Knobbe Martens

Patent Protection of AI-Powered Medical Devices

Presented by:

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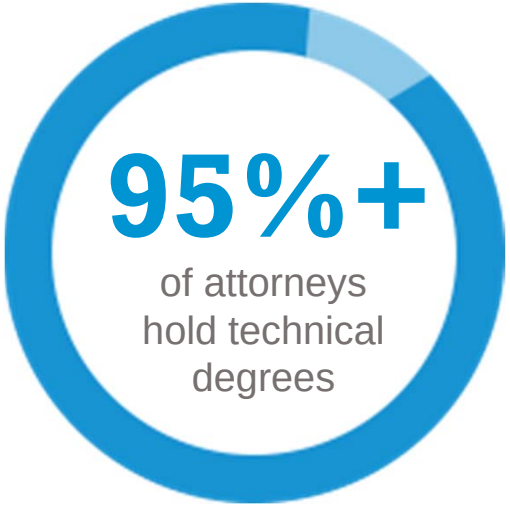
February 10, 2020

Firm Profile – By the Numbers



Global Practice

through large network of
Foreign Associates

7 **Offices Nationwide**

Orange County
Los Angeles
New York
San Diego
San Francisco
Seattle
Washington D.C.

200 Highest number of registered patent attorneys in the US practicing across a **vast array** of industries

250+ lawyers & scientists

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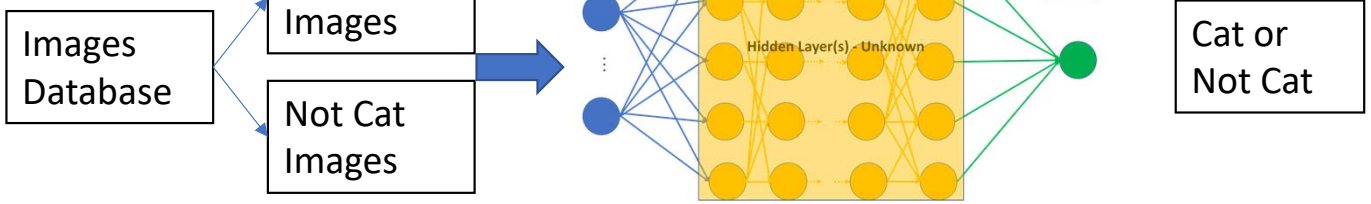
Machine Learning - Vocabulary

Training Data
e.g., images

Training Method
e.g. labeling

Learning Algorithm
e.g. neural network

Working Model
e.g., decision tree,
look up table



Machine Learning/Artificial Intelligence

- Minimal Requirements for an Algorithm to be ML
  - Representation – Classifiers or basic language that a computer can understand
  - Evaluation – Inputting data and generating output (score)
  - Optimization – Developing a strategy to get from inputs to outputs

