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Biotechnology, Chemical, and Pharmaceutical (BCP) Customer Partnership Meeting

Artificial Intelligence (AI) guidance updates

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Agenda

- Inventorship guidance & examples
- Guidance on use of AI-based tools in practice before the USPTO
- 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence
- Resources

Inventorship guidance for AI-assisted inventions

Background

Thaler v. Vidal

- The Federal Circuit upheld the USPTO's decisions to deny two petitions seeking to name an AI system as an inventor.
- Decision hinged on the interpretation of the definition of "inventor" in 35 U.S.C. 100(f) "the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention."
- Court concluded that an inventor must be a natural person.
- Court further explained that it was **not** confronted with "the question of whether inventions made by human beings with the assistance of AI are eligible for patent protection."

Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022)

Stakeholder engagement – AI and inventorship

- Request for comments (RFC) regarding AI and inventorship (February 2023)
- Listening sessions
  - Alexandria, VA (April 25, 2023)
  - Stanford, CA (May 8, 2023)
- Stakeholder feedback informed the Inventorship guidance.

Executive order

- Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (EO 14110)
  - *The USPTO Director shall "within 120 days of the date of this order, publish guidance to USPTO patent examiners and applicants addressing inventorship and the use of AI, including generative AI, in the inventive process, including illustrative examples in which AI systems play different roles in inventive processes and how, in each example, inventorship issues ought to be analyzed"*

Guidance and examples

Inventorship guidance for AI-assisted inventions

- USPTO issued inventorship guidance for AI-assisted inventions and Request for Comments (RFC) on February 13, 2024 (89 FR 10043)
- Key takeaways
  - AI assisted inventions are not categorically unpatentable for improper inventorship
  - Focus of inventorship analysis on human contributions, specifically - significant contribution (Pannu factors)
  - Five guiding principles to inform application of Pannu factors
  - Guidance applies to utility, plant, and design patents & applications
  - Potential impact to other areas of patent practice
  - Two examples illustrating application of guidance

AI-assisted inventions are not categorically unpatentable

- Patent applications and patents for AI-assisted inventions must name the natural person(s) who *significantly contributed* to the invention as the inventor or joint inventors (i.e., meeting the *Pannu* factors).
  - Use of an AI system (or other advanced tools) by a natural person(s) does not preclude that natural person(s) from qualifying as the inventor (or joint inventors) if the natural person(s) significantly contributed to the claimed invention.
- Applications and patents must not list any entity that is not a natural person as the inventor or joint inventor, even if an AI system may have been instrumental in the creation of the claimed invention.

Significant contribution

- Each named inventor must contribute in some significant manner to the invention. That is, each named inventor must satisfy the *three Pannu factors*:
  - contribute in some significant manner to the conception or reduction to practice of the invention,
  - make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and
  - do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Failure to meet any one of these factors precludes that person from being named the inventor or joint inventor.

- Things to remember
  - Focus of Pannu factors analysis is on the natural person(s) contributions
  - Joint inventors may apply for a patent jointly even though each did not make the same type or amount of contribution or each did not make a contribution to the subject matter of every claim of the patent.

Pannu factors – miscellaneous

- Application of *Pannu* factors to determine whether a natural person significantly contributed to an AI-assisted invention is made on a claim-by-claim and case-by-case basis
- When a single person uses an AI system to create an invention, that single person must make a significant contribution to every claim
- No requirement for a named joint inventor to contribute to every claim — a contribution to a single claim is sufficient; *but* each claim must have at least one natural person inventor
- Each inventor must make a significant contribution to the conception of the invention, and at least one inventor must have recognition and appreciation.

Guiding principles (Gp)

Gp1 A natural person's use of an AI system in creating an AI-assisted invention does not negate the person's contributions as an inventor.

Gp2 Merely recognizing a problem or having a general goal or research plan to pursue does not rise to the level of conception.

Gp3 Reducing an invention to practice alone is not a significant contribution that rises to the level of inventorship.

Gp4 A natural person who develops an essential building block from which the claimed invention is derived may be considered to have provided a significant contribution to the conception of the claimed invention even though the person was not present for or a participant in each activity that led to the conception of the claimed invention.

Gp5 Maintaining "intellectual domination" over an AI system does not, on its own, make a person an inventor of any inventions created through the use of the AI system.

Inventorship examples

- The USPTO also issued two examples to provide assistance on the application of this guidance
  - Transaxle for remote control car
  - Developing a therapeutic compound for treating cancer
- Available at www.uspto.gov/AI (Resources section)

Patent practice

Patent practice

- Naming the inventor
- Inventor's oath/declaration
- Applicant/ownership/assignments
  - Assignments from AI systems should not be recorded with the USPTO
- Duties owed to USPTO
  - Duty to disclose information material to patentability
    - Applies to parties identified in 37 CFR §§ 1.56(c), 1.555(a), and 42.11(a)
  - Duty of reasonable inquiry (37 CFR 11.18(b))
    - Applies to a party presenting any paper to the USPTO
    - Certification they performed an inquiry reasonable under the circumstances
    - Could include questions about whether and how AI is being used in the invention creation process.
  - Continued duty to ensure proper listing of inventorship during prosecution (e.g., due to amendments to claims).

