Navigating Software and Emerging Tech Patents:
A Retrospective and Future Outlook

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INTELLECTUAL PROPERTY LAW

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2024 Major Events

- Executive Order on AI- October 30, 2023
- **USPTO Inventorship Guidance for AI-Assisted Inventions- February 13, 2024**
- USPTO Guidance on AI-Based tools in Patent Practice- April 11, 2024
- Proposed Rulemaking on Terminal Disclaimers- May 10, 2024
- **Updated Subject Matter Eligibility Guidance- July 17, 2024**

Navigating Future Changes

- USPTO Rulemaking
- Internal changes at the USPTO
- Congressional Proposals
- Incoming Trump Administration

Webinar Outline

- Subject Matter Eligibility
- Inventorship in AI-Assisted Inventions
- Looking Ahead to 2025 and Beyond

Subject Matter Eligibility

Patent Eligibility and Software Inventions

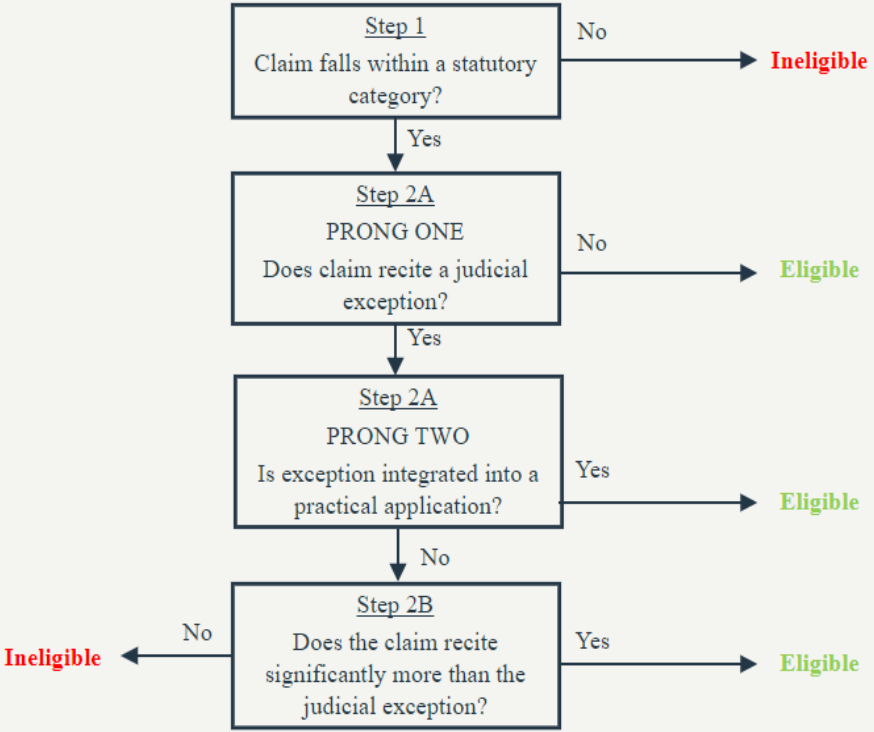
- Patent eligibility has significant impact on application drafting, prosecution, validity, and enforcement

- Across many types of software technologies including:
  - The “classics” – fintech, adtech, and business methods
  - Artificial Intelligence (AI) / Machine Learning (ML) technologies across many application domains
    - Examples: generative AI, chatbots, image processing, cybersecurity, automated guidance and navigation, speech and language processing and understanding, etc.
  - Software for Medical/Life Sciences applications
    - Examples: bioinformatics pipelines, biomarker discovery, molecular diagnostics, medical devices, drug design/discovery, sequencing, digital health, etc.

- Patent eligibility law is constantly changing, and differently depending on forum

USPTO Subject Matter Eligibility Analysis

Two-part test



- **Step 2A, Prong 1**: Abstract ideas are judicial exceptions often arising in software claims and include: (1) mathematical concepts; (2) mental processes; (3) certain methods of organizing human activity
- **Step 2A, Prong 2**: Integrated into practical application when reciting:
  - ***Improvements*** to functioning of computer or other technology
  - Effect of particular treatment
- **Step 2B**: Significantly more when reciting:
  - Inventive concept
  - ***Improvements*** to functioning of computer or other technology
  - Something other than what is well-understood, routine, conventional

