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Cooley Rx:

From Algorithm to Asset – Protecting AI Innovations

Topics of Discussion

- What is artificial intelligence (AI)?
- How do life sciences companies use AI?
- Protecting life science inventions related to AI
  - Trade secrets vs. patents
  - Practical recommendations
- Diving deeper
  - AI-related considerations for trade secret protection
  - AI-related considerations for patent protection

What is Artificial Intelligence?

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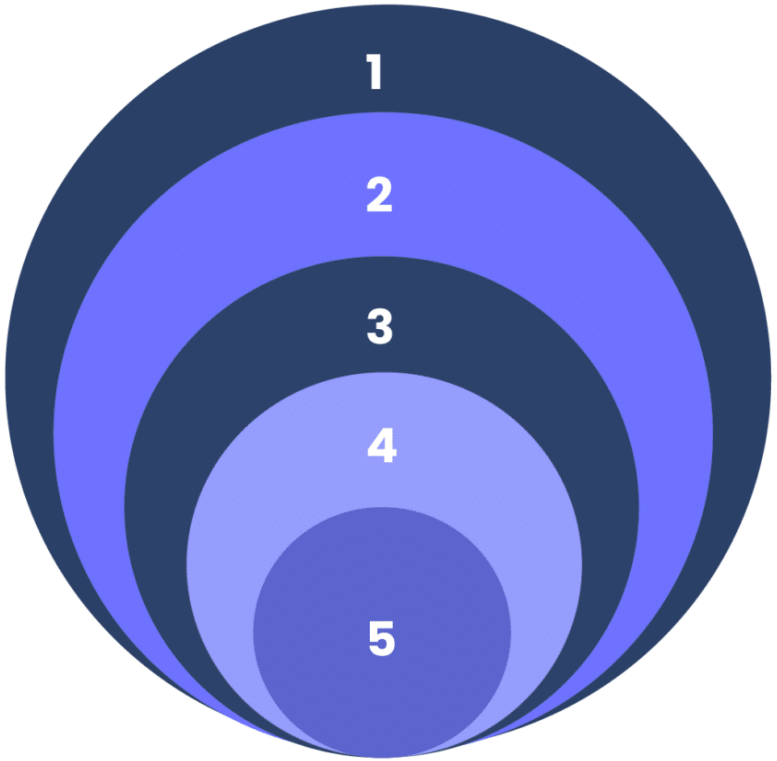
What is Artificial Intelligence (AI)?



1 Artifical Intelligence

A broad term encompassing the development and use of computer systems capable of performing tasks that typically require human intelligence.

2 Machine Learning

A subset of AI that trains systems to learn from data and make decisions or predictions based on patterns.

3 Neural Networks

A type of machine learning algorithm that mimics the structure and function of the human brain—allowing AI systems to learn and process complex data.

4 Deep Learning

A subfield of machine learning that uses neural networks with multiple layers to learn and extract features from data.

5 Generative AI

A subset of AI that focuses on generating new content, such as text or images, based on patterns learned from data.

How Do Life Sciences Companies Use AI?

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How Do Life Sciences Companies Use AI?

Biotechnology and Chemistry

- De novo drug design
- Virtual drug screening to predict efficacy or other desired characteristics
- Predicting protein structures (e.g., AlphaFold)
- Predicting molecular interactions
- Predicting new uses for old drugs
- Analyzing data (e.g., to identify new biomarkers or genetic variants)
- Designing drug synthesis routes

Medical Technology

- Simulating biological processes through predictive modeling
- Predicting patient outcomes to aid in medical decision making
- Analyzing, tracking, or detecting patient data to predict and inform medical decision making and treatments
- Improving and analyzing medical images
- Modeling patient responses for precision medicine
- AI-guided robotic systems assist surgeons in performing surgery
- AI-enabled remote monitoring devices

Categories of AI-Related Intellectual Property Created by Life Sciences Companies

Inventions developed using AI as an analytical tool

- Novel compositions screened or otherwise analyzed using AI
- Methods (e.g., treatment, diagnosis) relying on information gleaned from AI

Inventions with AI as a component

- Methods of diagnosis using AI
- Methods of analysis using AI
- AI-assisted devices, e.g., robotic surgery or monitoring devices

Inventions independently generated by AI

- Compositions with novel structures/sequences conceived by AI
- Patient-specific implants customized or conceived by AI

New AI algorithms, models, or training strategies

- AI itself is the invention

Trade Secrets vs. Patents

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Defining Trade Secrets and Patents

