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AI + Life Sciences + IP: Now & the Road Ahead

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Presenters

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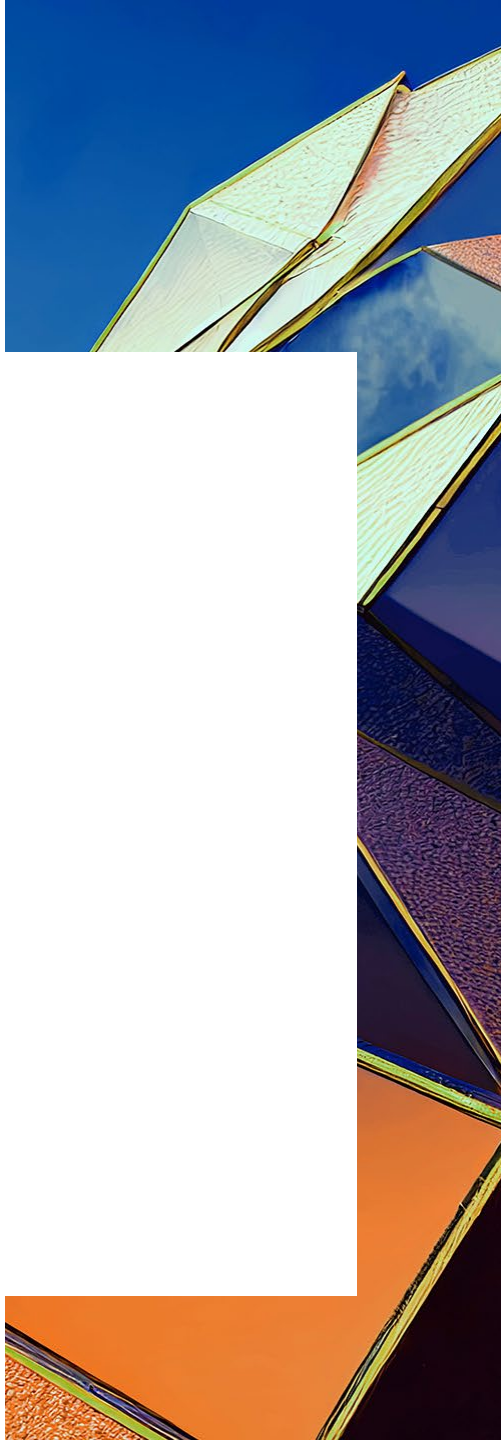
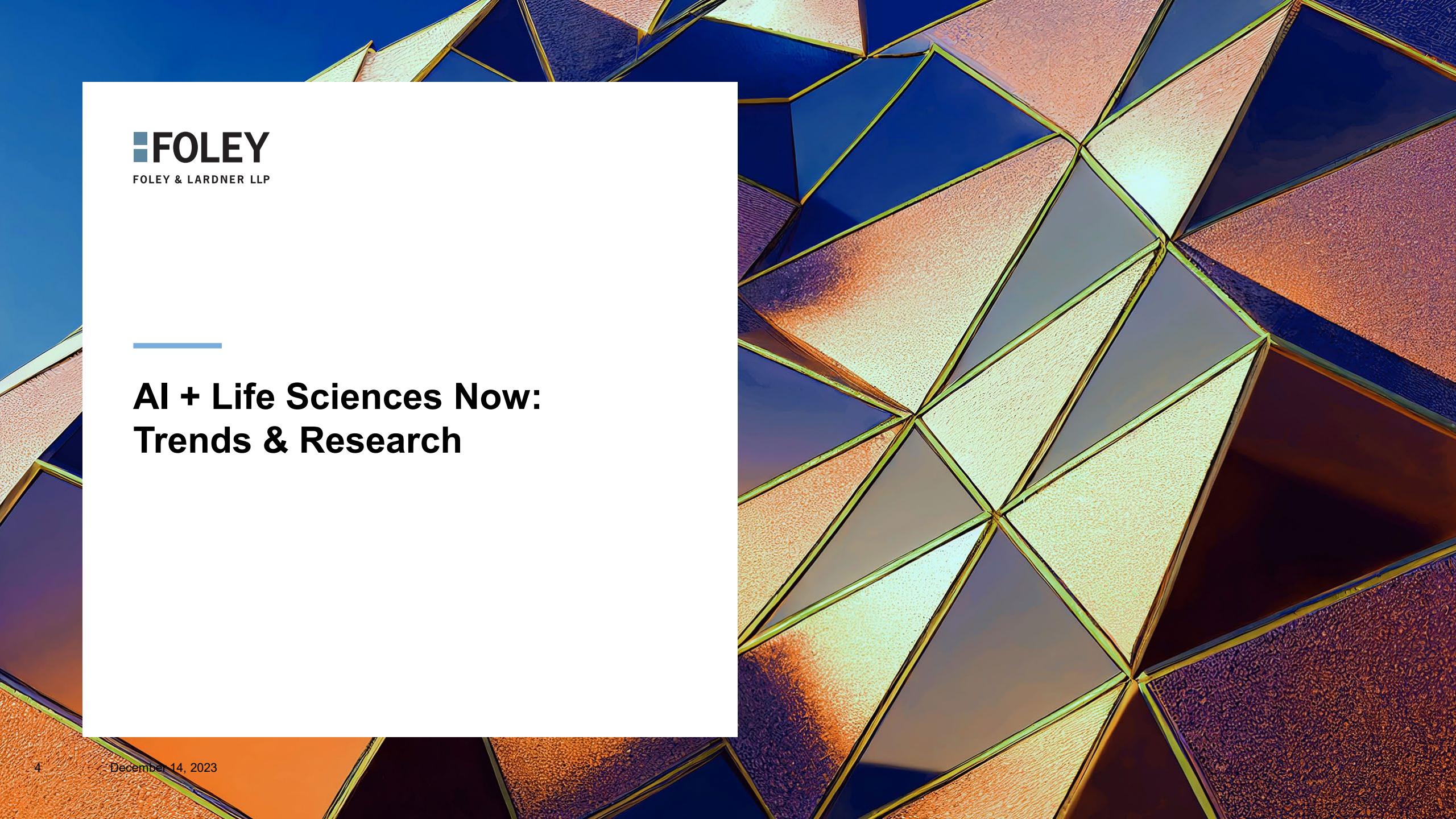
AI + Life Sciences: Discussion Overview

- Now: Trends & Research
  - Industry Movers & Players
  - Patent Landscape & Patent Filings
- Strategy: Trade Secrets or Patents?
- Patents: Perils to Avoid
  - Case Study: Diagnostics + AI
  - Case Study: Genomics + ML
- Ahead: Patent Rights + AI
  - AI Inventors?
  - Patents + Generative AI?





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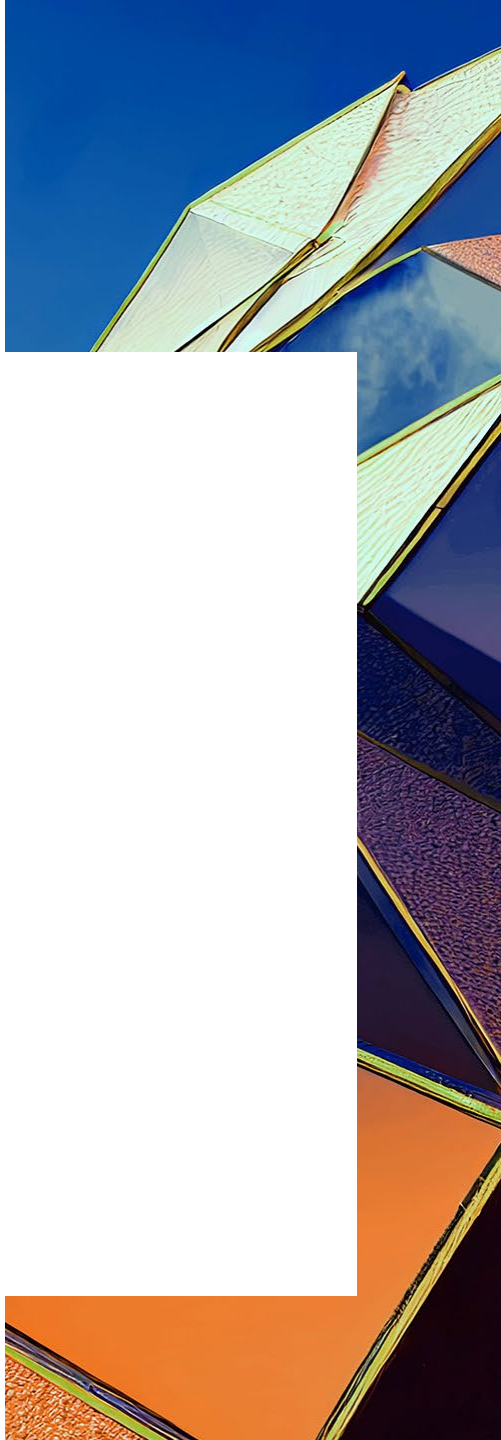
AI + Life Sciences Now: Trends & Research

