

## Protecting AI and Machine Learning Technologies Related To Biotechnology And Pharmaceutical Inventions

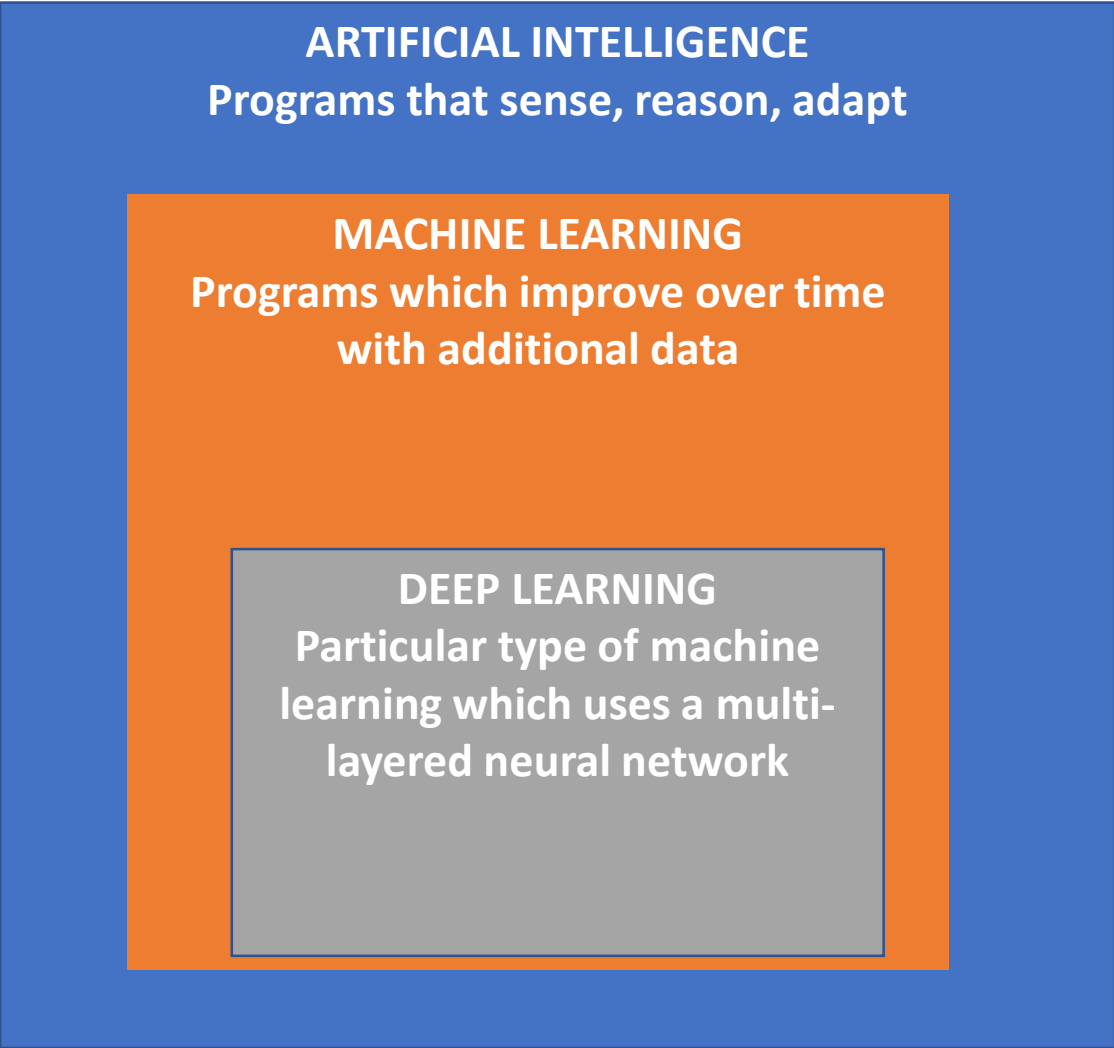
Michael L. Fuller  
USPTO BCP Meeting  
March 28, 2023