July 2024-Updated Guidance

- Focused on subject matter eligibility for AI and Bioinformatics inventions
  - "Many claims to AI inventions are eligible as improvements to the functioning of a computer or improvements to another technology or technical field."
  - Updates to MPEP by incorporating references to recent cases illustrating:
    - Determination of whether claim recites abstract idea (e.g., math, mental steps, human activity)
    - When a claim recites technological improvement, which renders it patent eligible

- Three New Subject Matter Eligibility (SME) Examples:
  - **Example 47 – Cybersecurity.** Use of an artificial neural network to identify or detect anomalies
  - **Example 48 – Speech and Language Processing.** AI-based methods of analyzing speech signals and separating desired speech from extraneous or background speech
  - **Example 49 – Personalized Medicine.** AI model that is designed to assist in personalizing medical treatment to the individual characteristics of a particular patient

Example 47: Detecting Network Anomalies

Cybersecurity

- ✓ A claim to an **integrated circuit implementing an artificial neural network** (ANN) to detect anomalies does not recite any judicial exceptions
- ✓ A claim to a method of using an ANN to detect anomalies represents a **technological improvement** to network security because it specifically **claims how the ANN's output is used** to remediate identified computer network anomalies
- × A claim to a method of training and using an ANN to identify anomalies is ineligible because it **does not specifically claim how the ANN output is used** to address them

Example 47: Ineligible Claim

Cybersecurity

2. A method of using an artificial neural network (ANN) comprising:

(a) receiving, at a computer, continuous training data;

(b) discretizing, by the computer, the continuous training data to generate input data;

(c) training, by the computer, the ANN based on the input data and a selected training algorithm to generate a trained ANN, wherein the selected training algorithm includes a backpropagation algorithm and a gradient descent algorithm;

(d) detecting one or more anomalies in a data set using the trained ANN;

(e) analyzing the one or more detected anomalies using the trained ANN to generate anomaly data; and

(f) ***outputting*** the anomaly data from the trained ANN.

Example 47: Eligible Claim

Cybersecurity

3. A method of using an artificial neural network (ANN) to detect malicious network packets comprising:

(a) training, by a computer, the ANN based on input data and a selected training algorithm to generate a trained ANN, wherein the selected training algorithm includes a backpropagation algorithm and a gradient descent algorithm;

(b) detecting one or more anomalies in network traffic using the trained ANN;

(c) determining at least one detected anomaly is associated with one or more malicious network packets;

(d) detecting a source address associated with the one or more malicious network packets in real time;

(e) dropping the one or more malicious network packets in real time; and

(f) blocking future traffic from the source address.

Example 48-Speech Separation and Denoising

Speech and Language Processing and Understanding

- ✓ Claims to a method/CRM for separating speech signals using a deep neural network (DNN), synthesizing, mixing and transmitting the signals integrates mathematical judicial exceptions into a practical application based owhn the **additional steps reciting how outputs are used**

- × The same claims are **not eligible without the additional limitations** because they **do not recite how the output of the underlying neural network technology is used** in any particular speech processing application

Example 49 - Fibrosis Treatment

Personalized Medicine

- ✓ A claim to **a method of treatment** by administering “compound X eye drops” to the patient once an AI model determines they are at risk is eligible because it encompasses **administering a particular treatment**, which integrates the abstract idea into a practical application

- × The same claim is not eligible when it recites administering “an appropriate treatment” because it **does not require application of the model output** and simply recites applying a judicial exception

Example 49 – Biomarkers and Treatments

Personalized Medicine

- [Claim 1 – **Not Eligible**] A post-surgical fibrosis treatment method comprising:
  - (a) collecting and genotyping a sample from a glaucoma patient to a provide a genotype dataset;
  - (b) identifying the glaucoma patient as at high risk of post-implantation inflammation (PI) based on a weighted polygenic risk score that is generated from informative single-nucleotide polymorphisms (SNPs) in the genotype dataset by an ezAI model that uses multiplication to weight corresponding alleles in the dataset by their effect sizes and addition to sum the weighted values to provide the score; and
  - (c) administering an appropriate treatment to the glaucoma patient at high risk of PI after microstent implant surgery.

- [Claim 2 - **Eligible**] … wherein the appropriate treatment is Compound X eye drops.

