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United States Patent and Trademark Office
Department of Commerce

AUTM's Comments on the USPTO's Inventorship Guidance for AI-Assisted Inventions (Docket No. PTO–P–2023–0043)

Thank you for this opportunity to respond to the USPTO's Inventorship Guidance for AI-Assisted Inventions ("the Guidance"). AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development and deployment 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. It is estimated that the American economy has received nearly $2 trillion in benefits from the technology transfer carried out by AUTM members over the past 30+ years.

As such, AUTM members are at the very crossroads of innovation, taking ideas from the laboratory and helping move those ideas into commercialization so that all Americans can benefit from these translated discoveries. This is why understanding AUTM's views on this issue is critical to retaining American leadership in innovation and technology.

Summary of AUTM Comments

AUTM has responded to previous requests regarding artificial intelligence from the USPTO and from the U.S. Copyright Office.[1] We appreciate that the USPTO continues to thoughtfully consider patent examination processes for emerging and rapidly evolving technologies, such as AI. As detailed below, we generally agree with the Guidance and the inventorship determinations in the provided examples. We provide comments and pose questions about the Guidance and examples to emphasize select points and to suggest ways to make the Guidance and examples more clear and helpful. Finally, we provide thoughts on additional steps the USPTO could take to incentivize innovation in the AI space—e.g., by establishing a repository for training datasets to be filed and protected.

AUTM's Comments on the Guidance

1. AI Is Part Of A Human Inventor's Toolkit

   As AUTM has noted in prior comments submitted to the USPTO, AUTM agrees that only a natural person can be an inventor. We also agree that "the use of an AI system by a natural person(s) does not preclude a natural person(s) from qualifying as an inventor (or joint inventors) if the natural person(s) significantly contributed to the claimed invention." In other words, AI is simply one of many tools in a human inventor's toolkit. AUTM also believes that as these AI tools evolve and are more commonly used, human contributions to AI system design, input, and output should be fully considered and appreciated in a manner that supports the patentability of new and useful technologies, including AI-assisted innovations.

2. Conception Is More Than Recognizing A Problem Or A Research Plan

   AUTM agrees that conception requires the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is . . . to be applied in practice"[2] and that "[m]erely recognizing a problem or having a general goal or research plan to pursue does not rise to the level of conception."[3] In the AI context, AUTM also agrees that prompt construction directed to a specific problem or designed to elicit a particular solution can qualify as "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is . . . to be applied in practice" because an inventor does not need to know that the invention will work for there to be complete conception.[4]

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[1] See 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).

[2] MPEP 2138.04.

[3] RFC quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.,* 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994).

[4] MPEP 2138.04

3. Reduction To Practice Alone Is Not Enough

AUTM agrees that the act of reducing an invention to practice, by itself, is insufficient to confer inventor status on the human actor. As AUTM knows well, activities that confer authorship on a scientific paper (e.g., merely performing an experiment designed by another) do not necessarily confer inventorship. In the AI context, AUTM agrees that the output of an AI system is ripe for further intellectual contributions and/or substantive further development, either of which may confer inventorship status on that contributor.

4. An Essential Building Block Can Be Enough

AUTM agrees that a foundational development, even if remote from the conception of the claimed invention—and especially if the development represents a significant mental contribution—can be considered as part of the conception of the claimed invention. In the AI context, designing or training a system capable of identifying a particular species (e.g., a cell-based therapy targeting a specific tumor) or even a particular genus (e.g., series of small molecules with potential activity at a receptor of interest) can be sufficient to confer inventorship status.

5. Ownership/Oversight Without More Is Not Enough

AUTM agrees that "a person simply owning or overseeing an AI system that is used in the creation of an invention, without providing a significant contribution to the conception of the invention does not make that person an inventor." However, as noted above, human contributions to AI systems and their input/output should be fully considered and appreciated in a manner that supports patentability of new and useful AI systems and inventions that result from the use of such AI systems.

6. What Role, If Any, Does The PHOSITA Play In The Inventorship Determination?

When determining inventorship, the Guidance uses concepts such as "the state of the art" (in, for example, the third Pannu factor) and what is "apparent to those of ordinary skill."[5] It is unclear whether these references require the examiner or the practitioner to undertake the inventorship analysis from the perspective of persons having ordinary skill in the art ("PHOSITAs"). As another example, the first and second Pannu factors assess which contributions are "significant" or "not insignificant," but it is unclear whether this is assessed from the perspective of a PHOSITA.

[5] Specifically, the Guidance states: "Therefore, a natural person who merely recognizes and appreciates the output of an AI system as an invention, particularly when the properties and utility of the output are apparent to those of ordinary skill, is not necessarily an inventor."

AUTM's Comments on the Examples

The Guidance provides two examples to demonstrate the appropriate inventorship analysis. Example 1, "Transaxle for Remote Control Car," is a mechanical example (a predictable art) and includes five scenarios. Example 2, "Developing a Therapeutic Compound for Treating Cancer," is a chemical example (an unpredictable art) and includes two scenarios. All the examples and scenarios provide considerable detail, including particular facts about the AI system; the data used to train the AI system; the people who build, control, maintain, and train the system; the people who frame the problem the AI is helping to solve; and the people using, modifying, and testing the output of the system.