# Agenda

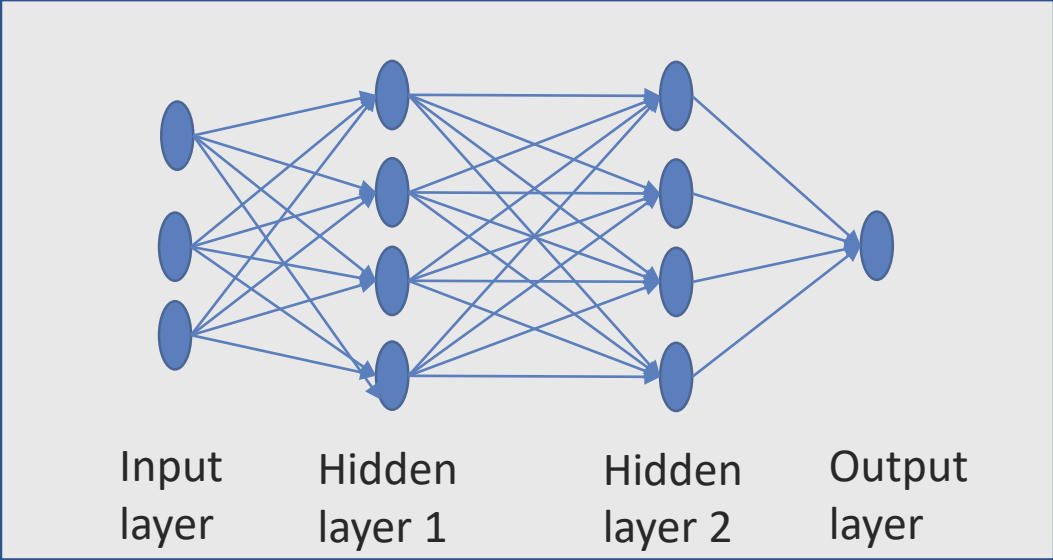
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- Overview of AI/ML technology
- Examples of AI/ML in Biotech
- Challenges of patenting AI/ML in Biotech
- USPTO Activities Related to AI
- Protecting AI Technologies
- IP issues in Protecting AI/ML Technologies
  - Inventorship
  - Section 112 - Enablement / Written Description
  - Section 101 - Patentable Subject Matter
- The Future

