USPTO directives on patents using AI

Presenters:

Benjamin Mak BASc, LLB,
Patent Attorney
SREDStakeholder.CA
David Sabina, CPA, MBA

Webcast
Nov 21, 2024

2024 USPTO guidance on AI

https://www.uspto.gov/initiatives/artificial-intelligence/artificial-intelligence-resources

1 **Guidance on practitioner use of AI**

1.1 Guidance on Use of Artificial Intelligence-Based Tools in Practice Before the USPTO
1.2 Director guidance on party and practitioner misconduct related to use of AI
1.3 Copyright office report on copyright and artificial intelligence (Part 1, July 2024)

2 **Inventorship**

The USPTO issued guidance and examples on inventorship specifically for AI-assisted inventions.

2.1 Inventorship Guidance for AI-assisted Inventions (February 2024)
2.2 Transaxle for Remote Control Car (Example 1)
2.3 Developing a Therapeutic Compound for Treating Cancer (Example 2)

3 **Subject matter eligibility**

The USPTO issued a guidance update on patent subject matter eligibility (SME) to address innovation in critical and emerging technologies (ET), especially AI.

3.1 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence (2024 AI SME update). (Effective July 17, 2024)
3.2 AI-related SME examples 47-49 issued in 2024
3.3 Information regarding current SME guidance, training, and other resources are available on the Subject matter eligibility page.

4 **Compliance with 35 U.S.C. 112**

4.1 MPEP 2161.01 provides guidance on disclosure requirements for computer-implemented functional claim limitations.
4.2 MPEP 2181 provides general guidance for examining means plus function (35 U.S.C. 112(f)) limitations. MPEP 2181(II)(B) provides guidance on the description necessary to support a claim limitation that invokes 35 U.S.C. 112(f).
4.3 MPEP 2173.05(g) discusses functional limitations that do not invoke 35 USC 112(f).
4.4 Examiner training on Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. 112.

4 of 5 new examples reviewed

New AI examples from USPTO	
#	**Project Name**
	Subject Matter Eligibility
2401	**AI Anomaly detection method**
2402	**AI Fibrosis Treatment**
2403	**AI Speech Separation *(not discussed)***
	Inventorship - 5 PANNU criteria
2410	**Transaxle design using AI**
2411	**Therapeutic cancer compound using AI**

Overview

- Discussion of:
  1) Patentable Subject Matter Eligibility (SME)
  2) Inventorship
- The new Guidelines do not change the law on patentability and inventorship. They are intended to clarify recent questions on these topics as applied to AI.
- All examples involve fictitious scenarios and AI models (e.g. “ezAI”)
- An inventor is a natural person. AI can never be an inventor.

AI Anomaly Detection Method

Patent Eligibility and Analysis for AI-Driven Technologies

Claim 1: ASIC for ANN

- • Description:
- - A hardware-based ANN implementation using ASIC.
- - Includes neurons, microprocessors, and synaptic circuits.
- • Eligibility:
- - Patent-eligible as a machine or manufacture.
- - Does not recite abstract ideas or mathematical concepts.

Claim 2: General Anomaly Detection

- • Description:
- - Uses ANN for detecting and analyzing anomalies in data.
- - Relies on mathematical calculations and mental processes.
- • Ineligibility:
- - Recites abstract ideas without a practical application.
- - Fails to integrate the exception into a technical improvement.

Claim 3: Malicious Packet Detection

- • Description:
- - Uses ANN to detect malicious packets and block source addresses.
- • Eligibility:
- - Integrates abstract ideas into a practical application.
- - Demonstrates real-time network security improvements.

Comparison of Claims

- • Claim 1:
- - Hardware-focused, patent-eligible.
- • Claim 2:
- - Abstract idea, not patent-eligible.
- • Claim 3:
- - Practical application, patent-eligible.
- • Insights:
- - Highlighting differences in patentability based on implementation.

