfairly preempt any use or application of that natural law. However, whether or not a claim improperly preempts future innovation should be assessed using the more traditional statutory requirements that are better suited for such analyses. For example, if the claim is drafted so broadly that it encompasses more than what the patent applicant described and enabled in the disclosure, then that claim should be rejected under 35 USC §112. In fact, recent cases have expanded the written description and enablement requirements, which has made them stronger tools against claim overbreadth and further eliminated any need to use subject matter eligibility to prevent preemption.

When subject matter eligibility is used in a way that removes entire categories of inventions from the patent system—even inventions that are new, useful, nonobvious, and adequately described and enabled—this harms innovation. Exceptions to the general rule that patentable subject matter should "include anything under the sun that is made by man"[8] should be few and should be expressly defined by statute. The USPTO should focus primarily on the other statutory requirements—e.g., nonobviousness, written description, enablement—to ensure that patented

[6] *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).
[7] *Interval Licensing, LLC v. AOL, Inc.*, 896 F.3d 1335, 1349-56 (Fed. Cir. 2018) ("The law, as I shall explain, renders it near impossible to know with any certainty whether the invention is or is not patent eligible. Accordingly, I also respectfully dissent from our court's continued application of this incoherent body of doctrine.")
[8] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

inventions are worthy and that claim breadth is consistent with what was actually invented and disclosed.

Similarly, use of "obviousness" considerations, such as what constitutes well-understood, routine, and conventional activity, is more appropriate and straightforward as part of the Section 103 analysis. Unlike obviousness, the determination on patent eligibility should be time-invariant. If an invention is ineligible for patent protection now, the same should have been true 50 years ago and should be true 50 years from now. A law of nature today always was and always will be a law of nature.[9] If the test for subject matter eligibility yields a different answer today than it would have in the past, then the test is wrong.

As with the subject matter eligibility test's reliance on what is "well-understood, routine, and conventional," we also see the potential for subjective and inconsistent analyses in the determination of what constitutes "significantly more" in Step 2B of the prescribed test. It would be helpful to have examples that (a) demonstrate the smallest necessary change that transforms an ineligible patent claim into an eligible one and (b) explain the significance of the change. When multiple variants are discussed, the reader cannot discern which are most important and/or which combination of variants led to the conclusion.

Finally, we note two areas where we urge caution. First, we caution against rules that identify claims containing mathematical formalisms—such as equations, inequalities, or quantitative design criteria—as automatically being directed to an abstract idea. For example, we caution against rules that a priori disqualify data analysis techniques from patent protection. We also caution generally against careless use of figures of speech, such as "gene"[10] and "artificial intelligence"[11]—such terms are by their nature fluid, subjective, and open to interpretation. It is better to be tedious and clear than to use evocative short phrases that promote ambiguity.

Comments on New Examples

First, we note that the new examples necessarily include a short summary of the disclosure to support the claims and must use already-published science and technology to illustrate the points they are trying to make. This makes it difficult for the reader to discern between (i) an invention that is ineligible for patent protection because of the subject matter claimed and (ii) an invention

[9] See https://www.fenwick.com/bilski-blog/bad-science-makes-bad-patent-law; https://www.fenwick.com/bilski-blog/bad-science-makes-bad-patent-law-no-science-makes-it-worse-part-ii. Abstract ideas and products of nature should similarly be time-in-history invariant.

[10] Gerstein MB, Bruce C, Rozowsky JS, Zheng D, Du J, Korbel JO, Emanuelsson O, Zhang ZD, Weissman S, Snyder M. What is a gene, post-ENCODE? History and updated definition. Genome Res. 2007 Jun; 17(6):669-81. doi: 10.1101/gr.6339607. PMID: 17567988. https://pubmed.ncbi.nlm.nih.gov/17567988/.

[11] See https://www.technologyreview.com/2024/07/10/1094475/what-is-artificial-intelligence-ai-definitive-guide/.

that is unpatentable because it lacks novelty or nonobviousness. Those analyses should not be intertwined.