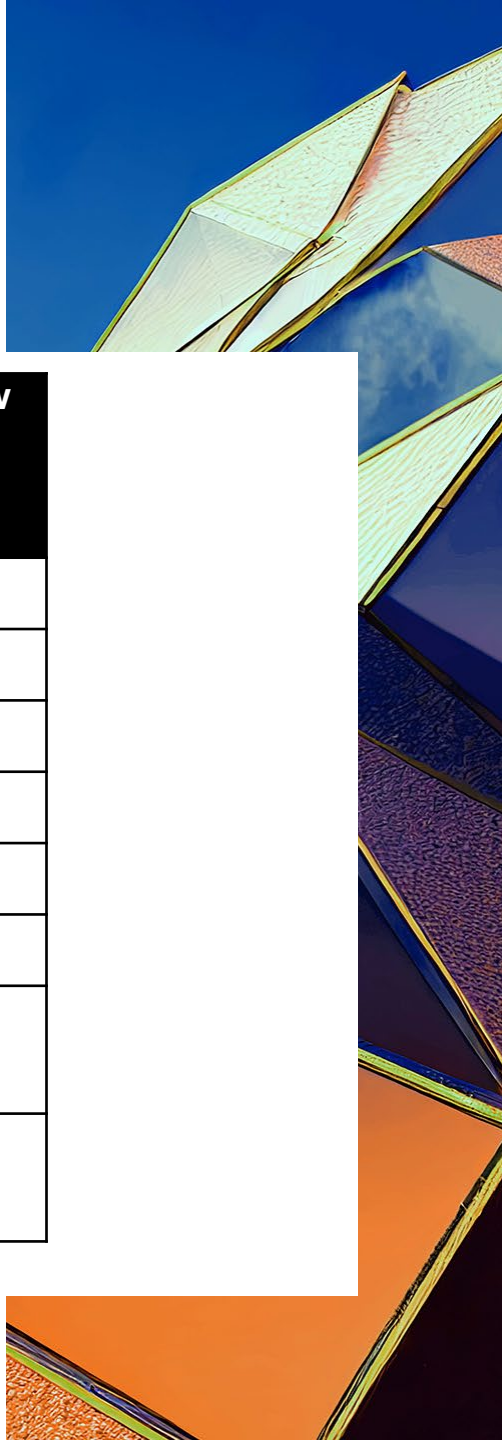
Value Drivers, AI Technologies Provide for Health Care Companies:

1. Adding new or complementary capabilities
2. Expanding customer and user bases
3. Enabling firms to extract new insights from existing data
4. Allowing access to new data sources



Industry Movers & Players

AI Value Propositions in 2022/2023 M&A Deals



M&A Event	Deal Size	New or Contemporary Capabilities	Expanded Customer or User Base	Extract Insights from Existing Data	Access to New Data Sources
Microsoft & Nuance	US $19.7 Billion	✓	✓		
R1 RCM & Cloudmed	US $4.1 Billion			✓	
BD & Parata	US $1.5 Billion		✓		
Quidel & Ortho	US $6 Billion	✓	✓		✓
Stryker & Vocera	US $3.1 Billion	✓			✓
BioNTech & InstaDeep	US $700 Million	✓		✓	
GE HealthCare & Caption Health	N/A	✓			
Healthful & Sympto Health	N/A	✓			

https://www.foley.com/en/insights/publications/2023/05/role-ai-health-care-m-a-value-difficult-market

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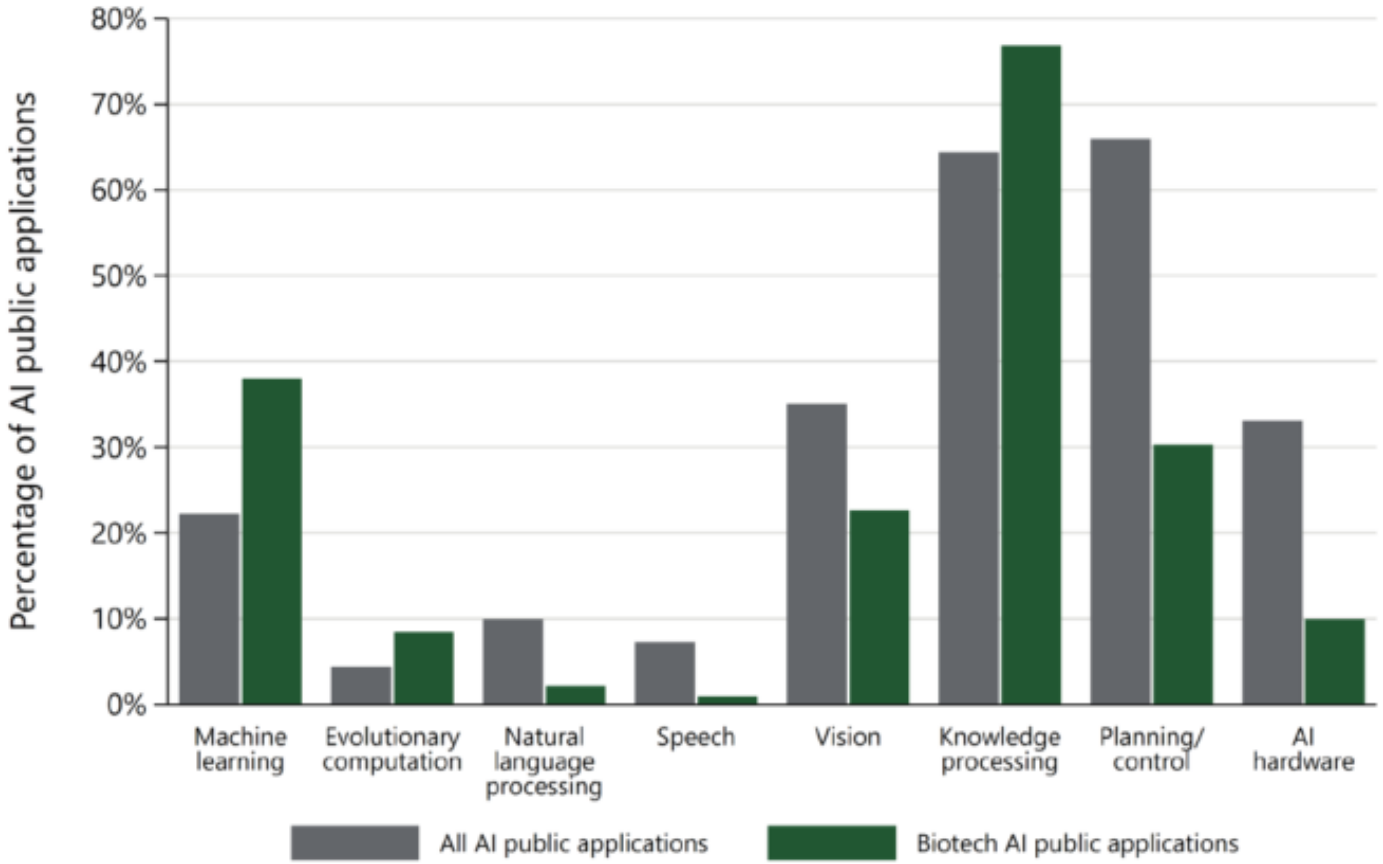
Patent Landscape & Patent Filings

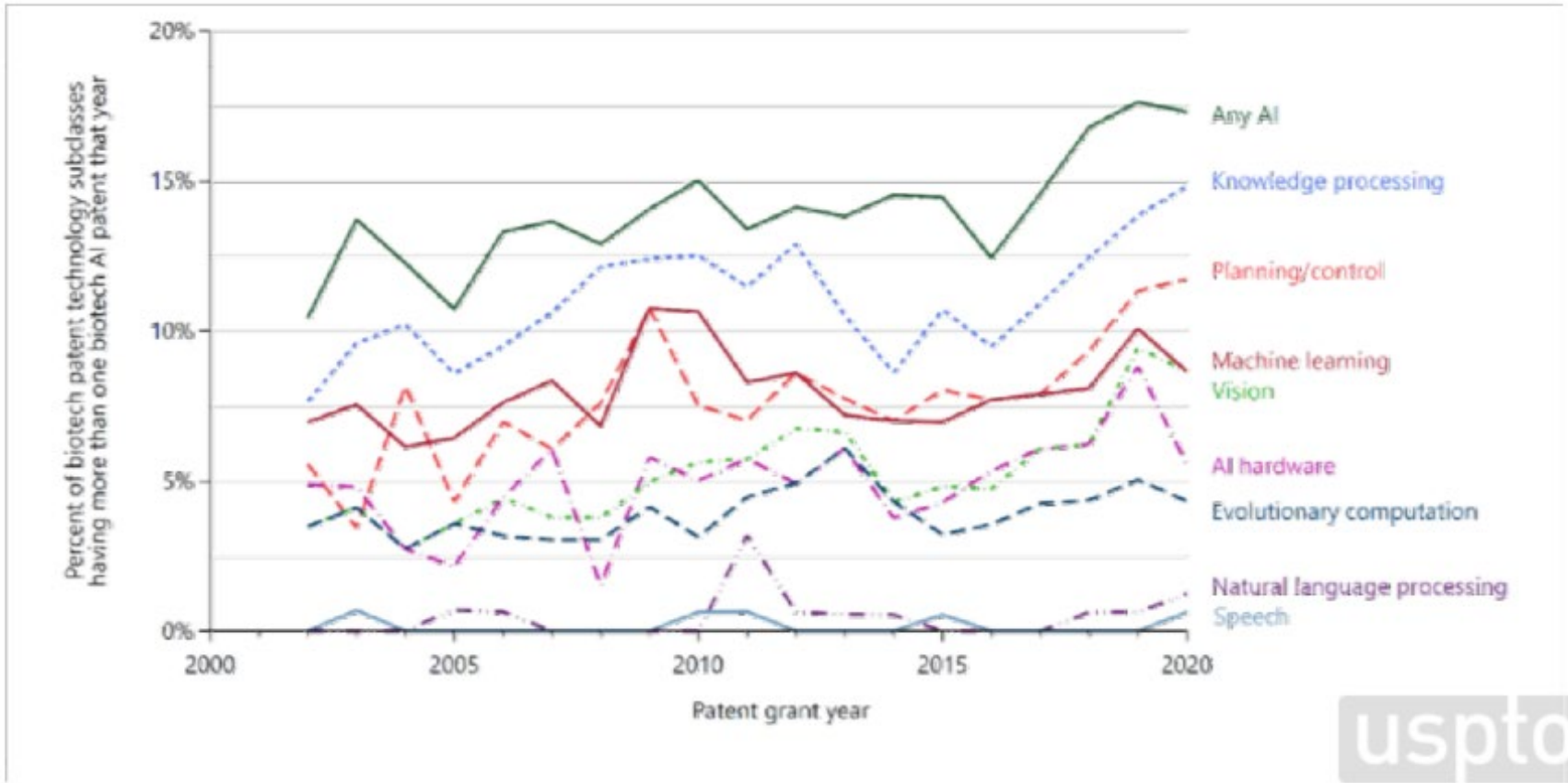
Share of AI and Biotech AI public applications by AI technology component, 2020



Based on earliest publication year CY2020.
Percentages are based on the number of public applications in an AI component out of those in any AI component.