# Overview of AI/ML technology

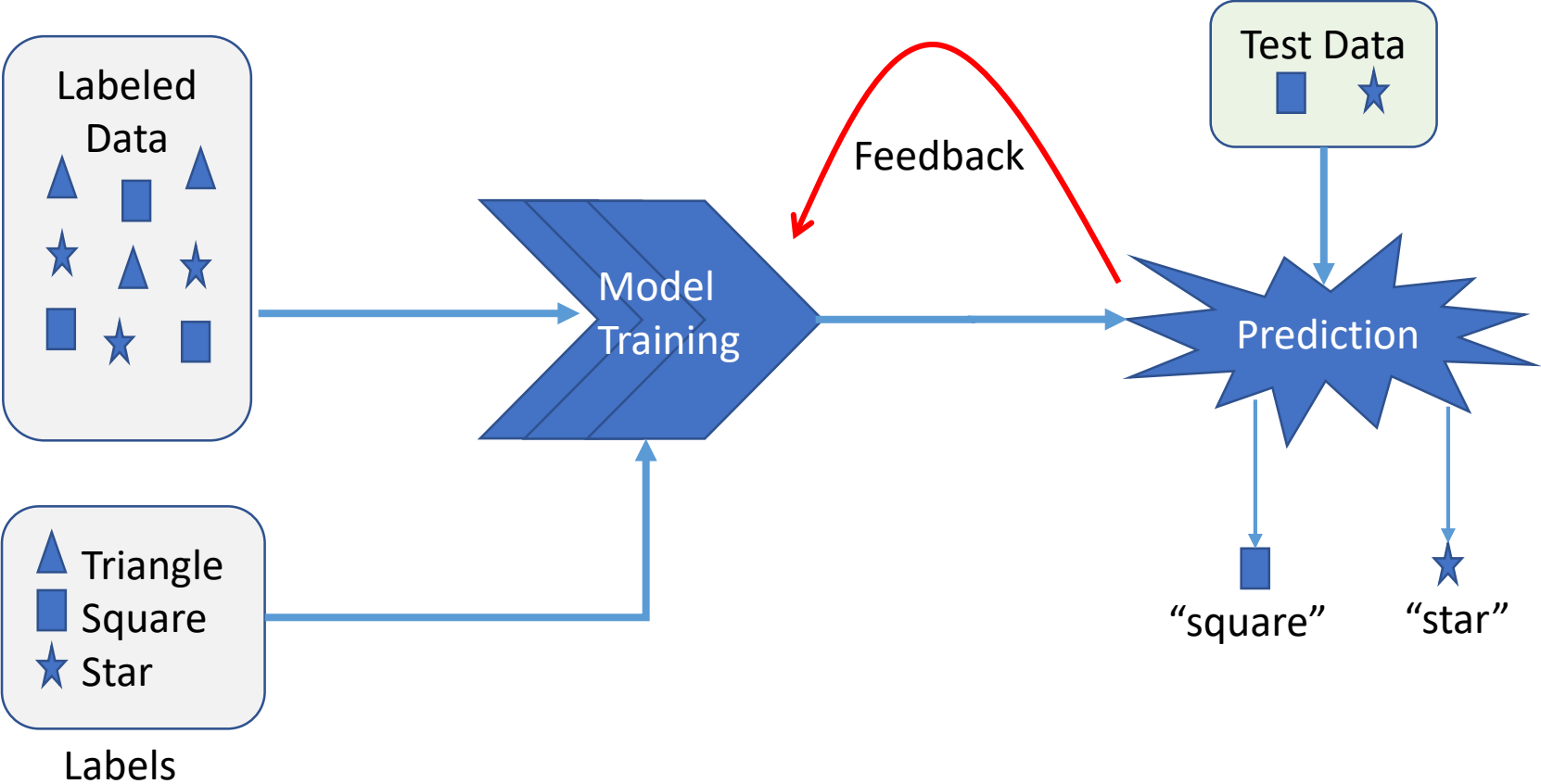


## Deep Learning Neural Network



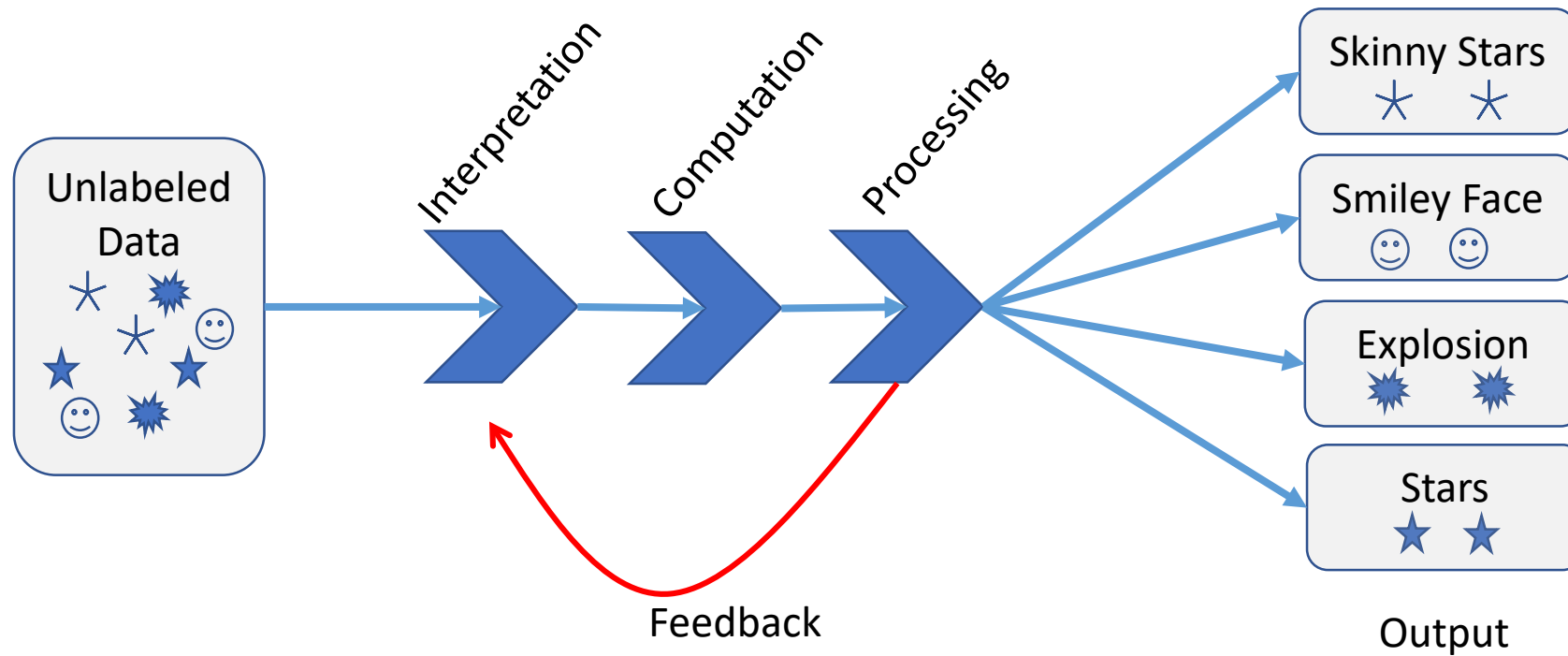
# Two Main Types ML: Supervised and Unsupervised