Guiding Principles

- • Patent eligibility requires:
- - Integration of abstract ideas into practical applications.
- - Demonstrable improvements to technology or technical fields.
- • Lessons:
- - Hardware implementations are easier to patent.
- - Abstract processes must show technical advancements.

Conclusion

- • Claim 1 demonstrates hardware innovation and patent eligibility.
- • Claim 2 highlights challenges with abstract AI methods.
- • Claim 3 showcases successful integration of AI for real-time security.
- • Key Takeaway: Practical applications strengthen patent eligibility.

2402 - AI Fibrosis Treatment

Patent Eligibility and Analysis for AI-Assisted Medical Innovations

Project Overview

- Project Name: AI Fibrosis Treatment
- Objectives:
  - Develop anti-fibrotic eye drops (Compound X).
  - Improve post-surgery inflammation and fibrosis outcomes.
  - Leverage AI for Single Nucleotide Polymorphism (SNP) analysis and personalized treatments.
- Focus: Patent eligibility analysis for Claims 1 and 2.

Claim 1: AI-Based Screening Method

- Description:
  - Use of AI ("ezAI model") for polygenic risk scoring (PRS).
  - SNP analysis to identify glaucoma patients at high risk of Post-Implantation Inflammation (PI).
- Ineligibility:
  - Relies on mathematical calculations and mental processes.
  - Does not integrate abstract ideas into a practical application.
  - Fails to demonstrate improvement to technology.

Claim 2: Anti-Fibrotic Eye Drops

- Description:

  - Administration of Compound X eye drops for patients identified via Claim 1.

  - Targets glaucoma patients at high risk of post-implantation inflammation (PI).

- Eligibility:

  - Integrates abstract ideas into a practical application.

  - Demonstrates a particular treatment for a medical condition.

  - Provides improved outcomes over existing treatments.

Comparison of Claims

- Claim 1:
  - Abstract idea, ineligible for patent.
- Claim 2:
  - Practical application, eligible for patent.
- Insights:
  - Focus on improved products (e.g., Compound X) strengthens eligibility.
  - AI methods require integration into actionable outcomes.

Guiding Principles (GP's)

- Patent eligibility requires:

  - Integration of abstract ideas into practical applications.

  - Demonstrable improvements to medical outcomes.

- Lessons for Life Sciences:

  - Focus on product improvements (e.g., new treatments).

  - Processes must go beyond abstract calculations.

Conclusion

- Claim 1 highlights challenges with abstract AI methods.
- Claim 2 demonstrates successful integration of AI into practical medical treatments.
- Key Takeaway: Focus on actionable, patient-specific outcomes for patent eligibility.

Project 2402 Summary

Aspect	Details
Project Name	AI Fibrosis Treatment
Objective 1	Develop anti-fibrotic eye drops (Compound X)
Objective 2	Improve post-surgery inflammation and fibrosis outcomes
Objective 3	Leverage AI for SNP analysis and personalized treatments
Claim 1 - Description	AI-based screening method using ezAI model for PRS calculation
Claim 1 - Eligibility	Ineligible: Relies on abstract ideas and lacks practical application
Claim 2 - Description	Compound X eye drops for treating glaucoma patients at high risk of PI
Claim 2 - Eligibility	Eligible: Integrates abstract ideas into a practical application, showing medical improvement

Project 2410 Context - Transaxle Design

Base Design Specifications:

- Used generative AI “Puerto5”
- Integrated transmission and axle system
- Casing with separable elements
- Removable transmission mounting
- Axle shaft integration
- Fastener system for assembly

Material Considerations:

- Steel (Initial design) - Industry standard
- Aluminum (Modified design) - CNC machinable

Direct USPTO Quote:

"The output from Puerto5 includes a preliminary design for a transaxle…"

The Pannu* Factors - Detailed Analysis Framework

USPTO Definition:

- Contribution must significantly aid conception.
- The test has not changed in view of AI.
- An answer of “no” to any one factor means non-inventorship.