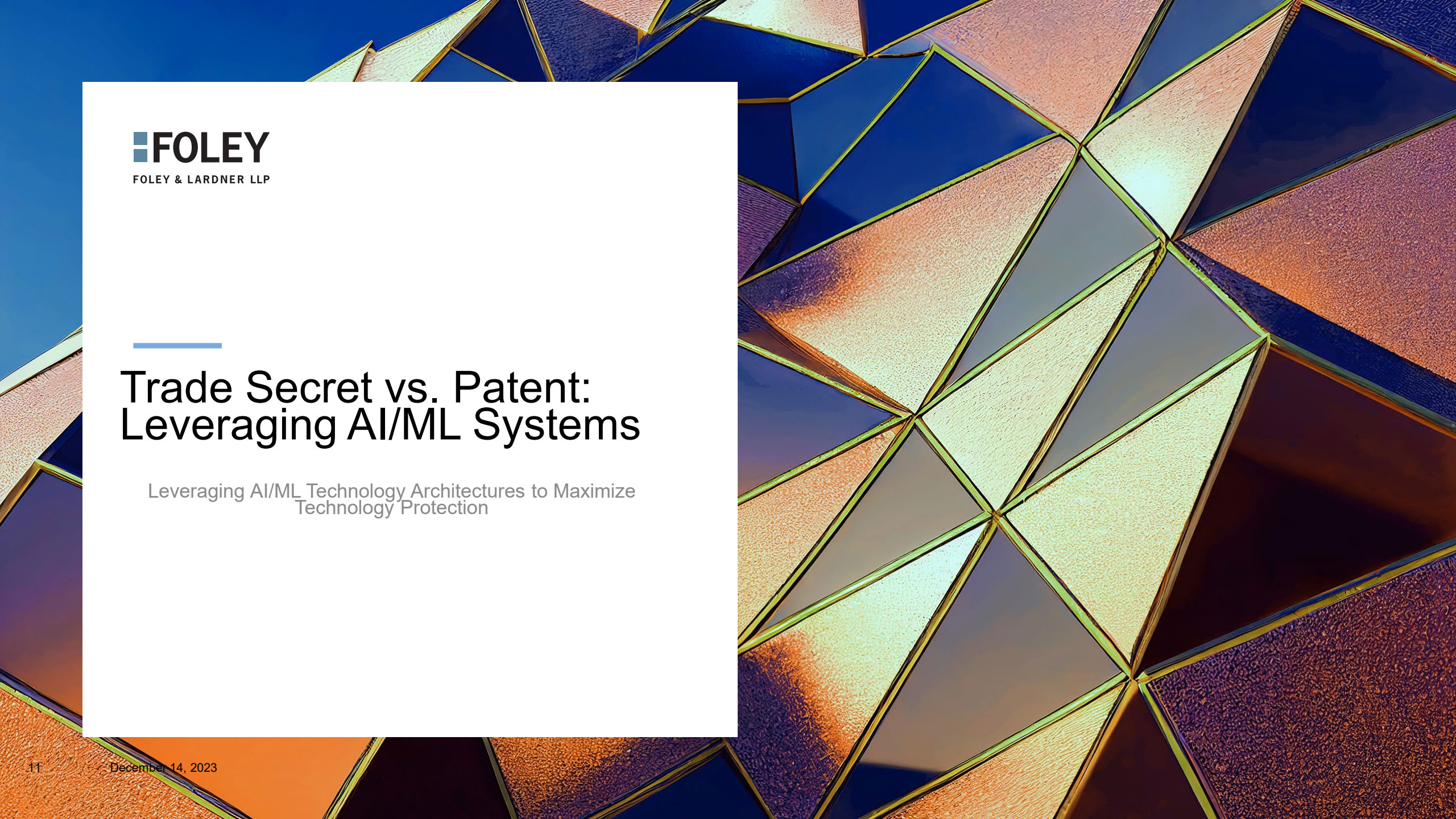
Chart courtesy of the USPTO

Diffusion of Biotechnology AI across biotechnology patent technology subclasses, overall and by AI component, 2002-2020



Includes only the first technology subclass listed on biotechnology patents.

Chart courtesy of the USPTO



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Trade Secret vs. Patent: Leveraging AI/ML Systems

Leveraging AI/ML Technology Architectures to Maximize Technology Protection

To Disclose or Not to Disclose (IP)?

A Trade Secret Requires

- Efforts to Maintain Secrecy

(Some) Trade Secret Obligations

- Efforts to Maintain Secrecy
- Indefinite Period of Protection

(Some) Trade Secret Advantages

- No Public Disclosure
- Open Period of Protection

A Patent Requires*

- Disclosure to the Public

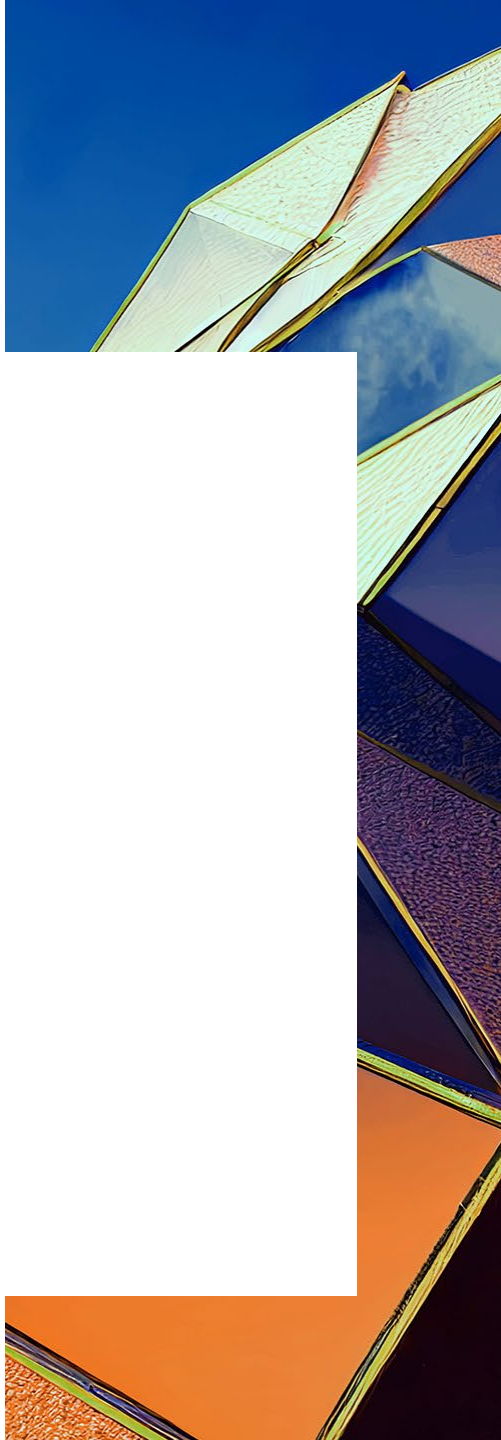
(Some) Patent Obligations

- Disclosure to the Public
- Specific Qualifications Required

(Some) Patent Advantages

- Public Knowledge Permitted
- Minimum Period of Protection

*Limited/Temporary Exceptions



Decision Driver: Commercial Footprint

Technology Deployment

- Desktop vs. Cloud
- Streaming vs. Downloadable
- Co-located vs. Datacenter
- Black Box vs. Customer Control

Technology Use Cases

- Population vs. Personalized
- Laboratory vs. Clinical
- B2C vs. B2B
- Sale vs. SaaS vs. PaaS vs. IaaS