## Supervised Machine Learning



# Two Main Types ML: Supervised and Unsupervised

## Unsupervised Machine Learning



# Examples of AI usage in Biotech/Pharma

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- **Google Alphafold / Meta ESMFold**
  - AI-based prediction of protein 3D structure from amino acid sequences
  - Trained on known 3D proteins to predict unknown structures
- **Drug Discovery**
  - Drug target identification
    - Receptor ligands (protein / small molecule)
    - Inhibitors / Enhancers
  - Novel drug design
  - Predictive modeling
  - Drug repurposing
- **Clinical Trials**
  - Find patterns in patient data
  - Stratify patient groups
  - Parse eHealth records to find eligible trial participants
- **Predict Patient Outcomes**
  - Find patterns in patient data with good or poor outcomes
  - Analyze all data for patients on treatment

# Challenges of Patenting AI/ML in Biotech and Pharma Industries

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- Want to protect AI/ML systems, but not disclose compounds too early in the process
  - Generally no enabling data for use of discovered compound (in vitro/in vivo studies)
- What level of priority to give to IP on an AI/ML system?
  - Want to protect novel AI/ML systems, but not give away trade secret discovery process
  - File patent applications?
  - Protect with Trade Secret Only?
- Generally AI system not the product being sold by biotech/pharmaceutical company
- May be considered a research tool

# Challenges of Patenting AI/ML in Biotech and Pharma Industries

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- Enforcement of AI/ML patents can be an issue
  - How do you know whether a competitor trained an AI system with the patented method?
  - How do you know what processes are performed with in-house AI system?
  - Challenge to know the protein/DNA/chemical structure data used in training the system