- Claim Pattern: (a) get ***data***; (b) compute ***biomarker***; (c) administer ***treatment*** based on biomarker

- Biomarker computation alone difficult (but possible) to get over patent eligibility bar

- Administering treatment helps, but (often subjective) degree of specificity required

Takeaways from New Examples

When are AI/Bioinformatics software claims patent eligible?

- Broadly speaking, all three examples stand for two propositions:
  1. Claims focused on "mere calculations" with AI and/or Bioinformatics software are likely to raise patent eligibility rejections
     - Outputting "anomaly data" isn't enough (Example 47)
     - Computing a biomarker alone isn't enough (Example 49)
  2. Claims with greater specificity about uses of the "mere calculations" may be deemed eligible
     - Dropping packets, blocking network traffic (Example 47)
     - Identifying and administering a specific treatment based on computed biomarker (Example 49)

- Comparative Tension with Earlier USPTO Patent Eligibility Examples
  - USPTO tends to de-emphasize older eligibility examples in favor of new ones (e.g., 1-36 vs. 37-49)
  - Tension between Example 39 and Example 47 regarding neural network training

- Nonetheless, ***multiple routes to eligibility remain***, with considered drafting and prosecution:
  - Avoiding claiming judicial exceptions
  - Arguing improvements to computer or other technologies, particular machine or manufacture, treatments, transformation to different state or thing, etc.

Drafting Takeaways: Claims

- Draft claims to steer clear of “reciting judicial exceptions” to the extent possible
  - Math: Avoid reciting mathematical formulas and linguistic equivalents
  - Mental steps: Avoid unnecessary breadth

- “Unnecessary” breadth:
  - “receiving genomic data” vs. “receiving at least one data structure encoding genomic data comprising at least one million sequence reads”
  - “receiving an image” vs. “receiving at least one data structure encoding an image having at least AxB pixels”
  - “processing data using a neural network” vs. “processing data with a neural network comprising at least 10 million parameters, the processing comprising determining output based on the input data and values of the 10 million parameters”

- Claim features that connect to 101 arguments
  - Claim features that arguably “improve” a computer or computer technology, where applicable
  - Claim administration of a therapy, where applicable

- Write claims for success at drafting to make sure you have explicit support

Drafting Takeaways: Specification

- Many arguments for patent eligibility involve demonstrating that something is an improvement and/or that something is unconventional

- Include arguments in the Specification where possible

- Draft Specification to include material to support patent eligibility arguments
  - The improvement argued must have nexus with the feature claimed
  - If any feature provides an improvement, explain in the Specification that it does so and why
  - Include story about any improvement that is or could be claimed

- Involve inventors and client in helping to tell the improvement story
  - Discuss and develop story
  - Identify and include data that supports improvement arguments

Prosecution Takeaways

- Patent eligibility rejections are examiner specific
  - Understand Examiner's practice (e.g., history of dispositions, same for SPE)
  - Investigate strategies that have worked with the Examiner
    - Arguments and Amendments
    - Specific cases or examples that were persuasive
    - Declarations

- Interviewing
  - Highly recommended
  - Consider interviewing together with supervisor

- Strategy
  - Consider narrowing issues prior to engaging with 101
  - Example: amendments to distinguish prior art may impact 101 strategy
  - Consider impact of lengthy 101 arguments on file history

Inventorship in AI-Assisted Inventions

USPTO Guidance on AI-assisted Inventions

Standard for Inventorship of AI-assisted Inventions

- **People invent.** Inventors and joint inventors must be natural persons.
  - *Thaler* v. *Vidal,* 43 F.4th 1207, 1213 (Fed. Cir. 2022), *cert denied,* 143 S. Ct. 1783 (2023); 89 FR at 100045.

- **But inventors can use AI tools.** AI-assisted inventions are not categorically unpatentable. Human inventors can use AI tools, but despite using those tools, the humans themselves must have made a significant contribution to the claimed invention.
  - The focus is on human contributions.

Who is an Inventor?

Conception – "The Touchstone of Inventorship"

- "The term 'inventor' means the **individual** or, if a joint invention, the **individuals** collectively who invented or discovered the subject matter of the invention" (35 U.S.C. § 100(f))
- "The threshold question in determining inventorship is who **conceived** the invention" (*Mueller Brass Co. v. Reading Indus. Inc.,* 176 U.S.P.Q. 361, 372 (E.D. Pa 1972), aff'd, 180 U.S.P.Q. 547 (3rd Cir. 1973))
- "**Conception** is the touchstone of inventorship, the completion of the mental part of invention" (*Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994))

Inventorship Questions and Policy

Inventorship Questions and Policy in view of AI Advancement – Where Do We Stand?