As noted above, it would be more helpful to have examples that clearly identify which claim elements or amended claim language transform an ineligible patent claim into an eligible claim. Such crisp comparisons make it easier for stakeholders (including examiners) to understand and apply the rules.

(1) Example 47: New and nonobvious uses for known hardware should be patent eligible.

The explanation of Example 47 implies that the chip was custom designed for a particular purpose. However, the eligibility of the invention should not depend on the hardware that implemented it. Hardware or software modifications can make a machine work better, and both should be patent eligible. Likewise, software that makes the hardware function better or that changes the hardware in a useful way should be eligible for patent protection.

Therefore, claim 1 of Example 47 should be patent eligible even if it recites "A non-transitory computer-readable medium for an artificial neural network …" or "An integrated circuit for an artificial neural network…" The patent examiner can address any issues of novelty, nonobviousness, or claim overbreadth under 35 USC §§102, 103, and 112.

(2) Example 48: Data processing innovations should be patent eligible.

Data processing inventions should not be deemed ineligible merely because humans are capable of doing some level of data processing in their heads. Imagine a time in history before there was a public disclosure that short time Fourier transforms (STFTs) can be used to generate a spectrogram of the frequency and phase content of audio signals. If such never-seen-before spectrograms were used for voice verification, that innovation should not be deemed unworthy of a patent under the guise of a Section 101 analysis. The examiner can determine whether the use is indeed new and nonobvious during the Section 102 and 103 analyses and can determine whether the claims are overbroad during the Section 112 analysis.

In claims 2 and 3, it is unclear how many of the additional recited elements are needed to render the claimed invention patent eligible. Such a detailed (and potentially arbitrary) assessment should not be used as a gateway test to determine whether an invention is patent eligible, and thus whether it is worthy of being assessed for novelty, nonobviousness, etc. As noted above, we are concerned that Step 2B—which takes into account whether or not the extra-solution activity is well understood, routine, and conventional in the field—risks improperly introducing "obviousness" considerations into patent eligibility. The fact that the USPTO included *two*

additional elements (g and h for claim 2 and e and f for claim 3) demonstrates the difficulty of explaining precisely how much and what kinds of extra-solution activity are required.

(3) Example 49: Subject matter eligibility should not prevent the patenting of new or improved uses for known biomarkers or known drugs.

The innovative work it takes to demonstrate an effective use for a biomarker (e.g., for detecting disease, determining treatment) should be eligible for patent protection. The same is true for the innovation necessary to discover and successfully validate a new use for a known drug. In this example, claim 1 should be patent eligible if the biomarkers are DNA, mRNA (a proxy for protein expression), a protein expression assay, or combinations thereof. Claim 2 should be patent eligible if X were a known drug. Questions of whether the claimed subject matter is nonobvious should be assessed under 35 USC §103, and questions of whether the claims are overbroad should be assessed under 35 USC §112.

Additional Examples Requested

Additional examples that more closely track the innovations we are seeing at universities and the issues we are analyzing would be helpful. The following are examples of claimed innovations that should be patent eligible. If the USPTO elects to generate new examples based on these, we again suggest that a discussion of the minimum required additions, amendments, or deletions that impact the eligibility determination will be most useful to our community.

(1) Proposed Example 1: Multiple Robot Activity Scheduling

Robots are increasingly used in routine and highly choreographed tasks. Scheduling robots and/or robot equipment, for instance on a manufacturing floor or in a warehouse, can become a highly complex task as the quantity of robot equipment and tasks increases. In most industrial settings, it is necessary to optimize the performance of a team, including robots, and to extract the highest value from the equipment. It is therefore important to reduce any idling time. AI-enabled methods to schedule robot equipment on the fly greatly improve the efficiency of the team, including robot equipment, as compared to a floor manager scheduling individual staff members.

Therefore, the application of Section 101, Step 2A as determining that any manner of task that could be done by a human mind (e.g. mental process) should be reviewed in light of the complex environment in which a claimed AI method is used and the real-world benefit of having AI-based systems to improve efficiency in industrial processes.

