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USPTO Issues Revised Inventorship Guidance for AI-Assisted Inventions – Key Implications for AI-Driven Antibody Discovery

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The US Patent and Trademark Office (USPTO) has issued revised guidance on inventorship for artificial intelligence-assisted inventions, completely replacing the February 2024 framework and clarifying how human contributions must be evaluated when AI tools play a role in the inventive process. In particular, the heightened inventorship standard for AI-assisted inventions outlined in the February 2024 framework has been rescinded. The current guidance reaffirms a core principle: Only natural persons can be inventors, and applicants must be prepared to demonstrate the specific human contributions that constitute conception.

For companies using AI tools to discover therapeutic antibodies, the updated guidance has immediate implications for patent drafting, prosecution and litigation risk. AI-assisted antibody discovery is accelerating, but so is scrutiny from challengers who may argue that patents relying heavily on AI lack proper inventorship, written description or enablement.

This alert summarizes the USPTO's key updates and provides practical strategies for strengthening the inventorship position of patents covering AI-assisted antibody inventions.

Key takeaways from the USPTO's revised inventorship guidance

1. **AI cannot be an inventor.**

Inventorship is limited to natural persons. AI is always a tool, and tools cannot be named as inventors or joint inventors. Applicants must identify the human(s) who conceived the claimed invention.

2. **Human conception remains the 'touchstone of inventorship.'**

A human inventor must have formed a definite and permanent idea of the claimed invention. In the AI-assisted context, this requires more than operating an AI tool or accepting its output. The human must contribute intellectually to at least one claim element.

When only one natural person is involved in developing an AI-assisted invention, this is a return to the traditional inventorship standard based on conception, and is in contrast to the February 2024 framework that required a heightened inventorship standard for AI-assisted inventions based on the Pannu factors.[1] However, when multiple natural persons are involved in creating an invention with the assistance of AI, the traditional joint inventorship principles apply, which includes the use of the Pannu factors to determine whether each person qualifies as a joint inventor.

3. **Priority claims may be jeopardized if foreign filings list AI inventors.**

A US application can only claim priority if the earlier filing lists at least one human inventor in common. Foreign filings that list only an AI inventor cannot support US priority. US filings must list only human inventors.

In Europe, priority is tied to ownership, not inventorship. Priority can be preserved by ensuring the priority filing includes at least one human inventor and/or human applicant, even if an AI tool is also listed. For subsequent Patent Cooperation Treaty and US filings, naming only the human inventors and/or applicants satisfies both US inventorship rules and European Patent Convention applicant identity requirements.

How litigants may attack patents covering AI-assisted antibody inventions

Inventorship challenges are a growing vulnerability for AI-assisted antibody inventions. Opponents may argue that the AI tool, rather than the listed inventors, conceived the claimed sequences and/or functional properties, or that the listed inventors merely selected or validated AI outputs without contributing to conception. Incorrect inventorship can render a patent invalid and/or unenforceable.

Antibody patents also face written description and enablement risks, particularly when only a few sequences are disclosed, or when broad genus claims lack supporting representative species or structure-function correlations. With an AI-assisted antibody patent, such written description and enablement risks are particularly true when the patent relies on undisclosed details of an AI tool, such as training data, architecture or reproducible workflows. Potential challenges to obviousness include asserting that applying known AI tools to known antigens is routine.

Practical strategies to strengthen inventorship in AI-assisted antibody inventions

A strong inventorship record is one of the most effective defenses against validity challenges. Applicants should document that humans defined the scientific problem, set the design constraints and directed the discovery campaign. The availability of such documentation reinforces that the AI tool was only used as a tool, within a human-defined inventive framework.

Human decision-making must also be evident in how AI outputs were handled. Selecting the best sequences, rejecting unsuitable ones, modifying sequences, such as complementarity determining regions (CDRs) or framework regions, and prioritizing candidates for testing are all acts of conception. Similarly, humans must design and interpret the experiments that gave rise to the claimed invention, including choosing appropriate assays to determine relevant functional properties and interpreting various data.

The patent should reflect this narrative by describing a human-driven rationale, and the constraints and decision-making involved, while avoiding language suggesting that the AI tool “designed” or “conceived” the invention.

Good hygiene must be practiced when keeping records. Lab notebooks, emails, internal presentations and notes explaining why certain AI outputs were accepted or rejected can make all the difference if a patent’s inventorship position is ever challenged.

Conclusion

While simplified, the USPTO’s revised inventorship guidance continues to underscore that AI-assisted inventions, particularly in antibody discovery, require careful consideration regarding the human contribution and patent drafting strategy. AI tools can accelerate discovery, but they also create new avenues for challengers to attack patents. Regarding inventorship, applicants that proactively document human conception and practice good record-keeping hygiene will be best positioned to defend their patents in litigation.

1. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998) setting forth the three-part test (Pannu factors) for determining inventorship: (1) The individual must contribute in some significant manner to the conception or reduction to practice of the invention; (2) the contribution must not be insignificant in quality when measured against the full invention; and (3) the individual must do more than merely explain well-known concepts or the current state of the art.

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