- So where are we now?

Traditional Invention	"with the assistance of AI"	*Thaler v. Vidal*
Only Human conception	Human and AI both involved in conception	Only AI conception
AI at most a tool to aid the Human in reduction to practice	**Refer to new USPTO Guidance**	No Humans involved in conception
Valid Inventors (only Human)		**No Valid Inventors (only AI)**

USPTO Guidance on AI-assisted Inventions

Standard for Inventorship of AI-assisted Inventions – Guiding Principles 1/3

GP1. Use of an AI system by a natural person to create an AI-assisted invention "does not negate the person's contribution as an inventor."

GP2. Recognition of a problem, or "having a general goal or research plan to pursue" is insufficient

- An individual who uses a ready-to-use deep neural network to predict drug compounds with high binding affinity to a mutated receptor not an inventor to a claim to the identified compound or a method of identifying the compound (akin to a general goal or research plan)
- Providing interesting input/prompt may suffice:
  - The manner in which a person "constructs the prompt [for the AI system] in view of a specific problem to elicit a particular solution from the AI system" may demonstrate a significant contribution to the conception of the invention

USPTO Guidance on AI-assisted Inventions

Standard for Inventorship of AI-assisted Inventions – Guiding Principles 2/3

GP3. Reduction to practice, without more, or recognition and appreciation of an invention, without contribution to conception of the invention, is insufficient to qualify that individual as an inventor

- An individual who synthesizes compounds predicted by a deep neural network to have high binding affinity and performs structural modifications to increase binding selectivity is an inventor of a claim to the modified compound and method of synthesizing the modified compound

USPTO Guidance on AI-assisted Inventions

Standard for Inventorship of AI-assisted Inventions – Guiding Principles 3/3

GP4. A significant contribution may be found where a natural person develops “an essential building block from which the claimed invention is derived.”

- An individual who develops, trains, and tunes a new generative neural network-based AI system which creates new molecules taking into account specific properties is an inventor to a claim for a compound generated using the system
- An individual who identifies desirable properties of compounds for training the system is also an inventor to the same claim

GP5. “[S]imply owning or overseeing an AI system” does not, on its own, constitute a significant contribution that qualifies an individual as an inventor

- An individual who trains a "ready-to-use" deep neural network model with training data (specifically, compounds and targets for a model configured to predict binding affinity) is not an inventor of a claim to a method of identifying a lead drug compound or a claim to the identified lead drug compound

Impact on Practice

Changes to Application Preparation and Prosecution

- Gather and keep records of information during application preparation
  - Whether and what AI was used
  - How the AI was prompted
  - What was done with the output
- Rejections on the basis of improper inventorship
  - Examiners may request information on inventor contribution for particular claims
- Duty of disclosure applies to questions of inventorship
- Consider other forms of protection, such as trade secret or contractual protection, particularly where difficult to argue human involvement in conception

Looking Ahead to 2025 and Beyond

Summary Regarding AI-based Inventions

- If drafted correctly, AI-based inventions are subject matter eligible – consider protecting:
  - New improvements relating to applications of AI to solve problems
  - AI model improvements and architecture
  - AI "helper" technology (e.g., hardware, database software, new UIs, etc.)
  - Inputs and outputs (e.g., training, output indications, GUIs, control or inputs to other systems)
- In cases where discoverability of infringement is an issue, consider trade secret protection (but take affirmative steps and be capable of keeping the improvement secret)
- Use of AI-based tools during the invention process does not defeat patentability, and the new guidance leads to finding some human activity that performs a significant contribution
- File early, as AI use is accelerating quickly
- Expect USPTO backlogs due to popularity – consider filing Track I applications to speed prosecution

Changes at the USPTO that Affect AI Cases

- Director Kathi Vidal to resign in December, new Director in 2025
- Final Rulemaking increasing PTO fees (in January)
- Proposed Rulemaking on Terminal Disclaimers
- Focus on overcoming the backlog of AI and software applications

Changes at the USPTO - Increasing Fees

- Key changes, mostly increasing costs for continuations, multiple RCEs:
  - Many of the increases are proportional across the board increases of about 7.5%.
  - Fees associated with post-grant proceedings will increase by 25%. In addition, request for review of a PTAB decision by the director will now come at a cost. Previously free, the request for review will be $452.
  - The USPTO is instituting notable new fees for certain continuation applications. There will be a $2,700 cost for filing a continuation after six years from effective filing date, with the fee increasing to $4,000 after nine years.
  - Fees for second Requests for Continued Examination (RCEs) and beyond will increase by over 40%.
  - The cost of applying for patent term extension (PTE) will go from $1,180 to $2,500. (The original proposal included increasing this fee to $6,700.)
  - Fees for filing a design patent application will go from $1,760 to $2,600.