Three Factors:

1. Conception Contribution:

- Beyond mere reduction to practice.
- Active problem-solving.

2. Quality of Contribution:

- Significant relative to claims.
- Not minor or insignificant.

3. Beyond State of Art:

- Original technical contribution required.

*Pannu v. Iolab Corp.(1998), 155 F. 3d 1344

Pannu Analysis: Scenario 1 (Ineligible)

Factor 1 - Conception:

- Problem recognition only.
- No specific solution contribution.

Factor 2 - Quality:

- No measurable contribution to claims.
- Entire design from AI output.

Factor 3 - Advancement:

- No technical advancement.

Scenario 3 - Technical Specifications – Enhanced Design

Casing Design:

- Elongated structure. (from Puerto5)
- Horizontal separation plane. (from inventors)

Component Placement:

- Transmission in lower two-thirds.
- Strategic fastener locations.

Manufacturing Specifications

Material Processing:

- CNC routing for aluminum components.
- Precision machining requirements.

Design Considerations:

- Material selection impacts.
- Assembly sequence optimization.

Pannu Analysis: Scenario 3 (Eligible)

Factor 1 - Conception:

- Elongated case specifications.
- Horizontal plane separation.

Factor 2 - Quality:

- Substantial design modifications.
- Essential fastener innovation.

Factor 3 - Advancement:

- Beyond existing solutions.
- Original technical contributions.

Critical Legal Framework

USPTO Guidance Principles:

- Significant technical contribution.
- Clear documentation of contributions.

Key Requirements:

1. Technical problem-solving.
2. Experimental results and evidence.
3. Novel solutions covering claim scope.

AI-Inventorship Guidance for Therapeutic Compound Development

Key Scenarios, Claims, and Inventorship Analysis

Project Overview

- This project examines AI-assisted inventions in developing therapeutic compounds for cancer treatment. It highlights inventorship guidance based on case scenarios and claim analyses.

Scenario 1: Drug Optimization via Wet-Lab Experiment

- Use of Drug Target Interaction Predictor (DTIP) to identify candidate compounds.
- Marisa and Naz synthesized and modified CID_1 to CID_6 (Compound ID).
- Resulted in CID_1-mod with improved efficacy and reduced side effects.
- Inventors: Marisa and Naz based on significant contributions to the invention.

Scenario 1: Drug Optimization via Wet-Lab Experiment

Human vs AI Contributions

Human Contributions:
- Identifying drug targets
- Synthesizing compounds
- Structural modifications

AI Contributions:
- Identifying lead compounds
- Binding affinity predictions

Scenario 2: Drug Optimization via Molecule Optimizer (MO)

Human vs AI Contributions

- Raghu developed the MO AI system to optimize drug properties.
- Marisa synthesized and tested outputs.
- MID_1 emerged as the optimal therapeutic compound.

Inventors: Raghu and Marisa based on AI design and synthesis contributions.

Scenario 2: Drug Optimization via Molecule Optimizer (MO)

Human vs AI Contributions

Human Contributions:
- Designing objective functions
- Validating outputs
- Synthesizing optimized compounds

AI Contributions:
- Optimizing compound properties
- Generating novel structures

Claims and Inventorship Analysis

Scenario 1:

- Claim 1: Method for synthesizing lead compounds (Inventors: Marisa & Naz).
- Claim 2: Specific compound CID_1-mod (Inventors: Marisa & Naz).

Scenario 2:

- Claim 3: Novel compound MID_1 (Inventors: Raghu & Marisa).

Contributions evaluated using Pannu factors.

Guiding Principles (GP's)

- 1. AI use does not exclude natural inventorship.
- 2. Merely recognizing a problem does not rise to the level of conception/inventorship.
- 3. Reducing an invention to practice alone is not a significant contribution for inventorship.
- 4. A natural person can develop an essential building block which contributes to the conception.
- 5. Maintaining "intellectual domination" over an AI system does not, on its own, establish inventorship.