Patent practice (cont.)

- Requirements for information
  - Examiner makes the request under 37 CFR § 1.105 (MPEP § 704.10)
    - Information need not be material to patentability
    - However, examiners may require information when there is a reasonable basis to conclude that a party under 37 CFR 1.56(c) or 1.555(a) has information reasonably necessary to the examination of the application or treatment of some matter.
  - Examples of instances where 37 CFR § 1.105 requests may be made
    - Inventorship is unclear because evidence suggests a human did not significantly contribute to the AI-assisted invention while the application names natural person(s) as the inventor
    - Contradictory statements by the applicant
- When facts or evidence (from file record or extrinsic) support a *prima facie* case that the named inventor or joint inventors did not contribute significantly to the claimed invention, a rejection under 35 U.S.C. 101 and 115 is appropriate.

Patent practice(cont.)

- Benefit/priority claims to prior-filed applications
  - For a U.S. application claiming priority to a foreign application or entering the national stage under 37 U.S.C. 371 that names both a natural person(s) and a non-natural person as a joint inventor, application data sheet (ADS) accompanying the U.S. application must list as the inventor:
    - Only the natural person(s) who significantly contributed to the invention; and
    - One of those natural persons must be in common with the foreign application.
- Correction of inventorship
  - When contributions by a named inventor to the claimed subject matter do not rise to the level of inventorship, inventorship must be corrected
  - When inventorship of a claim cannot be corrected (i.e., no natural person significantly contributed to the claimed invention), the claims must be canceled or amended.

Guidance on use of AI-based tools in practice before the USPTO

Background

Impact of AI proliferation

- Increased integration of AI in variety of sectors
- Growth in the use of AI in legal field and in practice before the Office
  - Examiners conducting AI-enabled prior art searches
  - Practitioners relying on AI-based tools to research prior art, create content for Office filings, gain insights into examiner behavior, etc.
- Uncertainties faced by practitioners in the use of AI tools
  - Positive impact: potential lower costs, improved quality and efficiency
  - Negative impact: incomplete or inaccurate information, confidentiality and ethical issues

Recent developments in the legal field

- 2023 Year-End Report on the Federal Judiciary
  - Chief Justice John Roberts addressed use of AI in connection with adjudication
- American Bar Association task force on law and AI
- Standing orders and local rules by several federal and state judges concerning use of AI in proceedings before courts

Guidance overview

USPTO guidance on use of AI-based tools

- Director guidance on party and practitioner misconduct related to the use of AI – memorandum issued February 6, 2024
- USPTO issued "Guidance on Use of Artificial Intelligence-Based Tools in Practice Before the United States Patent and Trademark Office" on April 11, 2024 (89 FR 25609)
- Takeaways
  - Use of AI-based tools by practitioners and parties is not prohibited
  - Practitioners reminded of existing rules that may be relevant to use of AI-based tools
  - Notice educates practitioners on possible risks associated with AI-based tools to promote healthy adoption of AI in practice before the USPTO
  - USPTO's existing rules and policies help mitigate risks of AI assistance
  - Guidance does not introduce any new rules or duties

Document drafting

- 37 CFR 11.18(b) applies to parties signing and/or presenting papers to the Office
  - Certification under 37 CFR 11.18(b)(1)
  - Duty of reasonable inquiry under 37 CFR 11.18(b)(2)
- All individuals associated with a proceeding before the Office have a duty of candor and good faith
- No obligation to disclose use of specific tools to the USPTO unless specifically requested by the USPTO

Filings with the USPTO

- Papers and filings submitted to the USPTO must be signed by the person submitting the paper
  - AI tool cannot sign for a natural person
- USPTO.gov accounts are limited to natural persons and cannot be obtained by non-natural persons
  - Practitioners may not sponsor AI tools as a support staff individual to obtain an account

Interacting with USPTO's Information Technology (IT) systems and websites

- An AI system is not considered a "user" for filing or accessing documents via USPTO's electronic filing systems
- Use of computer tools including AI systems for data mining information from USPTO databases are subject to Terms of Use for USPTO websites
  - USPTO's bulk data products are available for permitted and appropriate data mining
- Use of AI tools on USPTO websites for unauthorized access, use, etc. may constitute a violation of the Computer Fraud and Abuse Act