Learning Models

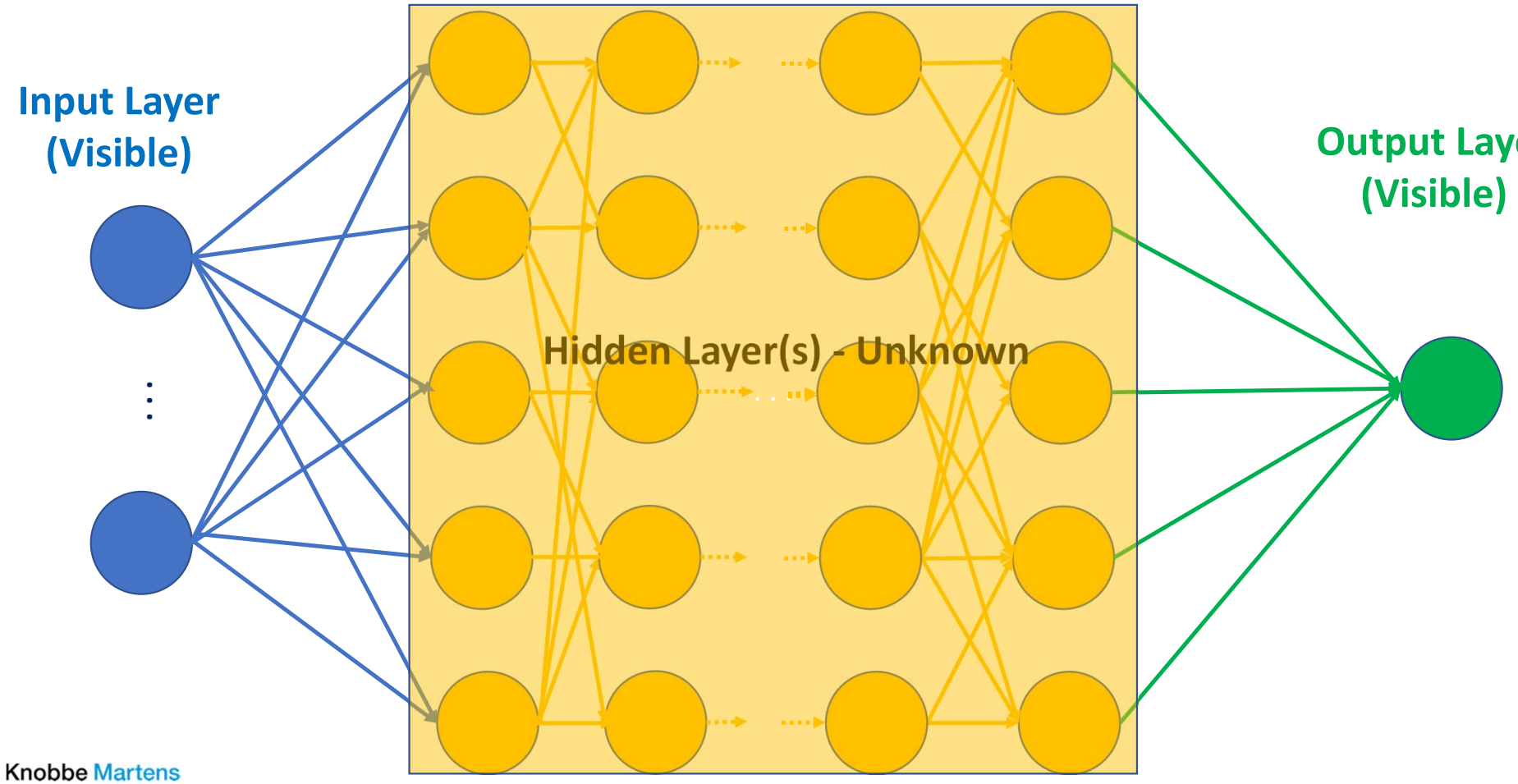
1 Supervised Learning

2 Unsupervised Learning

3 Semi-Supervised Learning

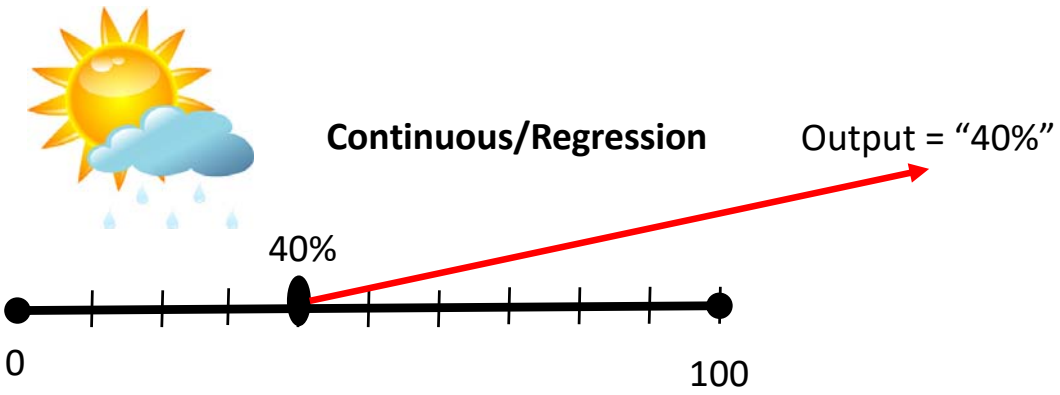
4 Reinforcement Learning

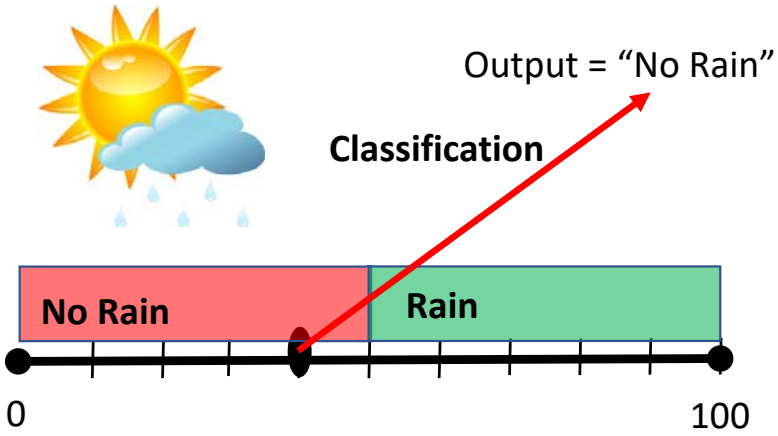
General Architecture of Neural Network



Machine Learning Outputs – Regression vs. Classification

- **Classification**: A model (function) which helps in separating the data into multiple categorical classes.
  - Data is categorized under different labels according to parameters
  - Labels are predicted for the data.
- **Regression/Continuous**: A model (function) distinguishing the data into continuous real values instead of categorical classes.
  - Function attempts to approximate value with the minimum error deviation.
  - No labels