Both examples state that "Readers should presume that all claims are properly supported under 35 U.S.C. 112." Example 2, "Developing a Therapeutic Compound for Treating Cancer," further states "The recited drug compounds are hypothetical and are assumed to be novel." However, neither example states any assumptions regarding other elements of patentability, such as obviousness. In addition, we note the following:

(1) Example 1, Scenario 3: In this scenario, Ruth and Morgan are deemed to be inventors because their mechanical design work involved "significant" experimentation on the transaxle. This "significant" contribution is described as follows:

> "They discover that creating an operable transaxle with a horizontal separation in the casing requires additional modifications and significant experimentation. They conduct those experiments and determine that the casing needs to be elongated, with a separation located in the upper third of the casing. In addition, Ruth and Morgan find that the axle shafts and transmission need to be located in the lower two thirds of the casing. Morgan further determines that conventional fasteners are cumbersome and designs a clip fastener for removably attaching the transmission to the casing."

However, it is unclear how much of this work was needed to cause Ruth and Morgan to become inventors of claim 3 when they were not inventors of claim 1 or 2 in Example 1. Specifically, what combination of the recited design elements were significant enough to make them inventors?

(2) Example 1, Scenario 4: In this scenario, an off-the-shelf commercial AI system suggests that the transaxle casing of claim 3 could be made of aluminum. The result of the inventorship analysis is that Ruth and Morgan are the proper inventors of claim 4 (which recites the use of aluminum) because the use of aluminum did not render their work on claim 3 insignificant. While the narrative states "The additional feature is conventional and achievable with routine experimentation," it is unclear whether this statement is based on how a PHOSITA would view the use of aluminum in this scenario.

(3) Example 2, Scenario 1: Scenario 1 of Example 2 similarly raises questions as to which contributions result in the determination that Marisa and Naz are inventors. As in Example 1, Marisa and Naz clearly did a lot of work. Marisa identified a problem, a method of solving the problem (identifying lead compounds that selectively bind a mutated receptor), and a public library of data to search using the AI tool. She also selected candidates for additional experimental testing. Naz's observation regarding undesired binding characteristics helped address toxicity and side effects. Both Marisa and Naz improved manufacturability by observing a stable intermediate of one candidate and further modifying it—thus creating a new and better candidate than the ones identified from the public library.

For claim 1, it is unclear whether all of the listed contributions were necessary for each of Marisa and Naz to be identified as inventors. Was the mutated receptor used by Marisa novel, and does it matter for the analysis? Which contributions (or combination of contributions) rose to the level of "significance" needed to confer inventorship? Because biology is an unpredictable art, was it necessary to demonstrate via wet lab experiments that the candidates possessed "sufficient anti-tumor potency"?

Although the Guidance is not directed to enablement or written description, this scenario shows how practitioners may be confused about how to meet the enablement requirement of 35 U.S.C. 112. For example, would any method of synthesis starting from any stable intermediate suffice for enablement? Would any structural modification to the stable intermediate be sufficient? Would the enablement analysis change if the mutated receptor is a novel mutation? For claim 2, if the University of Cancer Research prosecuted only claim 2—and not claim 1—and they provided experimental data "demonstrating sufficient anti-tumor potency," would the applicant need to disclose how it discovered the candidate?

(4) Example 2, Scenario 2: Similar to Scenario 1, Scenario 2 of Example 2 raises questions as to which contributions make Marisa and Raghu inventors. As in Example 1, Marisa and Raghu did a lot of work. For example, Raghu develops and trains a new generative neural network, and Marisa "synthesized a subset of drug compounds based on these outputs and validated the outputs … by characterizing and testing these drug compounds." Again, it is unclear which contributions (or combination of contributions) was "significant" enough to confer inventorship.

Moreover, when Scenario 2 states that Marisa "synthesized and characterized" the drug compounds, does this mean she performed real-world/wet-lab experiments? What type of work was performed when Marisa "validated the outputs"? Was this done via wet-lab experiments? For an unpredictable art, will some form of real-world or wet-lab experimentation/validation typically be required?

Was the synthesizing, characterizing, and validating done for all of the relevant molecules?

Does it matter that Scenario 2 does not say that MID_1 "showed anti-tumor potency," as was the case for CID_1 in Scenario 1?

Regarding claim 3, if a different human made each of the contributions identified in the inventor analysis, would each human be an inventor?

Conclusion and Recommendations

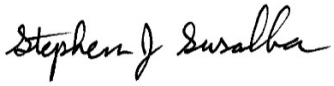
(1) The USPTO should continue to implement the Guidance and monitor its application to support patentability of inventions created with the assistance of AI in order to promote the progress of science and the useful arts. Updates to the Guidance and examples to reflect how examiners are applying them in practice would be appreciated.

(2) The USPTO should clearly state that all claims in both Examples 1 and 2 meet all other statutory criteria for patentability (not only the requirements of 35 USC 112). We think this is what the USPTO intended to convey, but it is unclear.

(3) The USPTO should consider providing additional and separate guidance or examples regarding appropriate written description and enablement of AI-assisted inventions.

(4) We renew our suggestion that the USPTO consider ways (potentially in partnership with other agencies, such as the U.S. Copyright Office) to incentivize the creation of AI training datasets that are publicly available. For example, the USPTO could establish a repository for these training datasets. Such a repository could be modeled on the current sequence listing resource: https://www.uspto.gov/patents/apply/sequence-listing-resource-center. The U.S. Copyright Office could host copyrightable AI training sets. The hosting resource(s) could i) be view-only and/or ii) allow downloads upon registration and agreeing to terms of use, as is the case with https://nyu.databrary.org/.

Sincerely,



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