Decision Driver: Lean into Competitive Edge

Competitive Environment

- Head Start
- Arms Race
- Singular Breakthrough

Legal Environment

- Open Source
- Blocking Patents
- Regulatory Barriers

Technology Environment

- Research Barriers
- Secret Sauce
- Simple Tools
- Key Expertise

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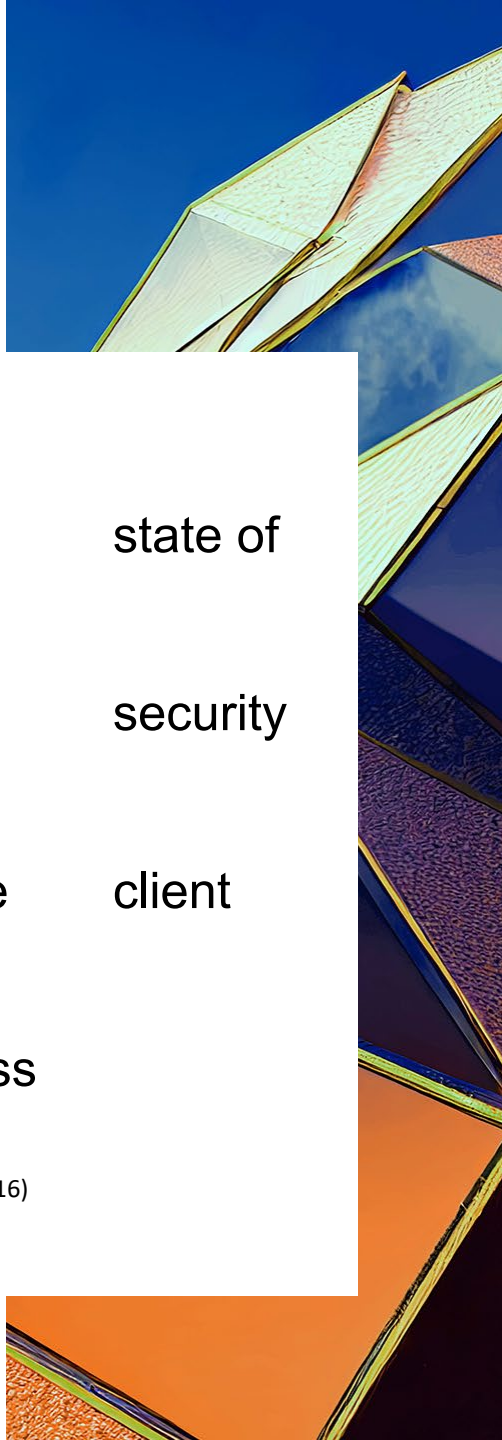
Patent Perils to Avoid: Life Sciences + AI/ML

Fortinet, Inc. v. Forescout Techs., 543 F. Supp. 3d 814 (N.D. Cal. 2021)

U.S. Patent No. No. 9,894,034, Claims 1, 5, 8, and 14



1. A method comprising:

during initialization of a client security application running on a client device:

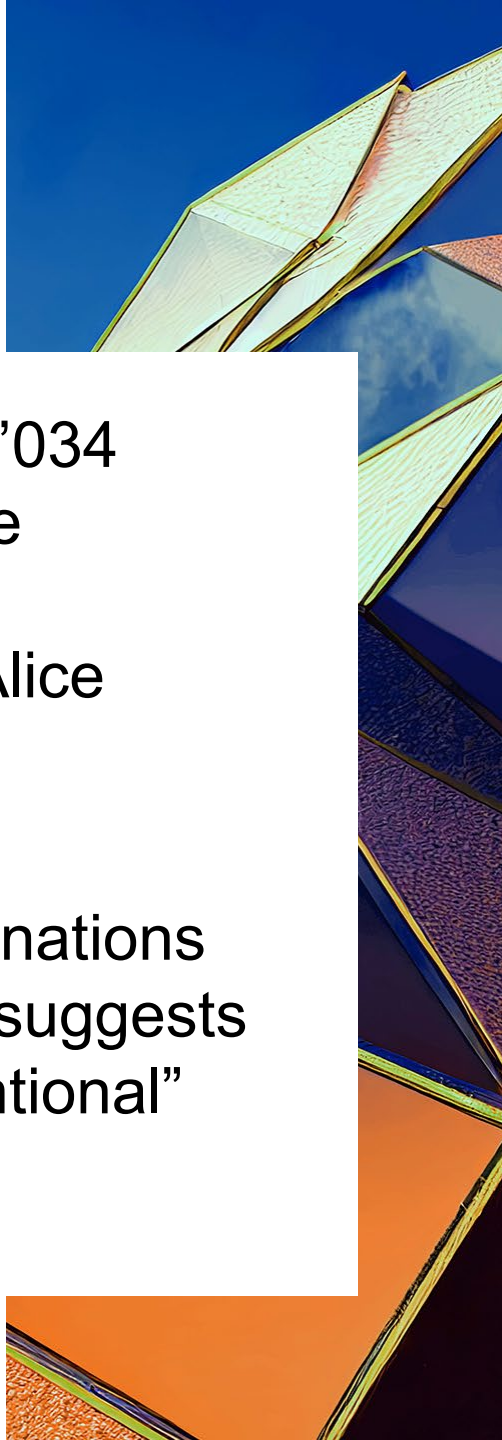
determining, by the client security application, a network connection state of the client device with respect to a private network;

selecting, by the client security application, a configuration for the client security application based on the determined network's connection state; and

launching, by the client security application, one or more functions of the client security application that are designated by the selected configuration to be performed by the client security application, wherein one or more functions include one or more web content filtering, anti-virus scanning, and network access Logging.

McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299, 1314 (Fed. Cir. 2016)

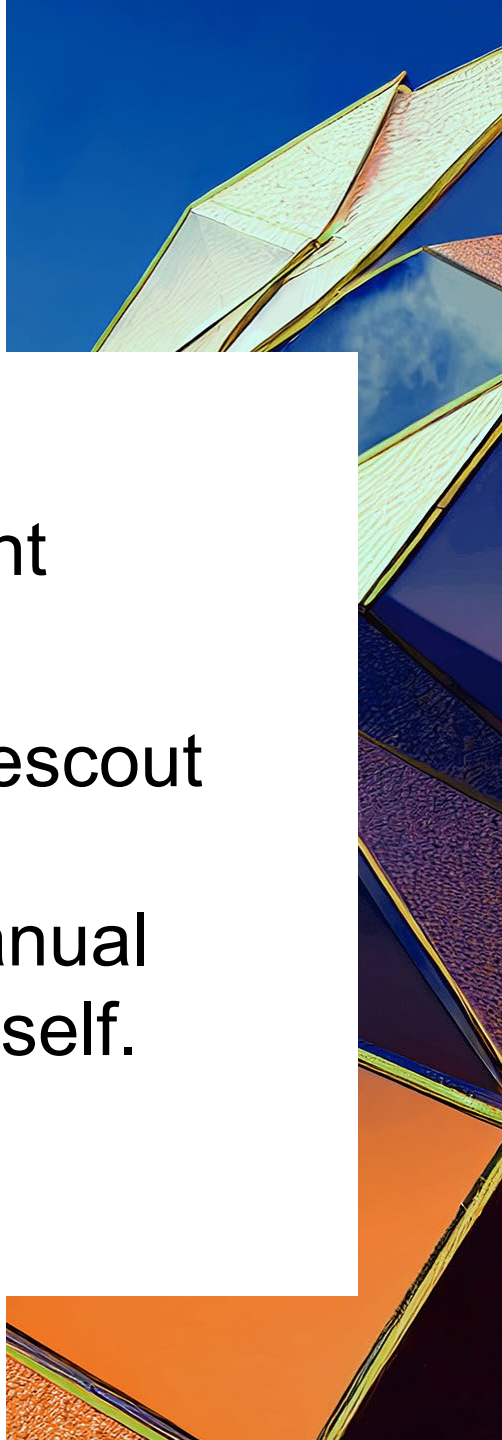
Fortinet – Advantages in Specification Support Allegations of Technical Improvements



- "The Court nevertheless agrees with Forescout that Claim 1 of the '034 Patent appears, on its face, to be abstract… Restricted solely to the language of Claim 1, therefore, the Court would have little trouble concluding that the '034 Patent recites ineligible subject matter at Alice steps one." *Fortinet* at 830.

- "The '034 Patent's specification provides reasonably detailed explanations *831 of how the invention functions in preferred embodiments and suggests "that the claimed invention achieves [multiple] benefits over conventional" technology in the field." *Fortinet* at 830-831.

Practice Note:



Describe potentially assertable abstract ideas as technical problems, to strengthen support of a Technical Improvement

“the manual application of security configurations” that Forescout posits as a substitute for the ‘034 Patent is a problem to be addressed, since [p]ast reliance on the user performing manual security tasks undercut the effectiveness of the computer itself. *Fortinet* at 827.