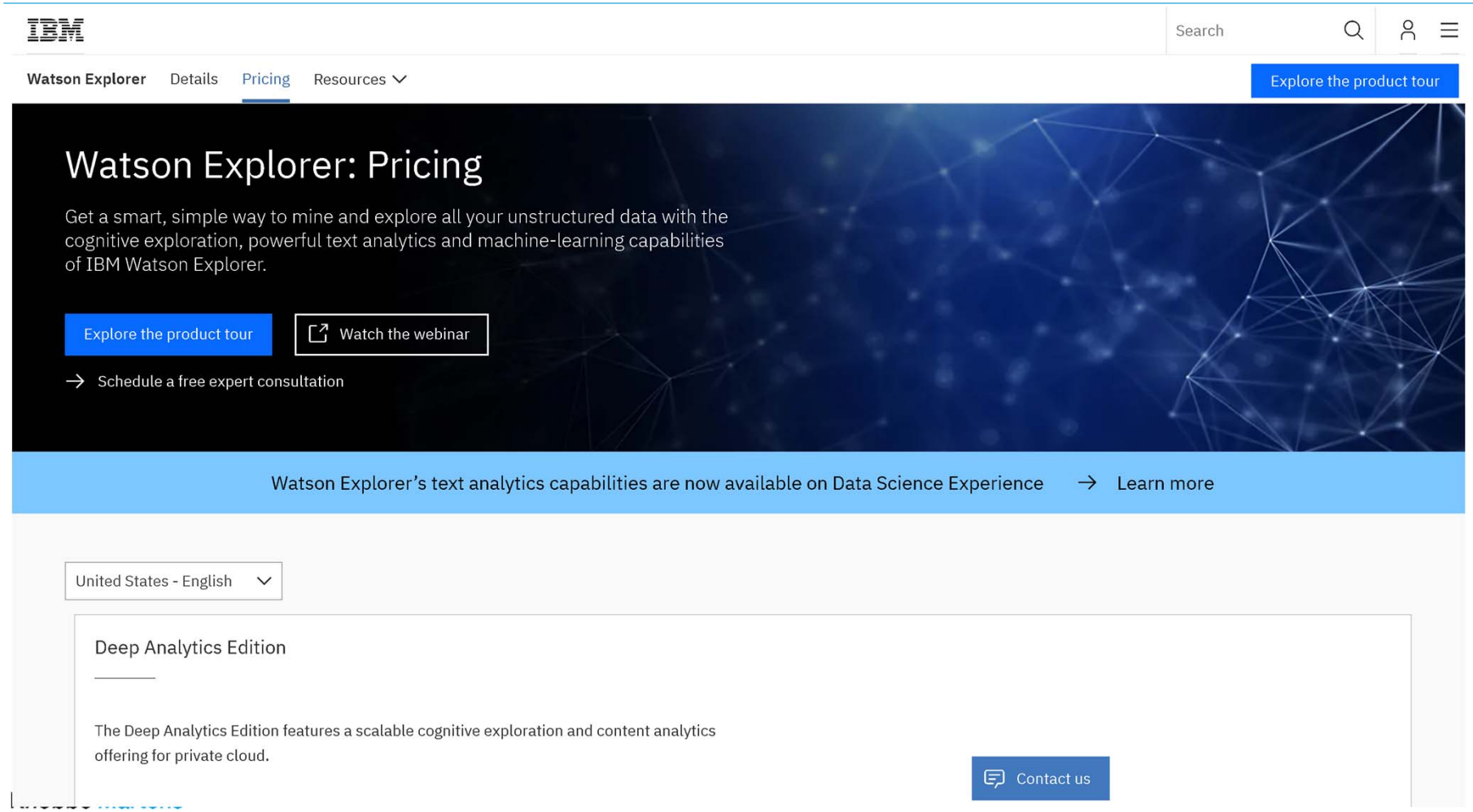
Exemplary Algorithm Types

	Unsupervised Learning Algorithms	Supervised Learning Algorithms

Classification Output	• Association Rule Analysis
	  • Apriori
	  • Equivalence Class Transformation
	  • FP-Growth
	• Hidden Markov Model
		• Classification
		  • K-Nearest Neighbors
		  • Decision/Boosted Trees
		  • Logic Regression/Naive-Bayes
		  • Neural Networks
		  • Support Vector Machine (SVM)

Continuous Output	• Clustering and Dimensionality
	  • K-Means
	  • Singular Value Decomposition
	  • Principle Component Analysis
		• Regression
		  • Linear Regression
		  • Polynomial Regression
		• Decision Trees
		• Random Forests

IBM's Watson line of AI Solutions



Google's AI offerings

Google Cloud | Why Google | Solutions | Products | Pricing | Getting Started | Docs | Support | Language | Console

AI & Machine Learning Products | Contact Sales

AI Platform

Create your AI applications once, then run them easily on both GCP and on-premises.

Contact sales | Try it free

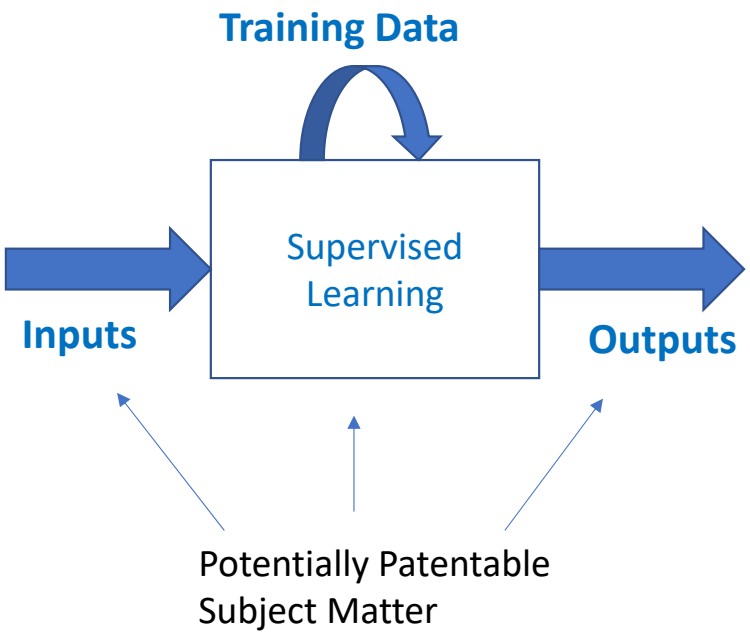
Take your machine learning projects to production

AI Platform makes it easy for machine learning developers, data scientists, and data engineers to take their ML projects from ideation to production and deployment, quickly and cost-effectively. From data engineering to "no lock-in" flexibility, AI Platform's integrated tool chain helps you build and run your own machine learning applications.