Interrelation of Claim 3 with Claims 1 and 2

- Claim 1 establishes the foundational methodology for identifying and synthesizing lead compounds using AI (DTIP).
- Claim 2 focuses on a specific compound (CID_1-mod) developed through structural modifications from Claim 1's methodology.
- Claim 3 builds upon Claims 1 and 2 by:

  - Introducing a new AI system (Molecule Optimizer, MO) to refine drug properties like ADMET.

  - Creating a novel compound (MID_1) that integrates advanced optimization.

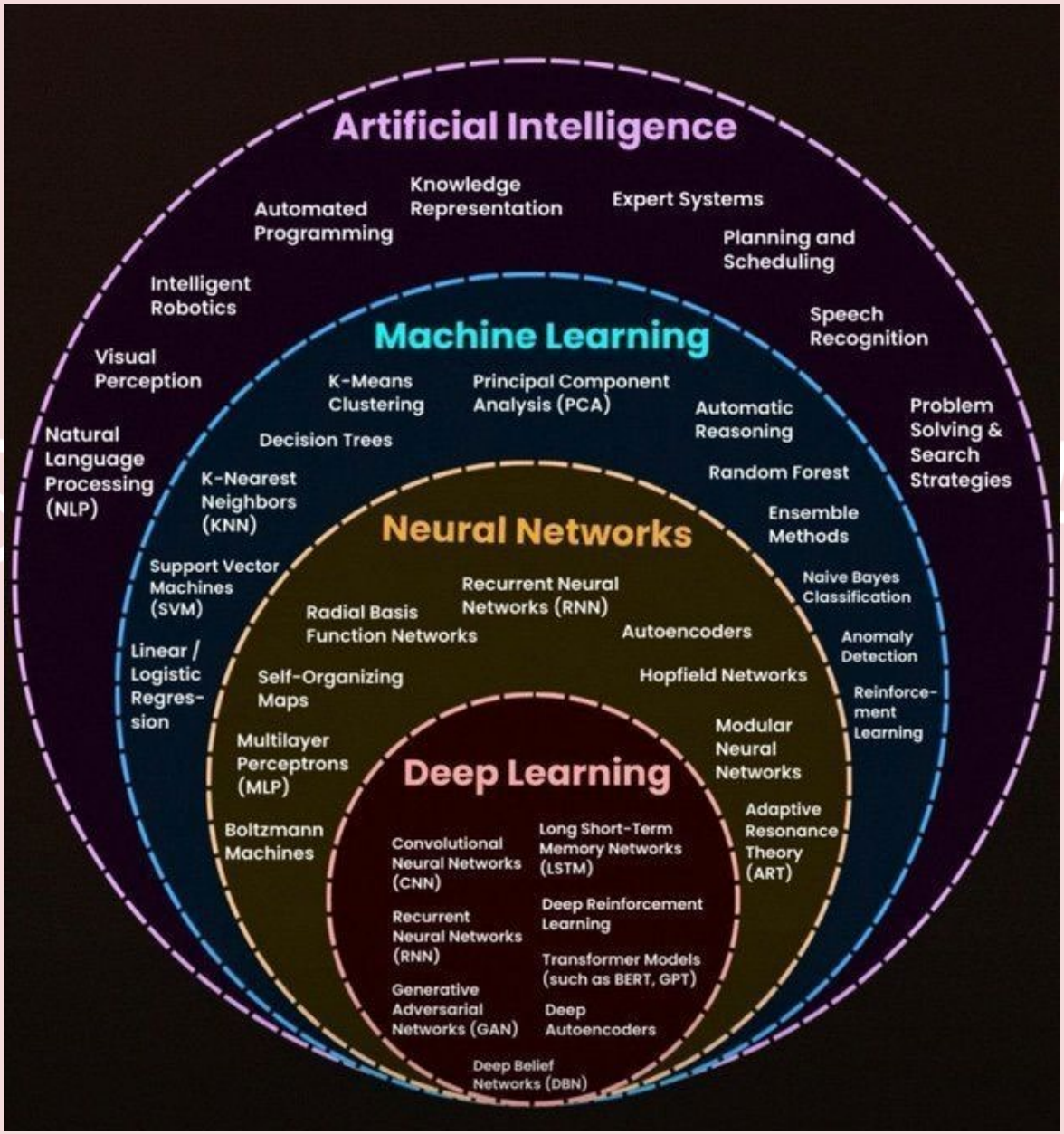
Interrelation of Claim 3 with Claims 1 and 2