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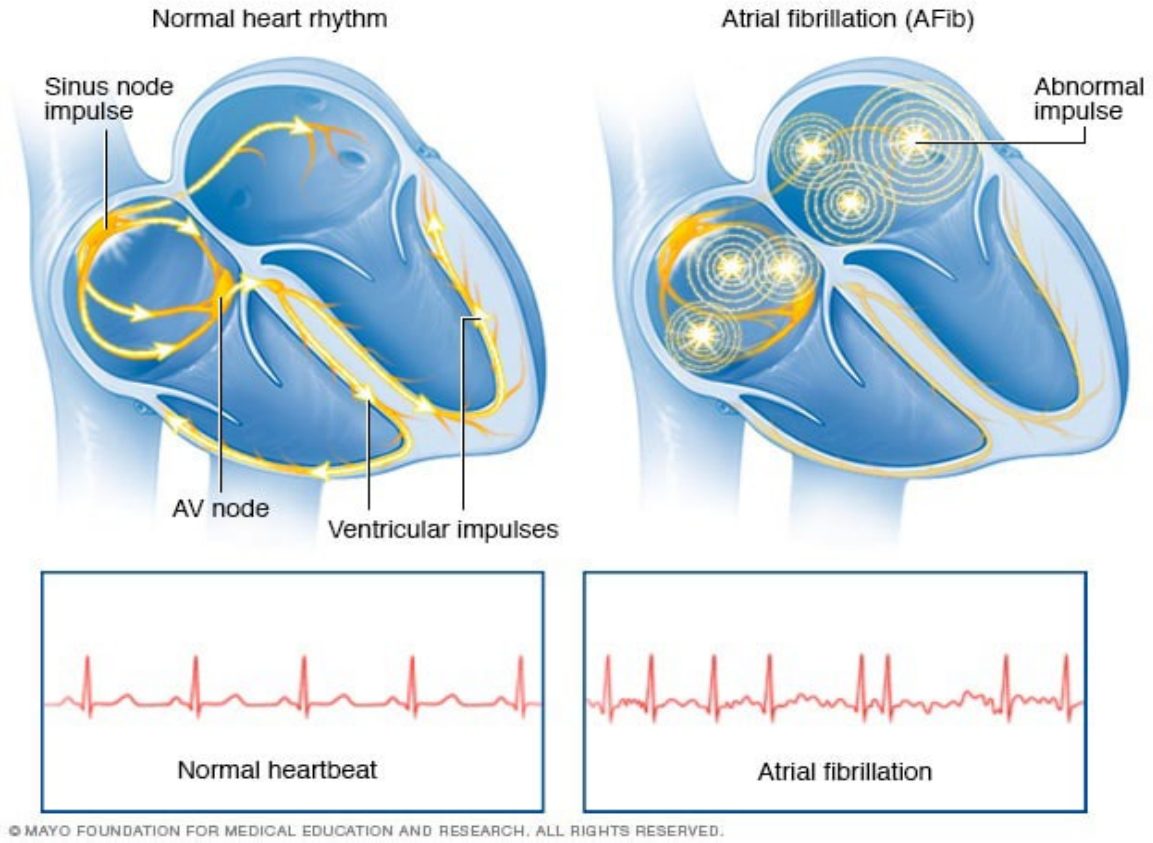
Case Study:
Diagnostics + Artificial Intelligence

CardioNet, LLC v. InfoBionic, Inc, 955 F.3d 1358, 1370–71 (Fed. Cir. 2020)

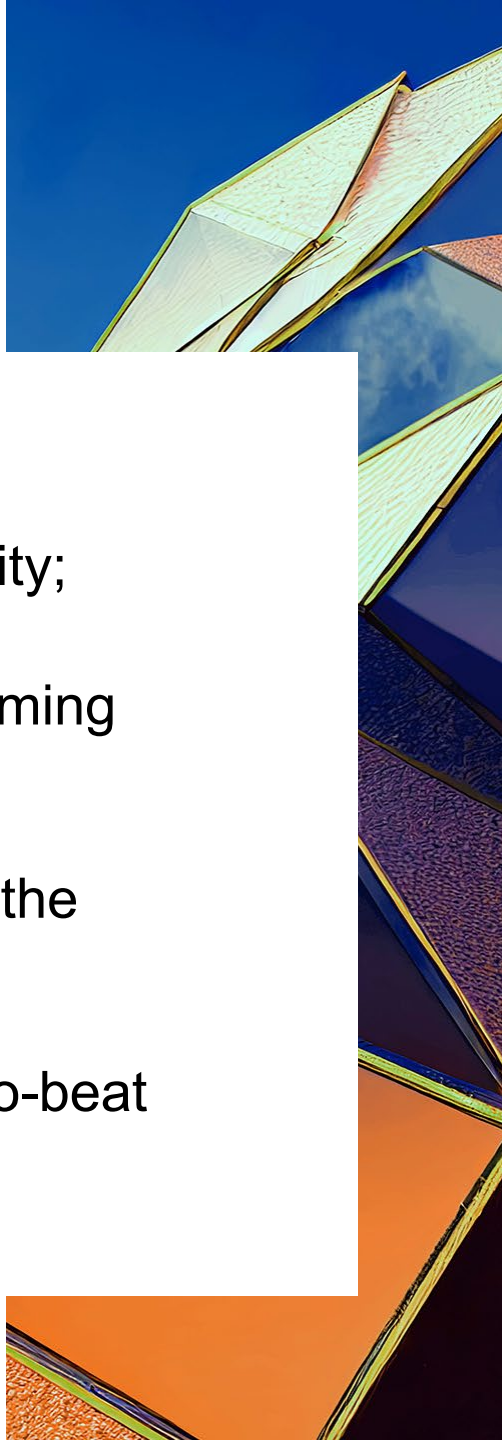
U.S. Patent 7,941,207 (“Cardiac Monitoring”)

Directed to detect anomalies in the electrical activity of a patient’s heart, namely “atrial fibrillation and flutter”



CardioNet, LLC v. InfoBionic, Inc, 955 F.3d 1358, 1370–71 (Fed. Cir. 2020)

CardioNet – Eligible Claim 1



1. A device, comprising:

a beat detector to identify a beat-to-beat timing of cardiac activity;

a ventricular beat detector to identify ventricular beats in the cardiac activity;

variability determination logic to determine variability in the beat-to-beat timing of a collection of beats;

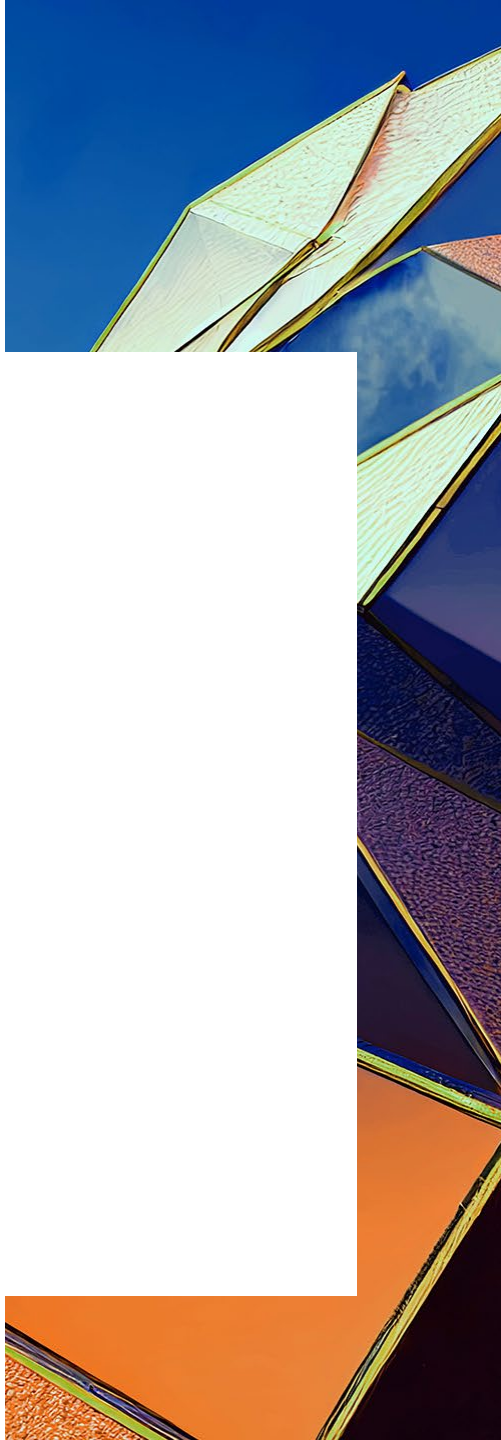
relevance determination logic to identify the relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and

an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to at least one of atrial fibrillation.

CardioNet – Claims Held Eligible

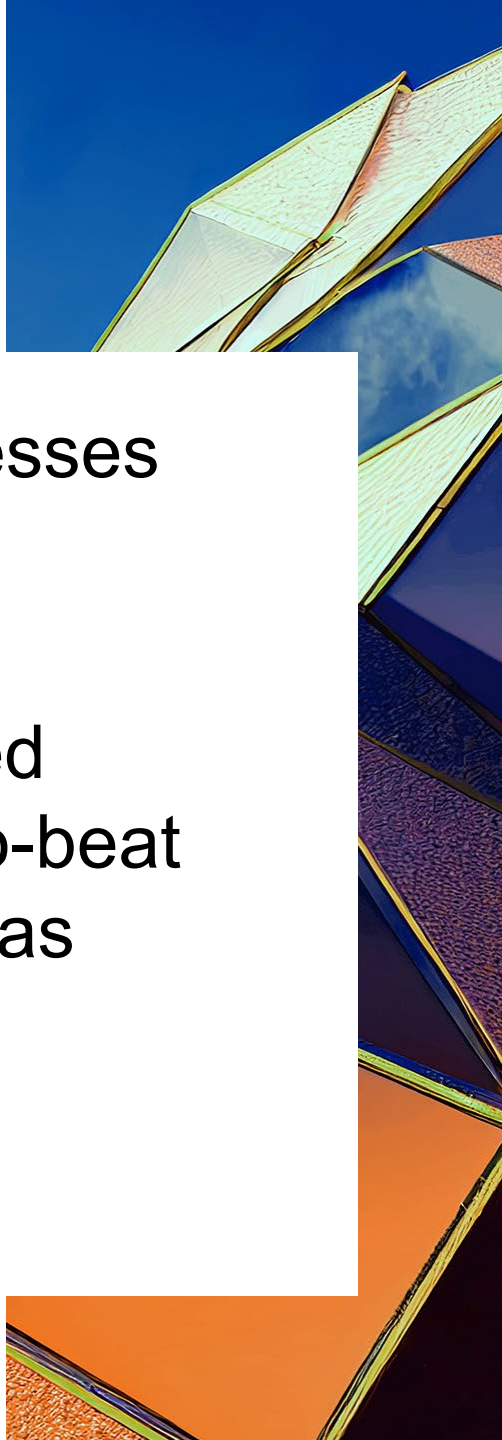
- "[W]ritten description does not disclose that doctors performed the same techniques as the claimed device in diagnosing atrial fibrillation or atrial flutter."
- "[D]ifficult to fathom how doctors mentally or manually used 'logic to identify the relevance of the variability [in the beat-to-beat timing]."
- Primarily relied on intrinsic evidence (i.e., written description)

CardioNet – Specification Support



"by identifying 'variability in the beat-to-beat timing ... as relevant to at least one of the atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector,' the claimed invention achieves multiple technological improvements." *CardioNet* at 1368.