Changes at the USPTO – Terminal Disclaimers

- Proposed changes issued in May 2024 - USPTO opened a 60-day period for the public submission of comments regarding the new rule.
- New rule identifies that a terminal disclaimer (TD) filed to overcome ODP must include an agreement that the patent in which the disclaimer is filed would be unenforceable if a claim in another patent tied to the subject patent through the disclaimer has been held unpatentable or invalid. If adopted, the rule likely will widely implicate how patent owners choose to prosecute multiple patent applications stemming from the same priority date(s) and/or effective filing date(s).
- While the USPTO suggests the rule would decrease competitors' costs in seeking to challenge multiple patents on the same invention, patent applicants would likely see increased patent prosecution costs associated with choosing to argue against ODP rejections, amending claims, or filing a terminal disclaimer.
- Changes likely forward looking, affecting future TD filings and filing strategies

Changes at the USPTO – Backlog Reduction

- The USPTO is currently facing a significant backlog of patent applications, with recent data showing 785,387 unexamined applications and a total pendency of 25.6 months for patents. Director Kathi Vidal has addressed this "inherited backlog" in a blog post, outlining several initiatives to tackle the issue:
  - Increased Hiring: The USPTO hired 644 patent examiners in FY 2023 and aims to exceed its goal of hiring 850 examiners in FY 2024.
  - Improved Application Routing: Since 2022, the USPTO has implemented processes to better match patent applications with examiners having the appropriate technical background.
  - Extended Working Hours: The Office has allowed for more flexible working hours to increase productivity.
  - Compensation Adjustments: The USPTO has made changes to its award structures to better attract and retain employees who contribute to pendency and quality goals.
- Despite these efforts, the backlog is predicted to increase to 820,200 by FY 2026 before decreasing to 780,000 by FY 2029
- In 2020, over 20% of all applications or about 80,000 applications filed at the USPTO involved AI. More than half of the art units at the USPTO are now involved in examining AI.

Congressional Actions

- Patent Eligibility Restoration Act (PERA)
  - Aims to resolve inconsistent application of case law to subject matter eligibility under §101, while still preventing patents on mere ideas, discovery of nature, and any other content universally accepted as beyond the scope of the patent system
  - Establishes categories of ineligibility
- PREVAIL (Promoting & Respecting) Act
  - Aims to strengthen patents
  - PTAB Reform with increased barriers for PGR and IPR

Congressional Actions (continued)

- Patent Eligibility Restoration Act (PERA)
  - Introduced in 2022, and in Jun 2023, revision to PERA introduced.
  - Aims to resolve inconsistent application of case law to subject matter eligibility under §101, while still preventing patents on mere ideas, discovery of nature, and any other content universally accepted as beyond the scope of the patent system.
  - Designed to foster innovation and increase protections for patentees in wake of Supreme Court case law which has invalidated many patents under §101.
  - Bill supported by many pro-patent groups, and judges seeking clarity on §101 issues.
  - Opposition from patients' rights group, drug patent watchdogs.
  - PERA is currently in a state of legislative limbo. As of November 2024, the bill has been introduced in both the Senate and the House of Representatives but has not yet been passed into law.

Congressional Actions (continued)

- PREVAIL Act
  - Significant PTAB changes, making filing more difficult
  - Changes to standing, real party in interest, burden of proof, procedural changes making it more difficult to challenge patents
  - Election Impact – Congressional changes, leadership
  - Likely a restart of the entire process, 2025 or beyond
  - New PTO Director in 2025
  - PREVAIL Act has made progress by clearing the Senate Judiciary Committee, but it still faces significant hurdles and ongoing debate before potentially becoming law. Its future remains uncertain as discussions continue and further modifications may be proposed.

Thank you!

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