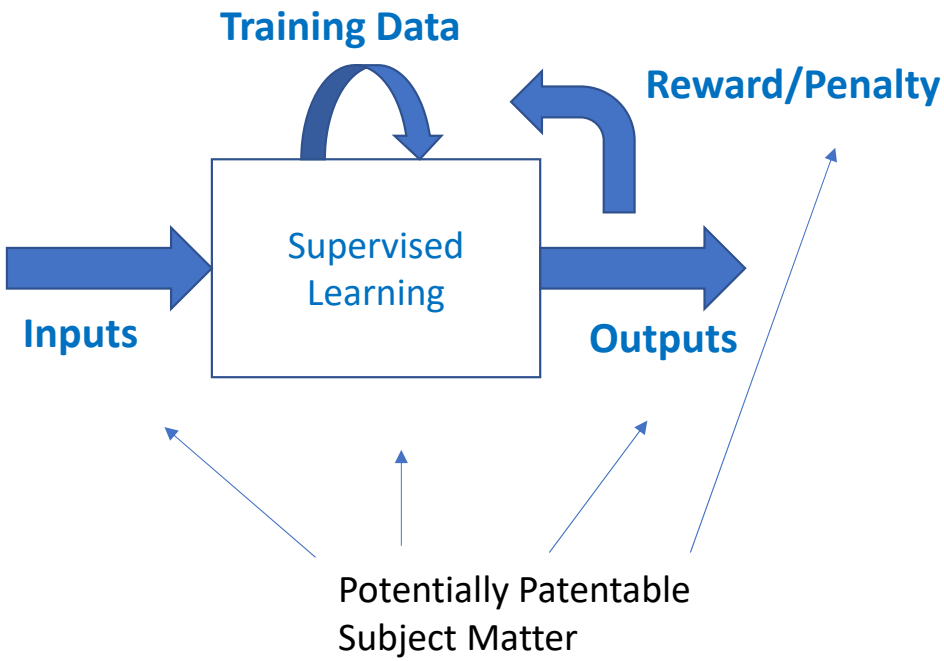
AI Platform supports Kubeflow, Google's open-source platform, which lets you build portable ML pipelines that you can run on-premises or on Google Cloud without significant code changes. And you'll have access to cutting-edge Google AI technology like TensorFlow, TPUs, and TFX tools as you deploy your AI applications to production.

Comparison of Supervised Learning to Reinforcement Learning

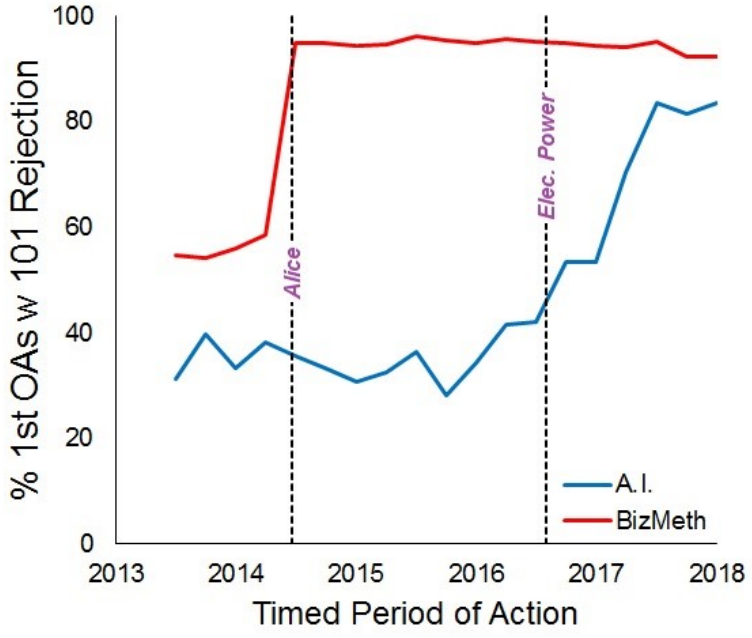
Supervised Learning Algorithms



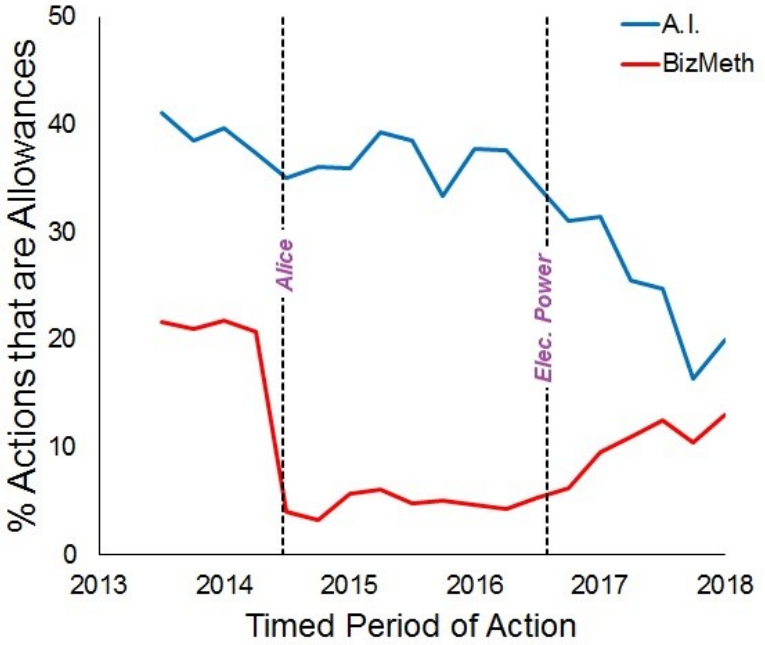
Reinforcement Learning Algorithms



Comparison of Section 101 Rejections "Business Method" vs. ML



Allowance Percentage "Business Method" vs. ML



Source: *Artificial Intelligence Technologies Facing Heavy Scrutiny at the USPTO*, IP Watchdog, November 28, 2018.