Practice Note



Distinguish the Operation of AI from Manual or Mental Processes with specific technical details.

“it is difficult to fathom how doctors mentally or manually used ‘logic to identify the relevance of the variability [in the beat-to-beat timing] using a non-linear function of a beat-to-beat interval’ as required by claim 10.” *CardioNet,* at 1370–71.

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Case Study: Genomics + Machine Learning

Health Discovery Corp. v. Intel Corp., 577 F. Supp. 3d 570 (W.D. Tex. 2021)

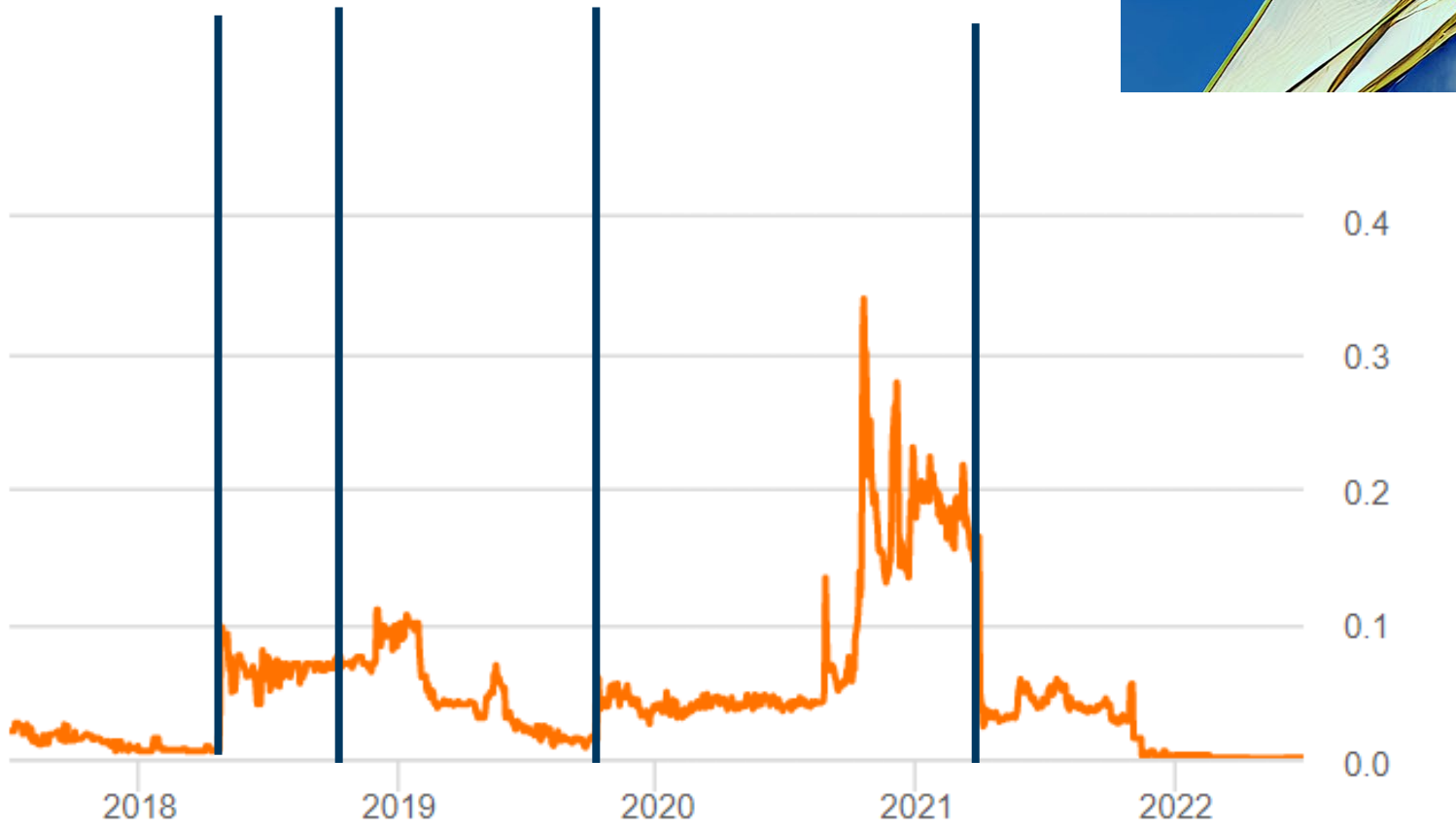
Health Discovery – So Goes a Licensor

2/27/2019: HD wins Interference against Intel Patent

9/3/2019: HD granted 10,402,685

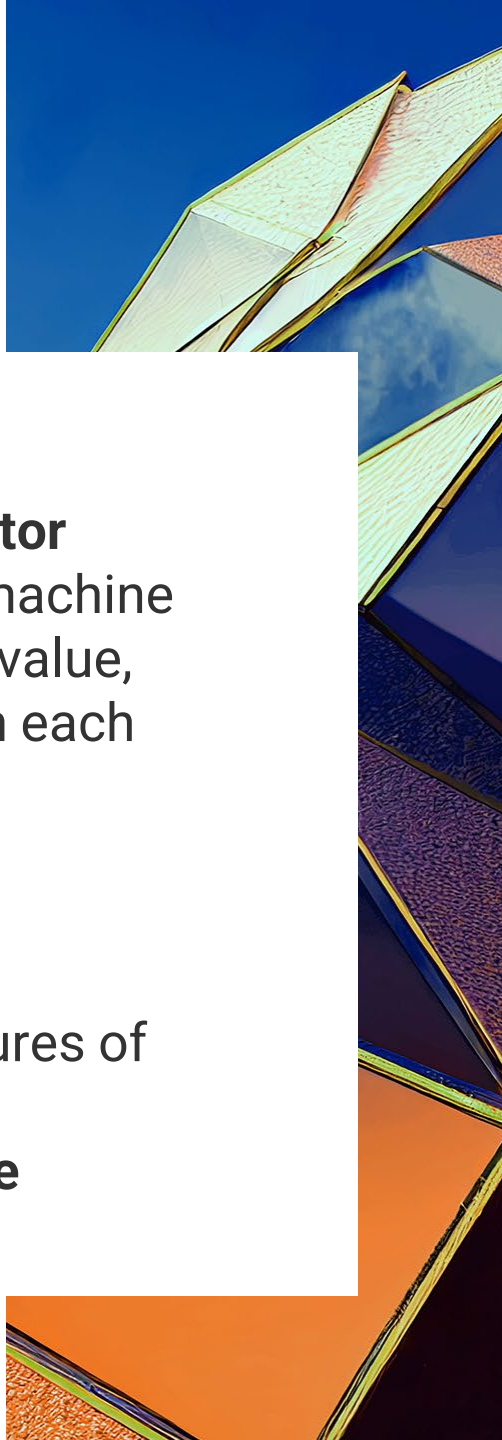
7/23/2020: HD files against Intel

12/27/2021: Intel MTD Granted



https://seekingalpha.com/symbol/HDVY
https://www.yahoo.com/now/health-discovery-corporation-files-infringement-002000427.html

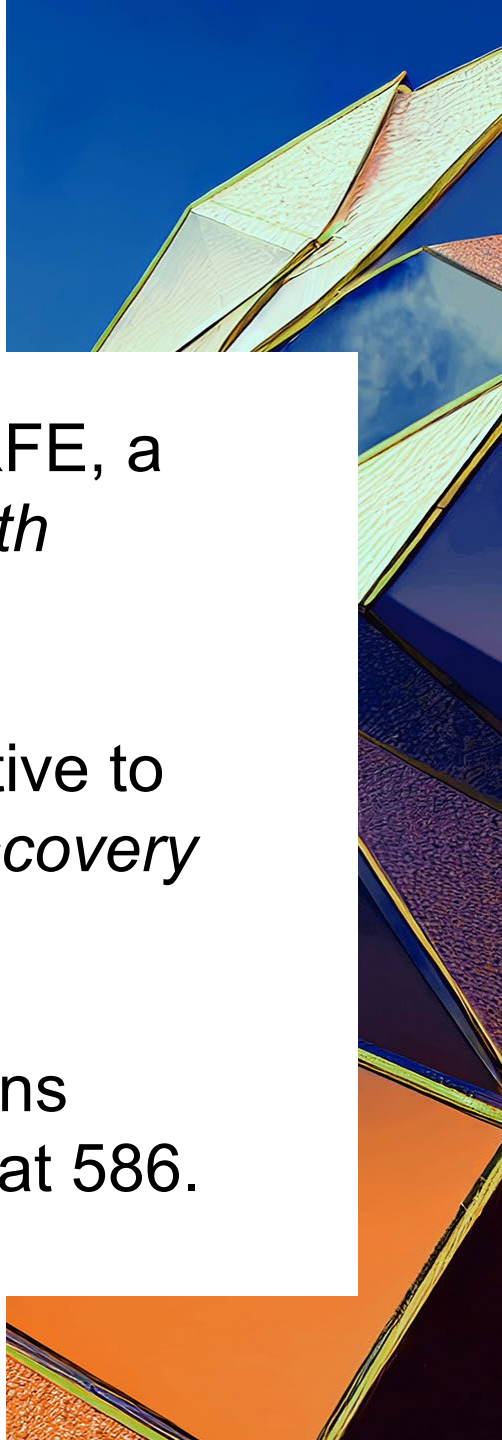
Health Discovery – U.S. Patent 7,117,188



1. A computer-implemented method for identifying patterns in data, the method comprising:
(a) inputting into at least one support vector machine of a plurality of support vector machines a training set having known outcomes, the at least one support vector machine comprising a decision function having a plurality of weights, each having a weight value, wherein the training set comprises features corresponding to the data and wherein each feature has a corresponding weight;
(b) optimizing the plurality of weights so that classifier error is minimized;
(c) computing ranking criteria using the optimized plurality of weights;
(d) eliminating at least one feature corresponding to the smallest ranking criterion;
(e) repeating steps (a) through (d) for a plurality of iterations until a subset of features of pre-determined size remains; and
(f) inputting into at least one support vector machine a live set of data wherein the features within the live set are selected according to the subset of features.