- Claim 3 represents an evolutionary step from identifying and refining compounds (Claims 1 and 2) to generating novel candidates using advanced AI techniques.
- Together, these claims show a progression in AI-assisted drug discovery, addressing increasingly complex challenges.

Closing thoughts

Advice from AI on using AI

The AI development environment

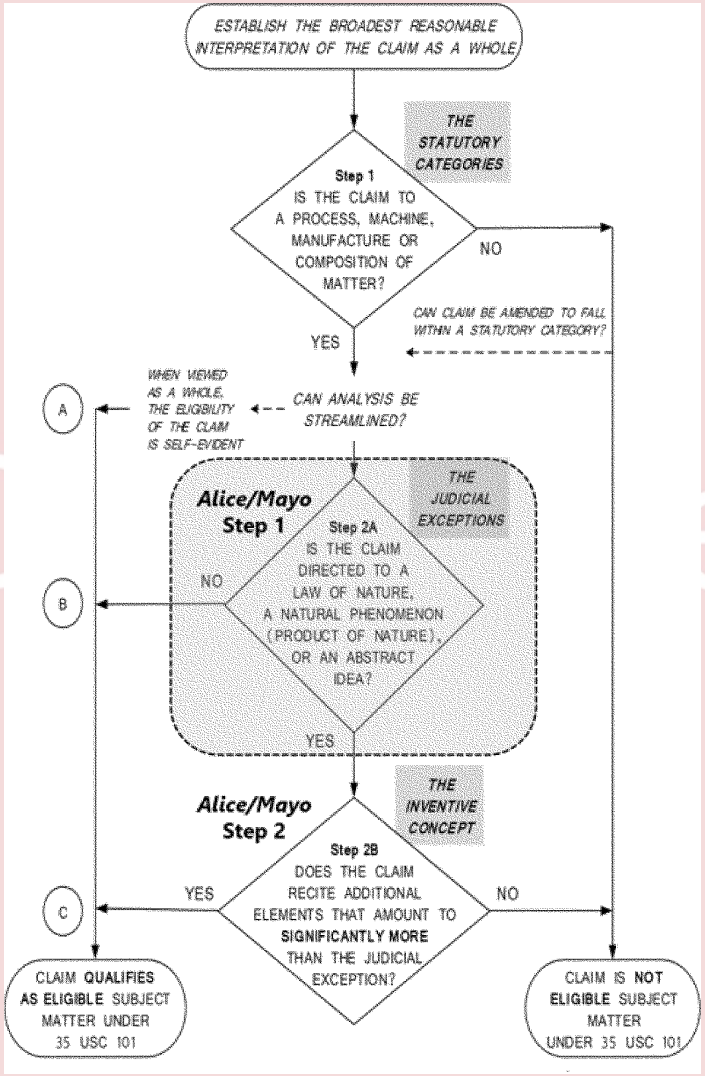


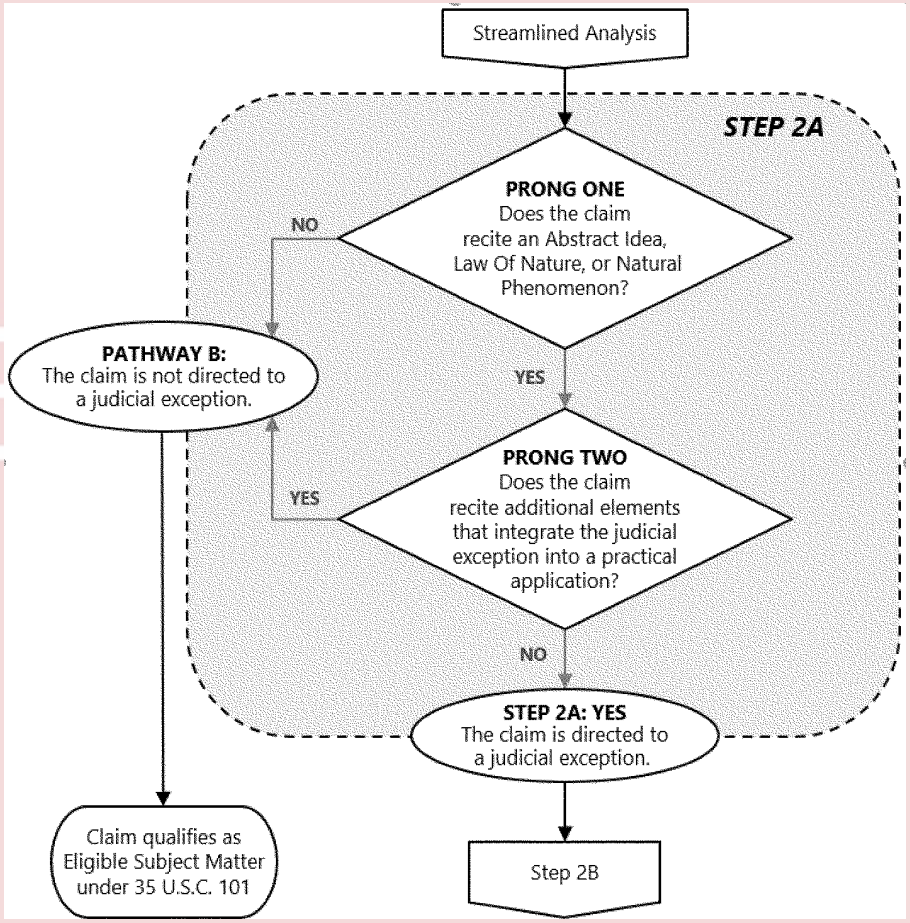
Determining eligibility of patent claims

- Step 1 of the USPTO's subject matter eligibility analysis addresses whether the claimed invention falls into at least one of the four categories recited in 35 U.S.C. 101.28 of invention that Congress deemed to be the appropriate subject matter of a patent:
- processes, machines, manufactures and compositions of matter.
- latter three categories define "things" or "products" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed

- Step 2 of the USPTO's subject matter eligibility analysis applies the Supreme Court's two-part framework (*Alice/Mayo* Steps 1 and 2 in the following flowchart) to identify claims that are directed to a judicial exception and to then evaluate if additional elements of the claim provide an inventive concept.

- Step 2A is a two-pronged inquiry as shown in the flowchart below.


ESTABLISH THE BROADEST REASONABLE INTERPRETATION OF THE CLAIM AS A WHOLE
THE STATUTORY CATEGORIES
Step 1
IS THE CLAIM TO A PROCESS, MACHINE, MANUFACTURE OR COMPOSITION OF MATTER?
NO
CAN CLAIM BE AMENDED TO FALL WITHIN A STATUTORY CATEGORY?
YES
CAN ANALYSIS BE STREAMLINED?
WHEN VIEWED AS A WHOLE, THE ELIGIBILITY OF THE CLAIM IS SELF-EVIDENT
A
Alice/Mayo Step 1
THE JUDICIAL EXCEPTIONS
Step 2A
IS THE CLAIM DIRECTED TO A LAW OF NATURE, A NATURAL PHENOMENON (PRODUCT OF NATURE), OR AN ABSTRACT IDEA?
NO
B
YES
Alice/Mayo Step 2
THE INVENTIVE CONCEPT
Step 2B
DOES THE CLAIM RECITE ADDITIONAL ELEMENTS THAT AMOUNT TO SIGNIFICANTLY MORE THAN THE JUDICIAL EXCEPTION?
YES
NO
C
CLAIM QUALIFIES AS ELIGIBLE SUBJECT MATTER UNDER 35 USC 101
CLAIM IS NOT ELIGIBLE SUBJECT MATTER UNDER 35 USC 101