USPTO Updated Guidance 2019 “Example 39” - Method for Training a Neural Network for Facial Detection

A computer-implemented method of training a neural network for facial detection comprising:

collecting a set of digital facial images from a database;

applying one or more **transformations** to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images;

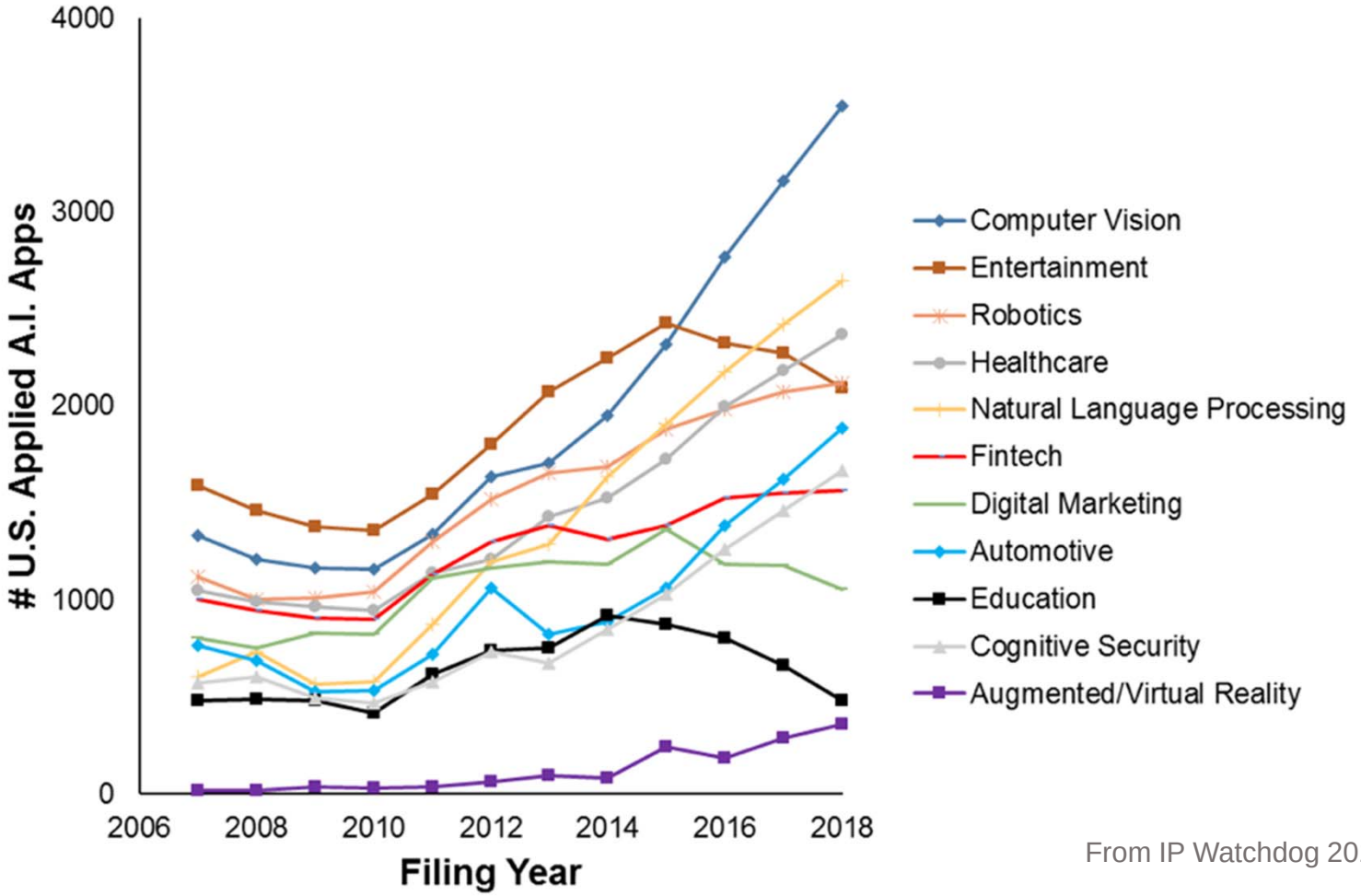
creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;

training the neural network in a first stage using the first training set;

creating a second training set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and