Health Discovery Corp. v. Intel Corp., 577 F. Supp. 3d 570 (W.D. Tex. 2021)

Health Discovery – U.S. Patent 7,117,188



"the claimed invention ranks and eliminates features using SVM-RFE, a purportedly novel but nevertheless mathematical technique." *Health Discovery* at 584.

"[T]he claims here merely produce data with improved quality relative to that produced by conventional mathematical methods." *Health Discovery* at 584.

"The Court concludes, then, that HDC has failed to plead allegations supporting the eligibility of the asserted claims." *Health Discovery* at 586.

Health Discovery – Specification Support

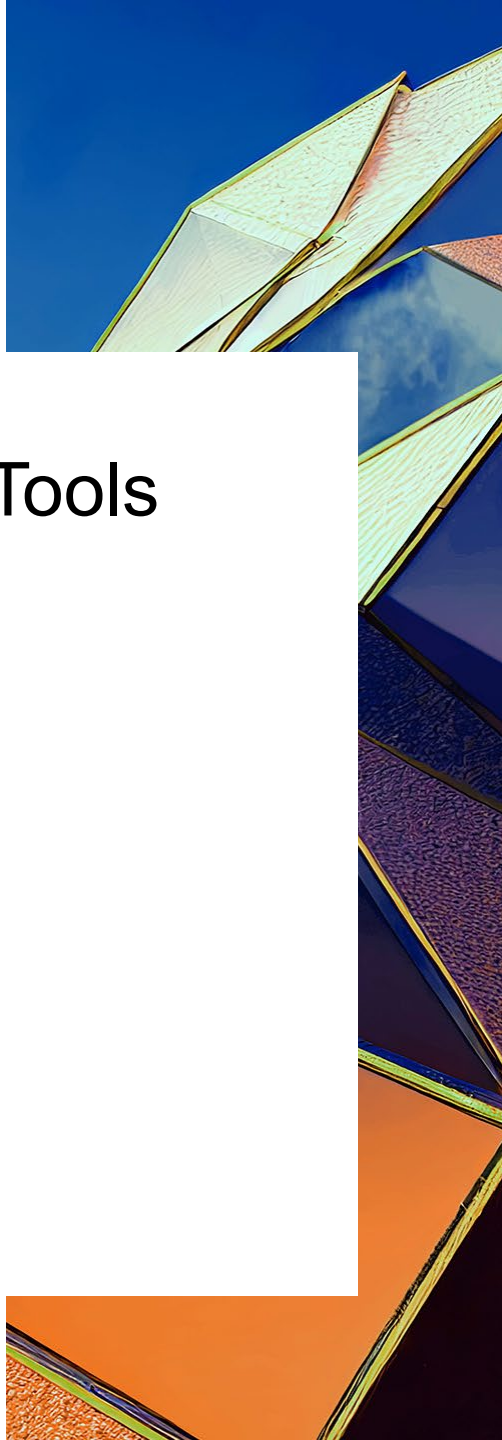
"To increase computations speed, RFE is preferably implemented by training multiple classifiers on Subsets of features of decreasing size." *Health Discovery* at 585, quoting '188 Patent, col. 30, lines 3-6.

"Eliminate the feature with smallest ranking criterion… The above steps can be modified to increase computing speed by generalizing the algorithm to remove more than one feature per step. " '188 Patent Col. 29, lines 49-62

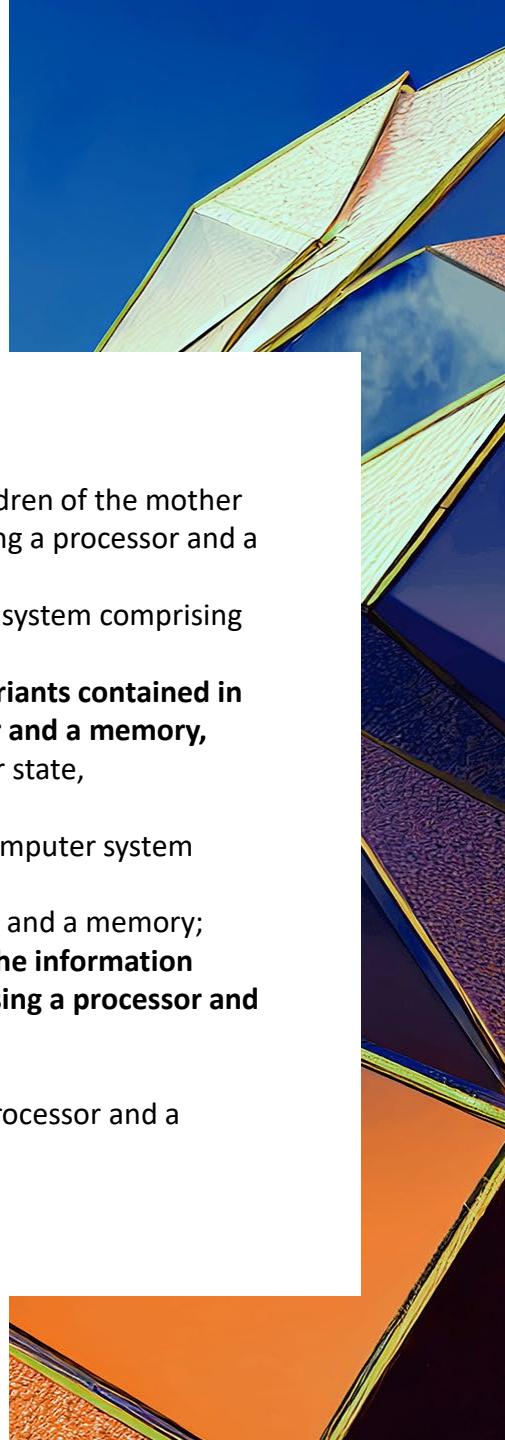
Practice Note

Avoid Describing Invention Only as a Collection of Existing Tools

"…merely describes how RFE functions, not how SVE-RFE improves upon the prior art." *Health Discovery* at 585.



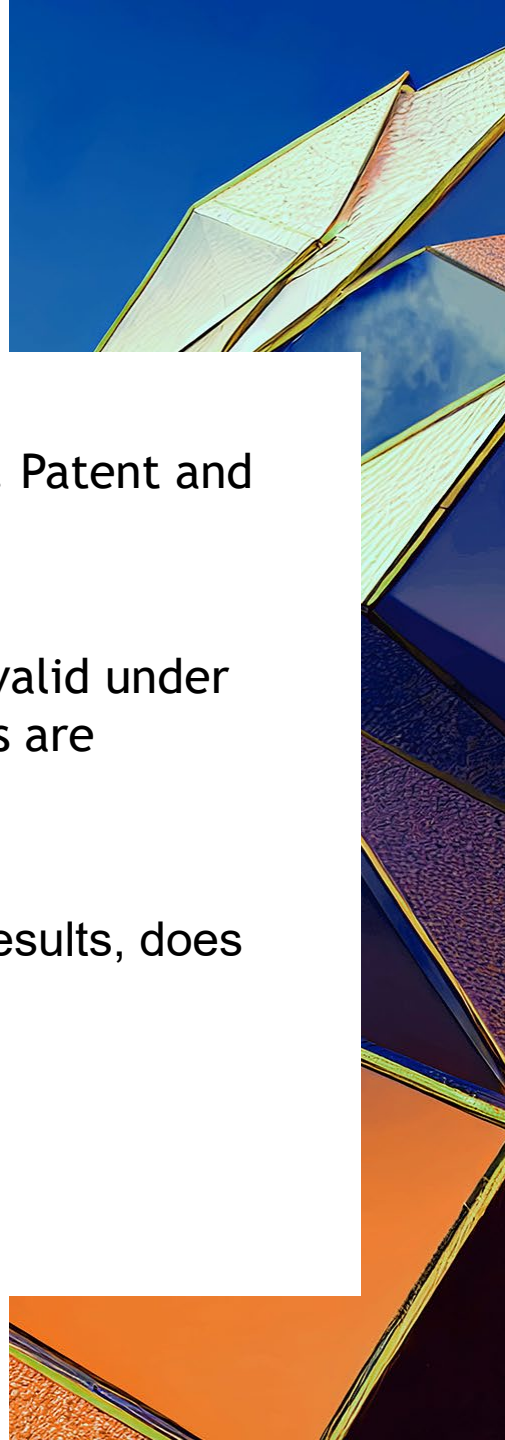
In re Bd. of Trustees of Leland Stanford Junior Univ., 991 F.3d 1245 (Fed. Cir. 2021)



- 1. A method for resolving the haplotype phase, comprising:
  receiving allele data describing allele information regarding genotypes for a family comprising at least a mother, a father, and at least two children of the mother and the father, where the genotypes for the family contain single nucleotide variants and storing the allele data on a computer system comprising a processor and a memory;
  receiving pedigree data for the family describing information regarding a pedigree for the family and storing the pedigree data on a computer system comprising a processor and a memory;
  determining an inheritance state for the allele information described in the allele data based on the identity between single nucleotide variants contained in the genotypes for the family using a Hidden Markov Model having hidden states implemented on a computer system comprising a processor and a memory,
    wherein the hidden states comprise inheritance states, a compression fixed error state, and a[Mendelian inheritance error]- rich fixed error state,
    wherein the inheritance states are maternal identical, paternal identical, identical, and non-identical;
  receiving transition probability data describing transition probabilities for inheritance states and storing the transition probability data on a computer system comprising a processor and a memory;
  receiving population linkage disequilibrium data and storing the population disequilibrium data on a computer system comprising a processor and a memory;
  determining a haplotype phase for at least one member of the family based on the pedigree data for the family, the inheritance state for the information described in the allele data, the transition probability data, and the population linkage disequilibrium data using a computer system comprising a processor and a memory;
  storing the haplotype phase for at least one member of the family using a computer system comprising a processor and a memory; and
  providing the stored haplotype phase for at least one member of the family in response to a request using a computer system comprising a processor and a memory.