Streamlined Analysis
STEP 2A
PRONG ONE
Does the claim recite an Abstract Idea, Law Of Nature, or Natural Phenomenon?
NO
YES
PATHWAY B:
The claim is not directed to a judicial exception.
PRONG TWO
Does the claim recite additional elements that integrate the judicial exception into a practical application?
YES
NO
STEP 2A: YES
The claim is directed to a judicial exception.
Claim qualifies as Eligible Subject Matter under 35 U.S.C. 101
Step 2B

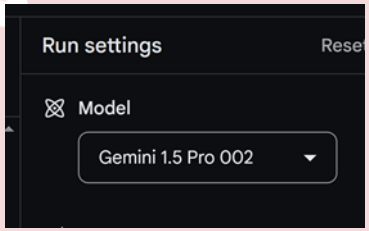
Correlation of Patent & SR&ED Concepts

Step	Question	Yes Path	No Path	Key Concepts	SR&ED Concepts
Step 1	Is the claim to a process, **machine,** manufacture, or **composition of matter**?	Move to Step 2A	not ESM under 35 USC 101	Statutory Categories	**Eligible fields of science**
Step 2A	Is the claim directed to a **law of nature, natural phenomenon, or abstract idea**?	Move to Step 2B	qualifies as ESM	Judicial Exception - Prong 1	**Standard Practice**
Step 2B	Does claim recite **additional elements** integrating into **practical application?**	qualifies as **Eligible Subject Matter (ESM)** under 35 USC 101	not ESM	Inventive Concept - Prong 2	**Technological Uncertainty (TU)**

Common question posed to 4 DIFFERENT AI engines:

Are there any specific steps that both

AI tools and users can take to enhance the likelihood of successful patent and SR&ED tax credit filings?

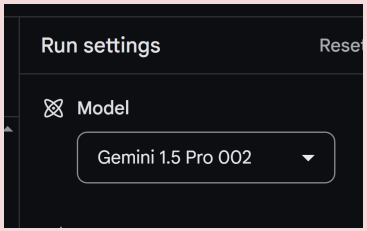


Grok 2 beta

ChatGPT 4o

Claude

Response from Google Gemini 1.5 Pro



Response from Google Gemini 1.5 Pro

Aspect	AI Tool Developers	AI Tool Users (Researchers/Inventors)
Design/ Planning	Design for transparency and explainability. Develop robust logging and documentation features. Facilitate user control and direction. Implement version control and reproducibility.	Clearly define the problem and objectives. Consult with patent attorneys and SR&ED consultants early in the process.
Execution/ Documentation	Ensure the AI tool automatically logs user interactions, data inputs/outputs, parameters, and model modifications.	Document the human-AI collaborative process: tasks, human design choices, hypotheses, modifications to AI suggestions, rationale.
SR&ED Focus	Provide features that track experiments, analyze data, generate reports, identify patterns, and highlight areas for investigation.	Focus on experimental development and uncertainty: frame AI use within systematic investigation, document uncertainties and challenges, demonstrate how human-AI collaboration addresses them.
Patent Focus	Assist in drafting claims/specifications by providing prior art, technical information, visualizations, and diagrams.	Emphasize human inventiveness: articulate human ingenuity and creativity, highlight novel aspects from collaboration, emphasize human-driven design and interpretation of AI output.
Claim Preparation	Organize and analyze project data to identify eligible SR&ED activities and expenditures. Generate reports.	Consult with an SR&ED consultant to prepare claim meeting CRA requirements.