Trade Secrets

Subject Matter: Commercially valuable secret information

How Obtained: No application or registration process

Term: Indefinite duration

Created By: Anyone, including AI

Remedies: Actual damages or reasonable royalties, unjust enrichment damages, injunctive relief, punitive damages and attorneys' fees

Patents

Subject Matter: Process, machine, or composition of matter

How Obtained: File patent application with government patent office

Term: 20 years (plus PTA/PTE)

Created By: A natural person

Remedies: Actual damages or reasonable royalties, and in exceptional cases, enhanced damages, attorneys' fees, or injunctive relief

Trade Secret Protection – Pros and Cons

- Pros
  - Immediate protection – ideal for rapidly changing technology
  - “Free” to obtain; no application
  - Covers any secret information that has commercial value
  - No requirement that a human created the trade secret
  - Complementary federal and state law protections
- Cons
  - Trade secrets must be identified with reasonable particularity
  - Owner must make reasonable efforts to maintain secrecy
  - Only protects against theft; others may develop [and patent]
  - Few companies have formal trade secret protections in place

Patent Protection - Pros and Cons

- Pros
  - Protects inventions even if publicly-available
  - Right to exclude all competitors
  - Infringement does not require knowledge of patent
  - May be easier to value
  - Patents are presumed valid
  - For pharma, added protections of Hatch-Waxman and BPCIA
- Cons
  - Lengthy application process
  - Requires human inventor
  - Complex requirements for validity are harder to satisfy
  - Cannot patent abstract ideas, algorithms, laws of nature, or anything obvious or not new
  - Reforms have weakened patent rights and remedies

Trade Secrets and Patents

Patent protection is preferred:

- Any machine, method, or product that is sold or in public use
- Technology that is fairly related to patentable subject matter
- Technology that is easy to reverse engineer
- Inventions that will have commercial value over long periods of time

Trade secret protection is preferred:

- “Back office” know-how
- Inventions that are not patentable or not created by humans
- Inventions that may have a short life span
- Inventions where proving infringement is challenging