Confidentiality and national security

- Risks associated with searching or drafting aspects of an invention using AI systems:
  - Inadvertent disclosure of client-sensitive information to third parties resulting in breach of practitioners' confidentiality obligations to clients
  - National security, export control, and foreign-filing license issues
  - Data breaches that subject user data to disclosure risks
- Practitioners may mitigate risks by:
  - Complying with USPTO Rules of Professional Conduct when relying on AI tools and/or related third-party services
  - Understanding AI tools' terms of use, privacy policies, and cybersecurity practices

2024 guidance update on patent subject matter eligibility, including on artificial intelligence

Background on subject matter eligibility (SME) efforts

Recent SME efforts

- Actively engaging with stakeholders
  - Director's blog: Providing clear guidance on patent subject matter eligibility (July 25, 2022)
  - Federal Register Notice: Submission of comments regarding the patent subject matter eligibility guidance (September 2022)
- Published reports
  - Adjusting to Alice - USPTO patent examination outcomes after *Alice Corp v. CLS Bank International* (April 2020)
  - Patent eligible subject matter: Public views on the current jurisprudence in the United States (June 2022)
- The 2019 Revised Patent Subject Matter Eligibility Guidance (2019 PEG) and the October 2019 Patent Eligibility Guidance Update have been incorporated into the Manual of Patent Examining Procedure (MPEP).

Ongoing SME efforts

- Monitoring subject matter eligibility (SME) related case law developments in the courts
- Updating examination guidance to bring clarity and consistency to the application of the subject matter eligibility analysis
  - 49 examples covering a wide range of technologies including biotechnology, business methods, diagnostic and treatment methods, pharmaceutical treatments, precision medicine, and software

Executive order

- EO 14110, Section 5.2 (Promoting Innovation) –
  - *[T]he USPTO Director shall "within 270 days of the date of this order, issue additional guidance to USPTO patent examiners and applicants to address other considerations at the intersection of AI and IP, which could include, as the USPTO Director deems necessary, updated guidance on patent eligibility to address innovation in AI and critical and emerging technologies"*

Guidance overview

Federal register notice

- 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence (2024 AI SME update) - 89 FR 58128 (July 17, 2024)
- Assists USPTO personnel and stakeholders in evaluating subject matter eligibility of claims in patent applications and patents involving inventions related to AI
  - Provides an overview of the USPTO's SME guidance including reminders about existing guidance on specific issues
  - Provides guidance updates with relevant subject matter eligibility case law information
  - Explains the applicability of the guidance to AI-assisted inventions
  - Announces three new SME examples 47-49 for AI inventions

Federal register notice (cont.)

- Not intended to announce any new USPTO practice or procedure and is meant to be consistent with existing USPTO's SME guidance.
  - The content of the FRN will be incorporated into the MPEP in due course.
- Comment period ends September 16, 2024.

2024 AI SME update overview

- Provides guidance updates on Step 2A of the USPTO's guidance, which evaluates whether a claim is directed to a judicial exception.
  - For Step 2A Prong One, provides additional discussion of claims that do not recite abstract ideas and claims that do recite abstract ideas, in particular mathematical concepts, certain methods of organizing human activity, and mental processes based on recent case law and USPTO-issued examples.
  - For Step 2A Prong Two, discusses the improvements analysis for AI inventions, including specific issues that may arise for AI inventions (e.g., whether a claim reflects improvement) and recent case law where the Federal Circuit found an improvement.

Examples

Examples 47-49

- New examples 47-49 present hypothetical claims that are analyzed under the USPTO's SME guidance.
    - Examples should be interpreted based on the fact patterns set forth therein as other fact patterns may have different eligibility outcomes.
    - It is not necessary for a claim under examination to mirror an example claim to be subject matter eligible under the USPTO's subject matter eligibility guidance.
    - Examples are not intended to alter the USPTO's SME guidance
- Examples illustrative only of the patent-eligibility analysis
- Examiner training on examples 47-49

Examples 47-49 (cont.)

Example	Invention	Teaching Point(s)
47: *Anomaly Detection*	A trained artificial neural network (ANN) is used to identify or predict anomalies in network packets. Claims are directed to training the ANN and remedial actions taken by the ANN.	Specific steps for using the output of the ANN to solve a technological problem amounts to an improvement to the functioning of a computer or technology and renders the claim eligible.
48: *Speech separation*	A deep neural network (DNN) separates speech signals from different speakers from a mixed audio signal. Claims are directed to how the DNN separates speech signals.	Claims that reflect the improvements discussed in the disclosure would integrate a recited abstract idea into a practical application, thereby rendering the claim eligible.
49: *Fibrosis treatment*	A personalized medicine application of a computer-implemented machine learning model (MLM). The claims are directed to a method of treating fibrosis after microstent implant surgery in glaucoma patients.	Claims to a particular treatment/prophylaxis are eligible.