Claim 1: A method to generate a schedule for a plurality of robot equipment in real time, the method comprising:

inputting temporal constraints comprising at least one of: deadlines and wait constraints of each of a plurality of tasks into a graph model, the graph model having a plurality of nodes and edges, wherein each node or edge of the plurality of nodes and edges comprises a representation of at least one of a start time node, a finish time node, a task, and a robot equipment;

building the graph neural network by convolutionally encoding the temporal constraints and at least one constraint related to the available robot equipment and shared tools employed by the available robot equipment, wherein the graph neural network is trained using supervised reinforcement learning on known training schedules;

computing input features for the graph neural network, wherein the input features comprise at least one of a minimum, a maximum, a mean, or a standard deviation of an expected time to complete a task;

employing the graph neural network and the input features into a greedy policy for sequential decision making by constructing a schedule as a Markov decision process using a tuple, wherein the tuple includes, at least one of states, actions, transitions, and rewards; and

determining a schedule for each of the robot equipment.

(2) Proposed Example 2: High Throughput Screening using Machine Learning

It is widely recognized (in biological, pharmaceutical, chemical, and materials sciences) that use of machine learning (ML) in bench testing and discovery of new compounds/materials and uses thereof is a significant improvement over traditional bench-top discovery. High throughput screening becomes a more efficient tool with the use of machine learning and generative AI and exceeds the capacity of discovery of bench-top scientists.

The determination of subject matter eligibility for screening-type ML and generative AI should consider the contribution of these tools as defacto more than mental processes. In the following examples, the training of a machine learning model, but not the use of the ML for high throughput screening in and of itself, is regarded as allowable subject matter.

In the following example, a set of training data including sets of molecules and related characteristic data is used to train a neural network. Using the trained neural network, a user provides a test molecule to the trained neural network for screening.

Claim 1: A method for training a graph convolutional neural network (GCNN) using transfer learning, the GCNN being configured for virtual screening of molecules for drug discovery, said method comprising:

receiving a first data set comprising a plurality of molecules and respective labels of a first target;

training the GCNN to predict the first target to initialize one or more parameters of the GCNN using the first data set;

receiving a second data set, wherein the second data set comprises a plurality of molecules and respective labels of a second target; and

training the GCNN to predict the second target to refine the one or more parameters of the GCNN using the second data set, wherein the molecules in the first data set are unrelated to the molecules in the second data set, and wherein the first target is different from the second target.

Claim 2: A method for virtually screening molecules on Plasmodium falciparum (P. falciparum) comprising:

providing a trained GCNN, wherein training the GCNN comprises:

pre-training the GCNN on a first data set comprising a first target; and

training the GCNN on a second data set comprising a second target, wherein the first target is unrelated to the second target;

receiving a candidate molecule; and

predicting, using the trained GCNN, whether the molecule inhibits P. falciparum.

(3) Proposed Example 3: Method of Alerting a User of a Suspicious Internet Domain

The current subject matter eligibility guidance does not account for the necessity of computer-specific and internet-specific methods and systems to manage the user experience on user devices through software applications. The determination of a claim reading on a "mental process" when describing software implementations to automatically manage other software misses the context of why such software implementations are necessary.

Claim 1: A method for displaying an error message on a Suspicious internet domain, the method comprising:

receiving a request for access to an internet domain;

checking identification information for the requested internet domain against a set of rules related to suspicious internet domains; and

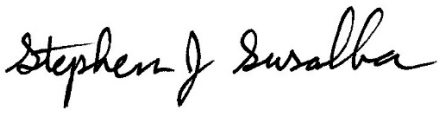
upon determination that the requested internet domain is a suspicious internet domain, generating a certificate with an extracted domain name and returning the generated certificate of the domain with a custom error message for the domain, said custom error message comprising a risk type and next actions for a user; and

displaying the custom error message at the requested domain.

Conclusion

In conclusion, we appreciate the opportunity to submit these comments and to continue our ongoing and productive communications with the USPTO regarding subject matter eligibility, AI, and other issues that impact innovation and technology transfer.

Sincerely,



Stephen J. Susalka, Ph.D.
Chief Executive Officer