U.S. Patent Application Serial No. 13/486,982

In re Bd. of Trustees of Leland Stanford Junior Univ., 991 F.3d 1245 (Fed. Cir. 2021)



- U.S. Patent Application Serial No. 13/486,982, claims 1 and 22-43 rejected by the U.S. Patent and Trademark Office Patent Trial and Appeal Board (PTAB) during *ex parte* examination
- The Federal Circuit affirmed the decision of the PTAB that claims 1 and 22-43 were invalid under 35 U.S.C. § 101, as directed to patent-ineligible abstract ideas. Specifically, the claims are directed to the use of mathematical calculations and statistical modeling.
- The different use of a mathematical calculation, even one that yields different or better results, does not render subject matter patent-eligible.

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Ahead: Patent Rights + AI

AI + Inventorship: A Possible Arms Race

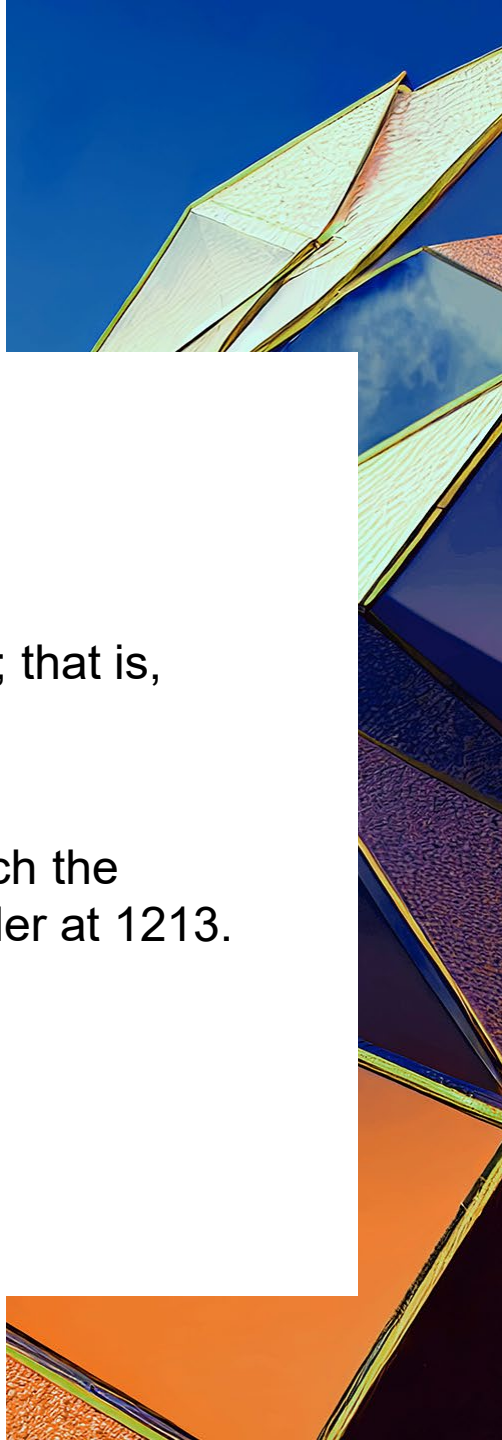
Regulatory Conditions

- AI-Enabled Inventorship Accommodated
- IP Rights with AI Inventorship Not Reduced

Technology Conditions

- Generative AI Gains IP Domain Knowledge
- Generative AI Platforms Permit Confidentiality

AI Inventors? Not Yet.



Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022), cert. denied, No. 22-919 (Apr. 24, 2023).

“Here, there is no ambiguity: the Patent Act requires that inventors must be natural persons; that is, human beings.” Thaler at 1210.

“Statutes are often open to multiple reasonable readings. Not so here. This is a case in which the question of statutory interpretation begins and ends with the plain meaning of the text.” Thaler at 1213.

Inventors + AI: New Federal Guidance?

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, October 30, 2023

5.2(c)(i) within 120 days of the date of this order, [the USPTO is to] publish guidance to USPTO patent examiners and applicants addressing inventorship and the use of AI

Inventors + AI: New Federal Guidance?

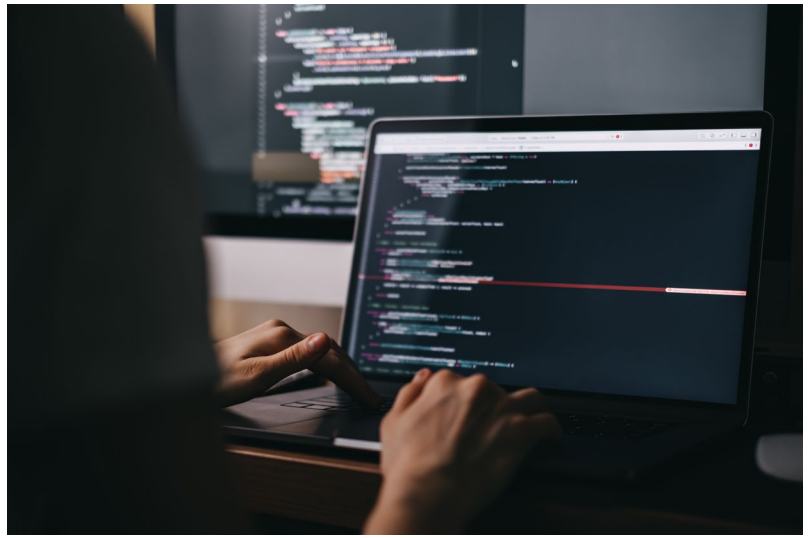
Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, October 30, 2023

5.2(c)(i) within 120 days of the date of this order, [the USPTO is to] 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.

AI + Inventorship: Possible Effects

Possible Regulatory Effects

- Significant Increase in the Rate of Patent Creation
- Freedom to Operate Becomes Exponentially More Challenging



Possible Market Effects

- AI-Enabled Inventors Crowd Out Human Inventors
- Innovation Outpaces Commercialization
- Exponential Increase in Patented Technology Dedicated to the Public

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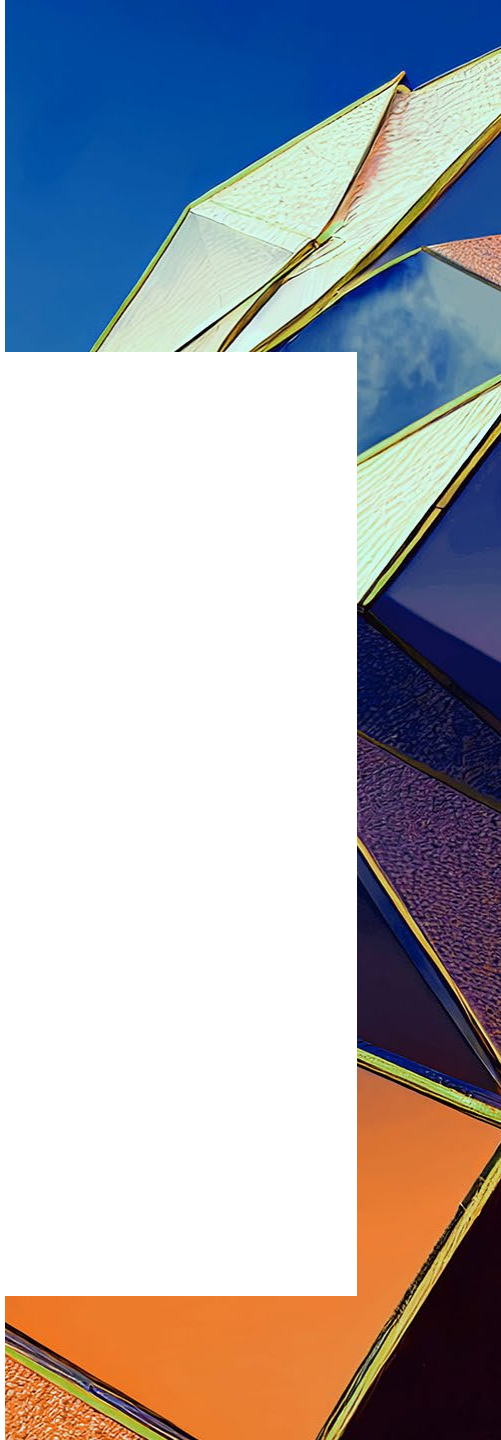

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