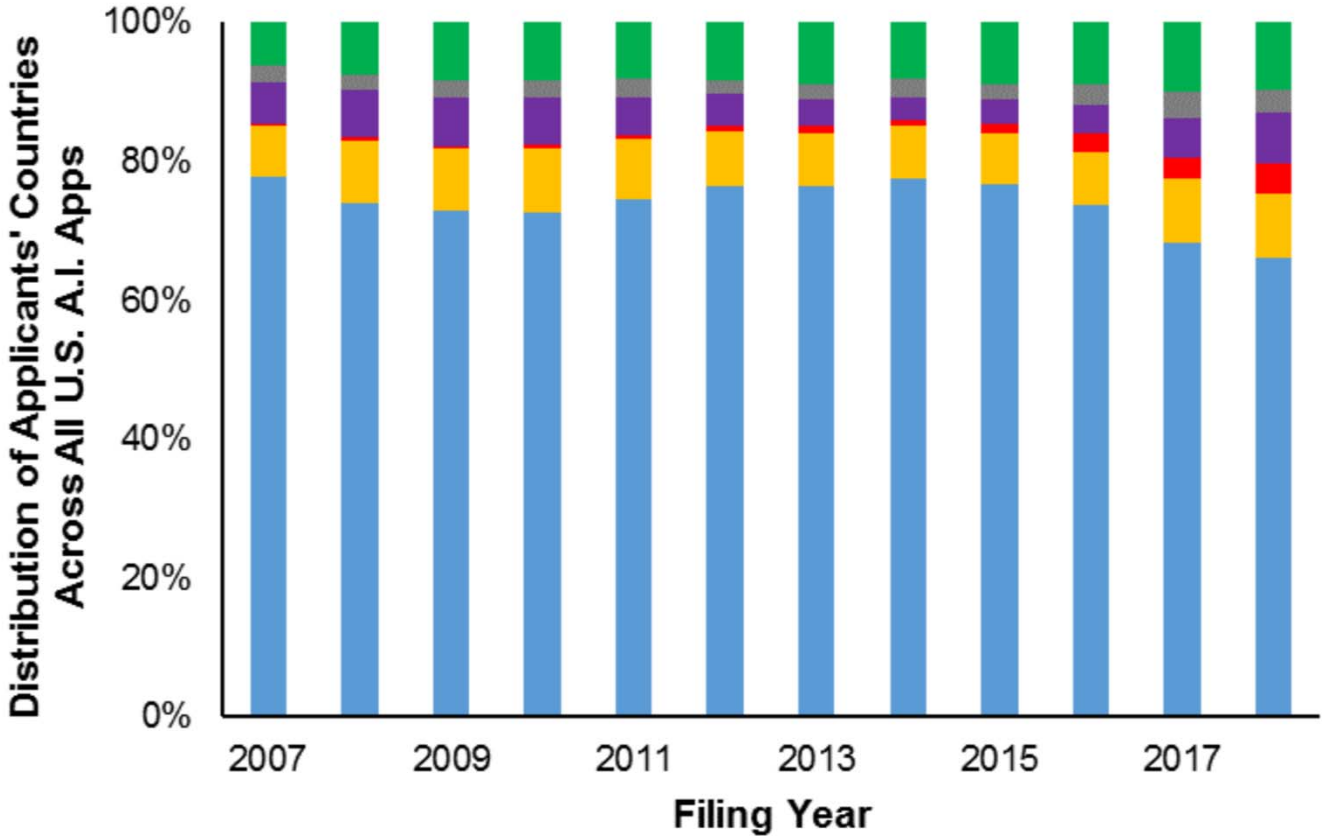
training the neural network in a second stage using the second training set.

Recent Trends in AI Patent Filings, By Industry



From IP Watchdog 2019

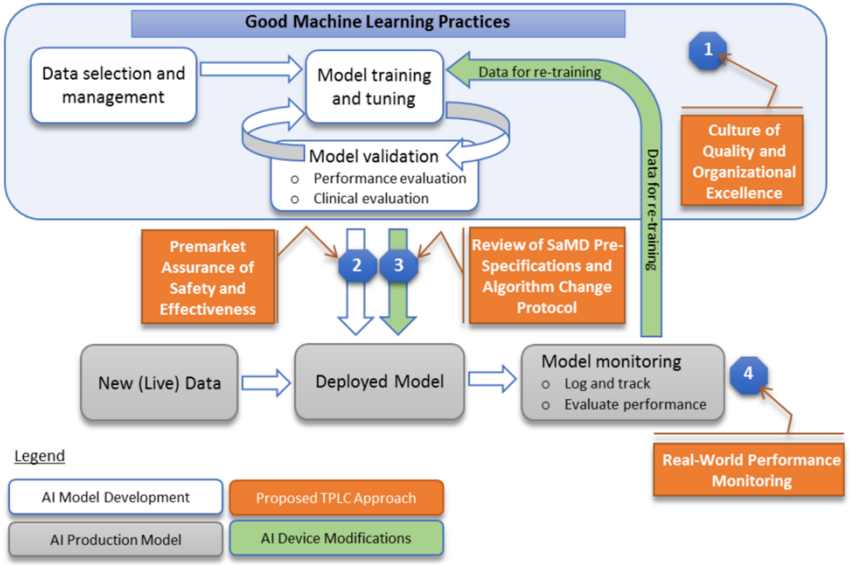
US Innovators File the Most AI Patents – By a Wide Margin