Practical Application

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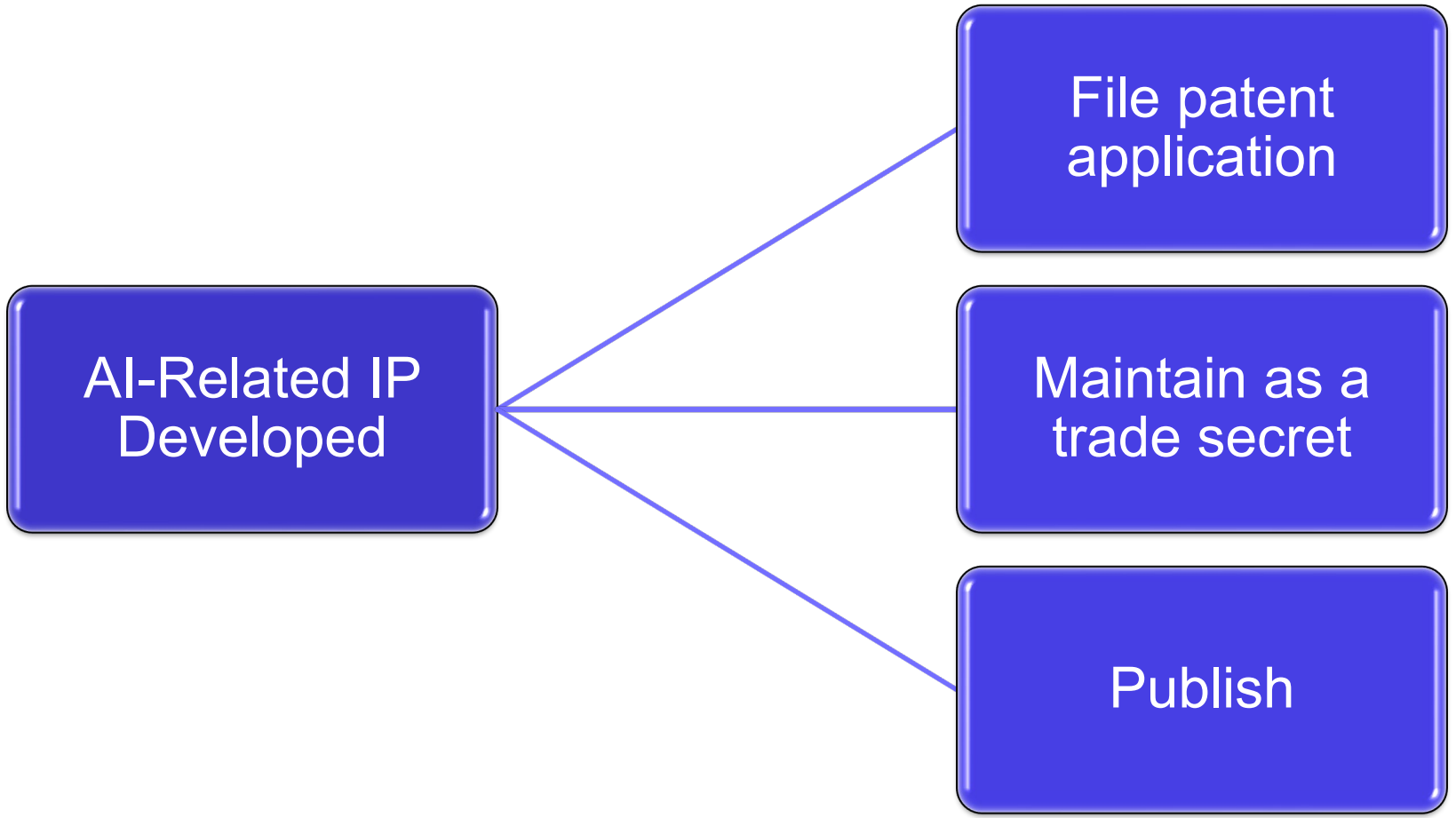
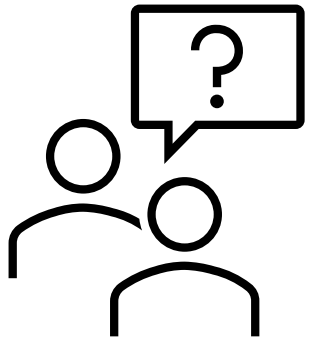
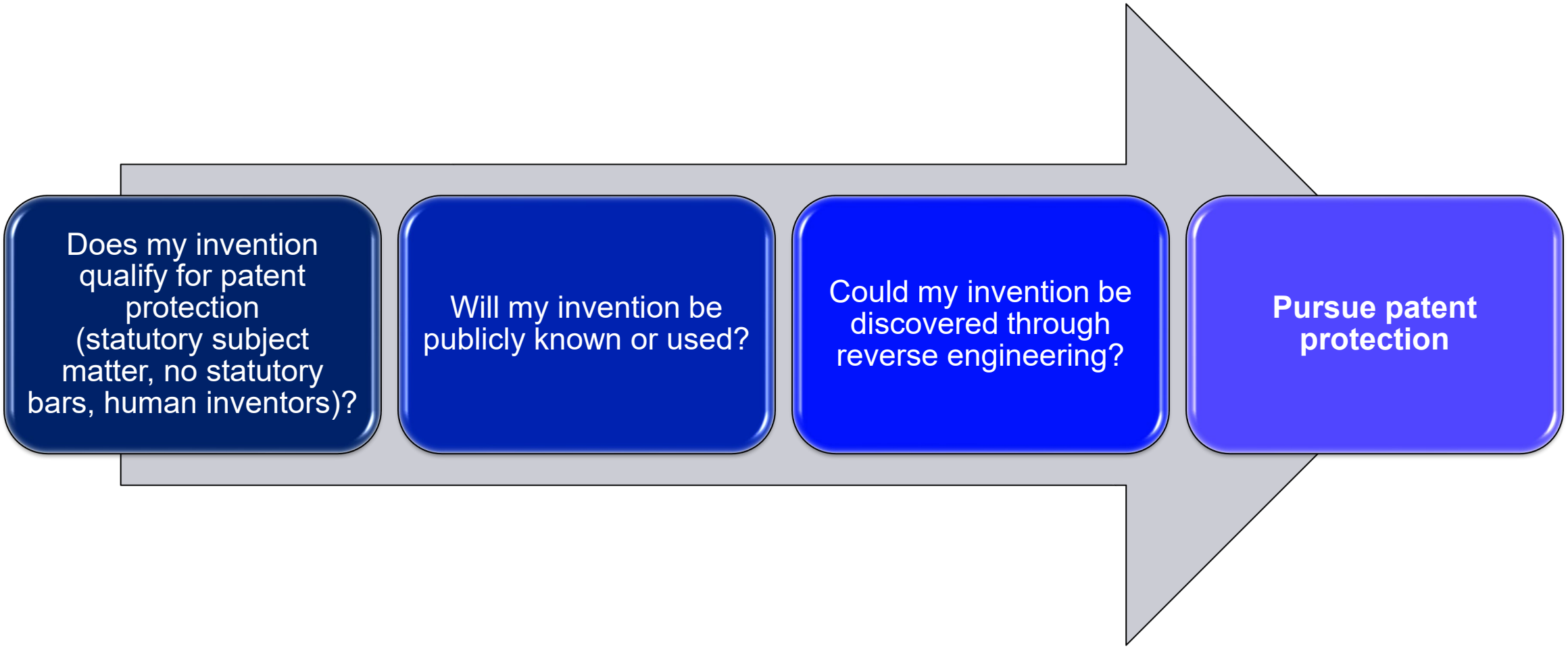
AI-Related Intellectual Property Protection Options