Response from Grok 2 (Tesla)

Grok 2 beta

Category	AI Contribution	Human Contribution	Rationale for Patent/SR&ED Eligibility
Algorithm Development	AI generates initial algorithm frameworks based on large data sets.	Humans refine, test, and apply these frameworks to solve specific, novel problems.	Combining AI's data analysis with human creativity ensures the algorithm's non-obviousness, a key patent criterion.
Material Science	AI predicts material properties or reactions based on theoretical models.	Humans design experiments to verify these predictions, leading to new material discoveries.	The experimental verification of AI predictions can qualify for SR&ED due to technological advancement.
Process Optimization	AI models optimize existing processes, reducing waste or increasing efficiency.	Humans implement these models in real-world settings, adjusting for practical issues.	

Response from Chat GPT 4 (Microsoft)

ChatGPT 4o

Aspect	Suggestions
Problem Framing	Humans should define clear, specific technical problems and objectives, ensuring they guide the AI to solve these problems.
Collaborative Refinement	Iteratively refine AI outputs, providing meaningful intellectual input at each stage to add value and originality.
Transparent Documentation	Maintain detailed documentation of the human-AI collaboration, including decision-making processes, prompt designs, and refinements.
Validation and Testing	Humans should validate and test AI outputs, ensuring their reliability and explaining their significance to meet eligibility criteria.
Claim Specificity	Draft claims with precise descriptions of technical implementations, emphasizing the human role in directing AI processes.
Ownership and Accountability	Clearly establish human ownership of the inventive steps, showcasing accountability in all stages of the innovation process.

Response from Claude AI (Anthropic)

Claude

Activity	Human Input Required	Documentation Needed	Success Tips
Problem Definition	Define technical uncertainty; Set research goals; Identify knowledge gaps	Project charter; Research objectives; Gap analysis	Be specific about technical challenges; Explain why standard solutions don't work
Research	Design methodology; Set test parameters; Lead investigations	Lab notebooks; Test plans; Meeting notes	Document all experiments; Include failed attempts; Track time spent
Development	Make key decisions; Evaluate results; Direct next steps	Decision logs; Progress reports; Code/design versions	Show systematic approach; Record all iterations; Explain technical choices
Innovation	Identify novel aspects; Apply expertise; Draw conclusions	Innovation claims; Technical narratives; Final reports	Highlight technological advancement; Document human insights; Show original contributions
Compliance	Review AI outputs; Modify suggestions; Lead documentation	Review records; Modification logs; Time tracking	Maintain 80%+ human input; Document all AI assistance; Keep detailed records

Common & unique responses

Aspect	Common Practices
Problem Framing	Clearly define technical problems and objectives aligned with patent or SR&ED goals.
Collaboration and Refinement	Iteratively refine AI outputs with significant human intellectual input to ensure innovation.
Documentation	Maintain detailed and transparent records of human-AI collaboration, including logs and refinements.
Validation and Testing	Validate AI outputs rigorously to ensure reliability and relevance to eligibility criteria.
Ownership and Accountability	Emphasize human ownership of inventive steps, showing leadership in direction and interpretation.
	Unique suggestions
Gemini 1.5 Pro (Google)	Robust logging features and reproducibility mechanisms; early consultation with experts.
Grok 2 (Tesla)	AI generates frameworks or predictions, while humans test and refine for practical applications.
ChatGPT 4 (Microsoft)	Focus on specific and transparent claim descriptions to highlight human contributions.
Claude AI (Anthropic)	Ensure compliance by keeping 80%+ human input; systematically document all AI assistance.

Welcome questions or feedback

Presenters:

Benjamin Mak, BASc., LLB
bmak@smartbiggar.ca

David Sabina, CPA, MBA
dsabina@meuk.net