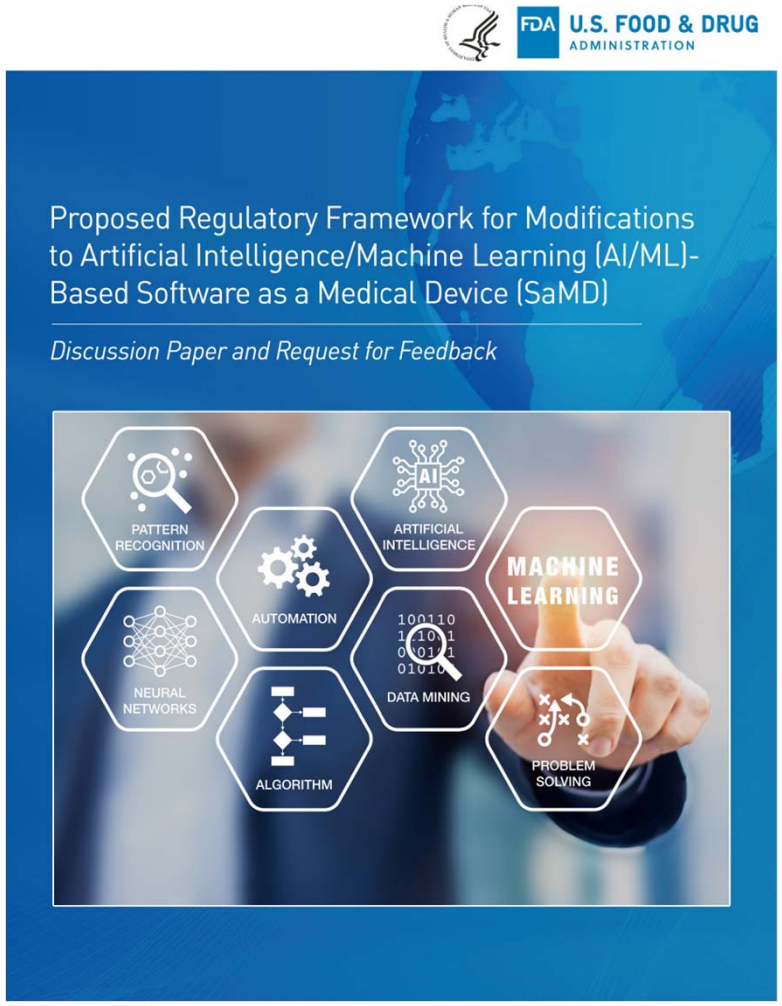


From IP Watchdog 2019

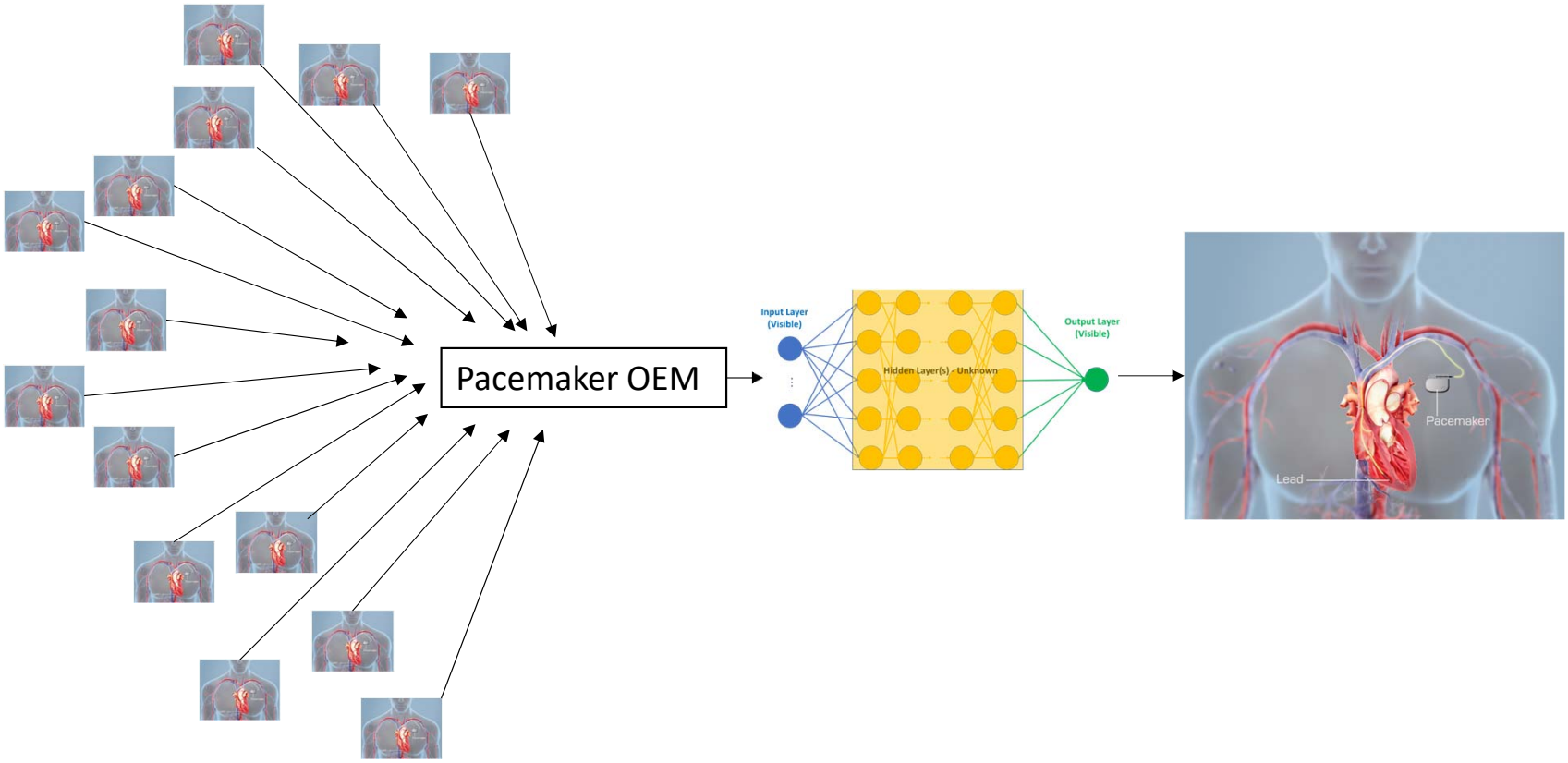
FDA Rule Making – Software as a Medical Device (SaMD)