Example 47: Anomaly detection

- An artificial neural network (ANN) is used to identify or predict anomalies in network packets.
  - If the ANN detects one or more anomalies in network traffic, the ANN can determine whether the detected anomaly is associated with a malicious packet. **If the detected anomaly is associated with a malicious packet, the ANN may cause a network device to drop the malicious packet and block future traffic from the sender of the malicious packet.** By automatically detecting network intrusions or other malicious attacks, the present invention **enhances network security** by allowing for automatic, proactive remediation of network attacks.
  - The ANN may alert a human network administrator, but may also **act independently to take remedial action.** Unlike conventional network remediation solutions, the disclosed invention is able to **remediate malicious network activity in real time.** The disclosed system realizes an **improvement in network security by avoiding the delay involved in waiting on a network administrator.**

Example 47 (cont.)

Claim 1

- Claim to an ANN realized by physical circuitry.
- Claim to a physical implementation of a neural network that does not recite any abstract ideas, such as a mathematical concept, mental process, or a method of organizing human activity.

Claim 2

- Claim with limitation that falls within a mathematical concept and a mental process grouping of abstract ideas.
- Analysis of additional limitations that do not integrate the abstract idea into a practical application and do not provide an inventive concept.

Claim 3

- Claim where additional elements, when considered in combination, integrate the recited abstract idea into a practical application because the claim improves the functioning of a computer or technical field.

Example 48: Speech separation

- A deep neural network (DNN) separates speech signals from different speakers from a mixed audio signal. The signals so separated are used for downstream applications like transcription or removal of undesired background conversations from recordings.
  - The invention improves over prior speech separation methods because it provides a particular speech-separation technique that solves the problem of **separating speech** from **different speech sources belonging to the same class,** while **not requiring prior knowledge** of the number of speakers or speaker-specific training.
  - A type of Artificial Neural Network (a Deep Neural Network, or DNN) could be **trained with mixed speech signals** comprising a **fewer number of speakers** and could be used to **separate speech signals from a larger number of sources.**
  - As this speech separation process utilizes both **temporal and spatial features** of the speech signal and derives information based on the **global properties** of the input signal, it performs well with **inter-speaker variability within the same audio class** for applications like automatic speech recognition (ASR).

Example 48 (cont.)

Claim 1

- Limitations that merely claim using a DNN at a high level of generality to implement an abstract idea are not sufficient to integrate the abstract idea into a practical application or provide an inventive concept.
- Treatment of a claim with limitations that fall within the same grouping of abstract ideas.

Claim 2

- Example of a claim that reflects the improvement described in the specification.
- Treatment of a claim that recite limitations that fall within different groupings of abstract ideas.

Claim 3

- Distinguishes limitations that recite mathematical concepts from those that generally involve mathematical concepts.
- Claim recites specific steps to realize the particular technical improvement over existing speech-separation methods described in the specification.

Example 49: Fibrosis treatment

- A personalized medicine application of a computer-implemented machine learning model (MLM).
  - Applicant developed a new **anti-fibrotic drug,** Compound X, that effectively reduces scarring around a microstent implantation site in **glaucoma patients at high risk of PI** after microstent implant surgery, **without the undesirable side effects** of known drug A.
  - Further, applicant describes how compound X may be **topically administered** in eye drop form after microstent implant surgery.
  - Applicant developed a **polygenic risk score (PRS) mode**l to provide a **weighted PRS** and identify **glaucoma patients at high risk of PI.**
  - The disclosure teaches that **determining patient risk** using a weighted PRS as disclosed and accordingly **customizing treatment lends to better prognosis** after implant surgery.
  - Applicant also discloses a machine learning model **("the ezAI model").** Given an input of a patient's genotype dataset, the ezAI model **calculates a weighted PRS** from **informative SNPs** in the dataset—**using multiplication to weight** corresponding alleles in the dataset by their effect sizes and **addition to sum** the weighted values.

Example 49 (cont.)

Claim 1

- Treatment of a claim limitation that can be categorized as a law of nature or abstract idea.
- Distinguishes between a particular treatment/prophylaxis limitation, which renders a claim eligible, and a generic treatment step, which does not render a claim eligible.
- Addresses the difference between an improvement to the abstract idea *v.* an improvement to the functioning of a computer or another technical field.

Claim 2

- Demonstrates a "particular treatment" limitation that integrates the abstract idea into a practical application of the abstract idea.

Resources

USPTO AI landing page	www.uspto.gov/ai
Inventorship RFC, subject matter eligibility guidance update, and examples	www.uspto.gov/initiatives/artificial-intelligence/artificial-intelligence-resources
Practitioner use of AI	www.uspto.gov/initiatives/artificial-intelligence/artificial-intelligence-reports
SME guidance page	www.uspto.gov/PatentEligibility
Manual of patent examining procedure	www.uspto.gov/MPEP

Thank you!

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