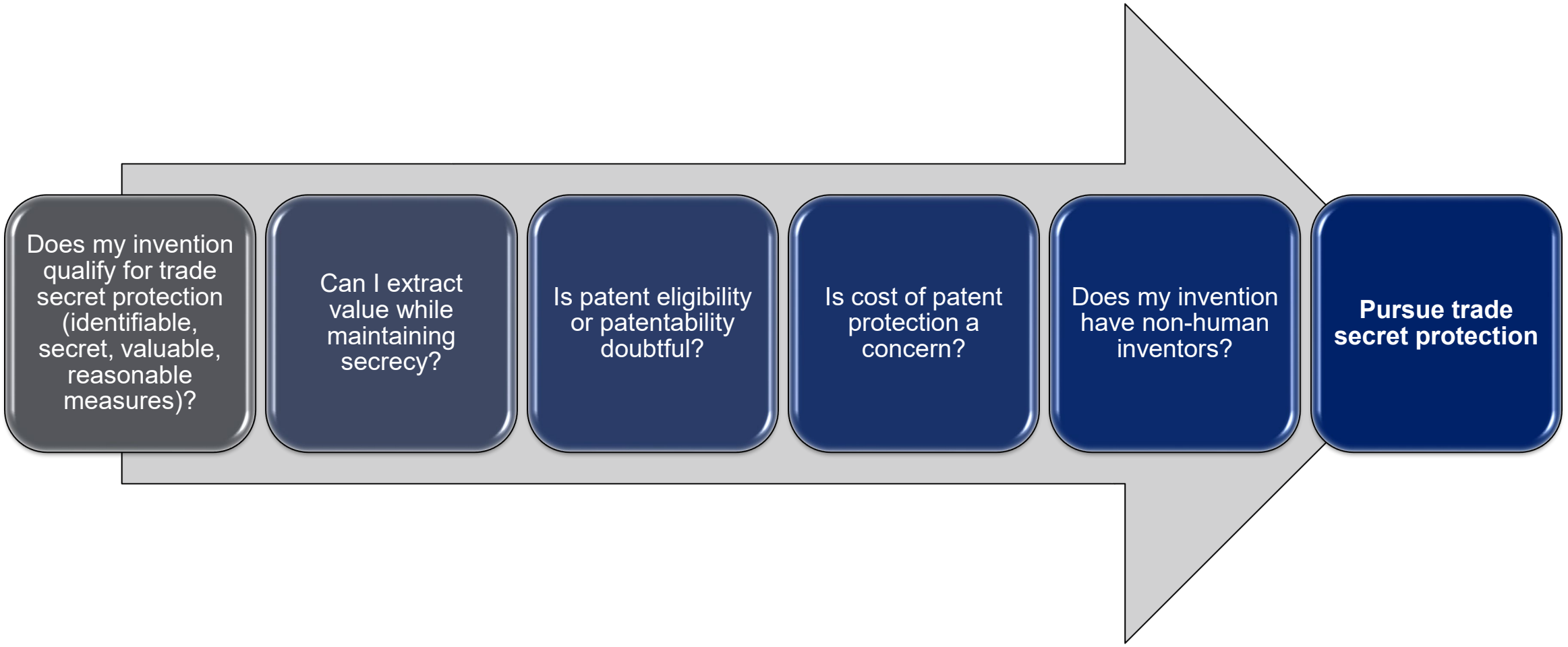




Patent Protection is Preferred When…



Trade Secret Protection May Be Preferred When…



Diving Deeper:
Trade Secret Considerations

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Trade Secret Laws Protect Against Multiple Forms of Misappropriation

- Trade secret laws provide protection for multiple types of misappropriation
  - Theft by a current or former employee
  - Corporate espionage or hacking
  - Access by third parties to that go beyond contractual or legal limits
    - Violation of Terms of Use
    - Violation of NDA
    - Breach of contract between business partners

Trade Secret – Legal Protection Contingent On Ability to Identify With Reasonable Particularity

- Trade secret plaintiffs must identify misappropriated trade secrets with particularity to distinguish what is protected from what is not
- It is not enough to "merely describe the end results or functions performed by the claimed trade secrets" or use conclusory terms such as "artificial intelligence" or "machine learning"
- Courts require support from "tangible trade secret material" such as source code, algorithms, or design documents
- Companies that do not have mechanisms in place for identifying and protecting trade secrets may struggle to identify them after theft has occurred

T2 Modus LLC v. Williams-Arowolo, No. 4:22-cv-00263, 2023 WL 6221429, at *5 (E.D. Tex. Sept. 25, 2023); *Neural Magic, Inc. v. Meta Platforms, Inc.*, 659 F.Supp.3d 138, 166-67 (2023).