- **Currently**: AI enhanced medical devices must be "locked"
  - **no autonomous adaptation of therapy**
- **August 2019**: FDA issued "Proposed Regulatory Framework"
  - Recognizes potential value of autonomous therapy adaptation
  - Aims to harmonize with the International Medical Device Regulators Forum (IMDRF) – risk principles
  - Suggests best practices for AI data/workflow

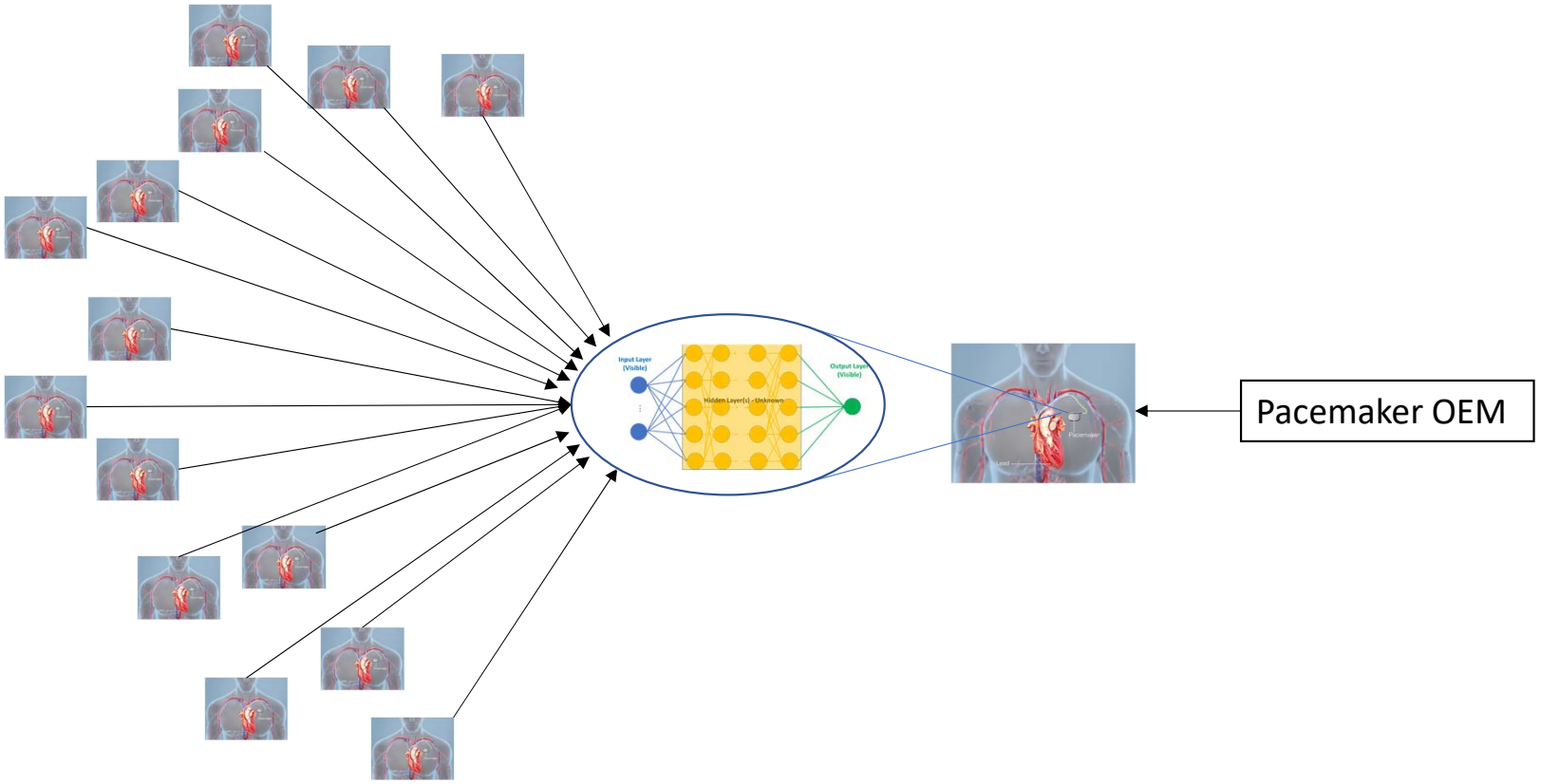




Hypothetical – AI Powered Pace Maker – OEM Intermediary



Hypothetical – AI Powered Pace Maker – Peer to Peer



Protecting ML Technologies

Data Set Generation and Inputs

- Contract/Copyright
- Data Privacy
- Potential Patentable Subject Matter

ML Processing

- Contract/Copyright
- Data Privacy
- Potential Patentable Subject Matter

ML Results and Post Processing

- Contract/Copyright
- Data Privacy
- Potential Patentable Subject Matter

Best Practices

1. Include brief description of the technical substance underlying the AI technology. Simply relying on black box description of “artificial intelligence” or “machine learning” will likely not be sufficient.

2. Avoid personification of “modules” or “processors”.

3. Include detailed step-by-step algorithms and concrete examples of how the AI/machine learning can be applied. Identifying technical problems in the specification coupled with the specific, technical solutions—and claiming those solutions—remain viable approaches for AI inventions in both the U.S. and Europe.

4. Describe improvements to how a computer performs machine learning or executes AI (e.g., by running faster, using less memory, etc.) helps both in the U.S. and Europe.

5. Describe specific use cases.

6. Despite on-going debate re inventorship, patent the **result** of ML (working model).
   Law might be resolved in favor of patentability