Trade Secret – Legal Protection Requires Reasonable Measures to Maintain Secrecy

- Reasonable measures must be used to protect trade secrets
  - Company policy on protecting trade secrets
  - Nondisclosure agreements with third-parties
  - Employee confidentiality agreements and training
  - Offboarding process with collection of trade secret information
  - Physical and network security and monitoring
  - Limiting access to trade secrets on a need-to-know basis
- Companies that do not have a trade secret protection program may fail to meet statutory requirements for reasonable measures

Diving Deeper: Patent Considerations

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Patent Inventorship – US Law

- The term ‘inventor’ means the individual or the individuals who invented or discovered the subject matter of the invention. 35 U.S.C. § 100(f)
- Conception:
  - “The threshold question in determining inventorship is who **conceived** the invention. Unless a person contributes to the conception of the invention, he is not an inventor.” *Fiers v. Revel* (Fed. Cir. 1993)
- Patent inventor must be a natural person (*Thaler v. Vidal*)
  - Compare: trade secret protection is available even if the secret is AI-generated

Subject Matter Eligibility – US Law

- Supreme Court has acknowledged "… Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond v. Chakrabarty,* 447 U.S. 303 (1980)
- But Supreme Court cases have found "judicial exceptions"
- In 2014, the Supreme Court held that abstract ideas are not patent eligible. *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014)
- Since then, many computer-related inventions have been found ineligible for patent protection

Applying Established Machine Learning Methods to New Environments is Not Patent Eligible

- **Appellate Court's Ruling**: "Claims that do no more than apply established methods of machine learning to a new data environment" are not patent eligible
- Recentive sued Fox Corp. for infringing patents directed to using machine learning to generate network maps and schedules
- Recentive's patents claimed the use of any machine learning algorithm for:
  - Receiving current broadcasting schedules;
  - Creating a network map;
  - Incorporating real-time changes to the data inputs;
  - Determining program broadcasts based on the updated map.
- The Federal Circuit found the claims ineligible for patenting

Recentive Analytics, Inc. v. Fox Corp., 134 F.4th 1205 (Fed. Cir. 2025).

Inventions That Claim a Technological Advancement May Be Patent Eligible Even if They Involve Generic Application of Machine Learning

- **District Court's Ruling**: The combination of a 3D medical image overlaid with a risk map was patent-eligible because the invention improved the reliability and accuracy of cancer diagnosis
- Progenics' patent claimed medical imaging analysis software that creates a cancer risk map overlaid on a 3D medical image
- Claims recited creating 3D medical images overlaid with visual depictions of geographic boundaries of regions of cancer risk
- Court found that the claims' use of machine learning did not confer patent eligibility because the invention was not limited to a particular machine learning algorithm
- But the court found that the claims were patent eligible anyway because overlaying a risk map on a 3D image was an inventive concept and technological advancement

Progenics Pharms., Inc. v. MIM Software Inc., 762 F.Supp.3d 100 (D. Mass. Jan. 14, 2025).

Inventions that Use Machine Learning Algorithms In Novel Combinations May Be Patent Eligible

- **District Court's Ruling**: Claims reciting the use of two distinct machine learning algorithms working independently and simultaneously to generate a risk estimate are patent eligible
- Aon Re's patent claimed using machine learning to evaluate real property from aerial imagery using an unconventional combination of two algorithms
- The court found the claim "implements machine-learning technology in a specific way to address a practical technical problem: how to accurately and quickly assess the physical characteristics and condition of a property from an aerial image using machine learning models."
- A finding of patent eligibility is distinct from the question whether a claimed invention is new and non-obvious. The Federal Circuit Court of Appeals has a history of stringently applying the law on patent eligibility-unclear if this decision would withstand scrutiny.

Aon Re, Inc. v. Zesty.AI, Inc., No. 25-cv-201, 2025 WL 1938214, at *5 (D. Del. Jul. 15, 2025).

Questions?

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