# USPTO Artificial Intelligence Related Activities

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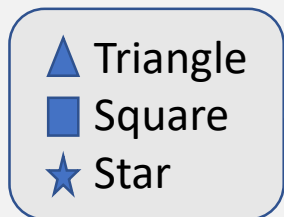
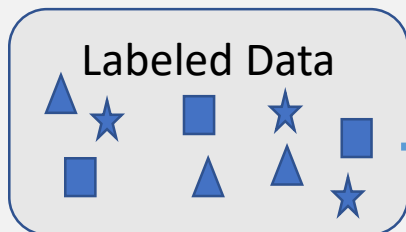
- August 27, 2019 - RFC issued for public comments on patenting AI inventions
- October 30, 2019 – second RFC issued on impact of AI on other IP policy areas
  - copyrights, trademarks, database protections, and trade secret law
- October 2020 - Report on Public Views on Artificial Intelligence and Intellectual Property Policy
  - comments suggested that current AI could neither invent nor author without human intervention
  - comments suggested that AI could be handled by current USPTO guidance
  - special rules didn't appear necessary for AI innovations
- June 2022 - USPTO held inaugural AI/Emerging Technologies (AI/ET) partnership meeting
  - USPTO formed the AI/ET Partnership
  - Bring stakeholders together through a series of engagements to share ideas, feedback, experiences and insights on the intersection of intellectual property and AI/ET.
- February 14 2023 - USPTO issued new RFC on a list of AI related questions regarding inventorship, ownership and examination of AI related inventions

# Protecting AI Technologies

- **Data Set Generation and Training**

- Potential Patentable Subject Matter

- Improvements in collecting or forming data sets
- Supplementing data sets



- **AI Processing**

- Potential Patentable Subject Matter

- Modifications or improvements to AI algorithms
- Improved neural network structures

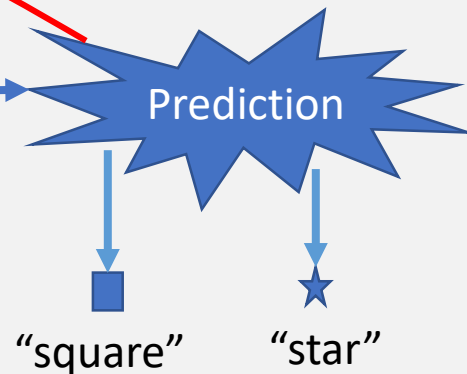


Feedback

- **AI Results and Post Processing**

- Potential Patentable Subject Matter

- Post-processing feedback
- Estimating loss
- Use of AI processed data



# Protecting AI Technologies

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- Data Set Generation and Training
  - Lots of innovation
  - Generally patentable
  - Methods and systems for improving the data sets and inputs to an AI system
    - Better images
    - More efficient data – smaller but better for training/categorizing
    - Pre-processed data which is easier for AI system to manage
    - More efficient data labeling systems
    - Better systems for autonomously generating data and labels
  - More readily overcomes Section 101 issues

# Protecting AI Technologies

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- AI Processing
  - Focus on modifications or improvements to AI algorithms
  - Improved neural network structures may be patentable
    - Data structure which improves function of computer
    - Claims should be drawn to improved data structure
  - More efficient process for ingesting data and setting weight/biases of neural network
    - Can be challenging to overcome Section 101 rejections

# Protecting AI Technologies

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- AI Results and Post Processing
  - Post-processing feedback to improve AI system results
  - Links to real-world outcomes and systems
    - Results connect/move external system
    - Results control further experiments
    - Results determine future processes
  - Estimating Loss (improving feedback loop)
    - Generally more easily overcomes Section 101 issues than AI processing

# Inventorship

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- Can an AI system be the inventor?
- Who is the inventor of a discovery made by a computer system?
- Thaler v. Vidal, 43 F. 4th 1207 - 2022 - CAFC
  - Thaler listed his system “DABUS” as the inventor
  - PTO sent notice of missing parts, indicating no valid inventor was listed
  - Thaler appealed to U.S. District Court
  - District Court found that only an “individual” can be an inventor
  - Thaler appealed to the Federal Circuit
  - Federal Circuit:
    - “Here, there is no ambiguity: the Patent Act requires that inventors must be natural persons; that is, human beings.”

## Section 112 Written Description

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- No unique disclosure requirements currently exist for a patent application claiming an AI-based invention
- Written description of AI system generally needs at least an algorithm and a description of computer hardware
- Additional description should detail the AI process:
  - How system solves a technical problem
  - Include information on data set inputs, such as training data
  - Describe functions and any new structure to AI neural network
  - Show process from input of training data to final results
  - Describe how loss is calculated and how system improves
  - Flowcharts and system diagrams should detail the claimed invention

## Section 112 Enablement

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- Black-Box Problem
  - How AI system determines outcomes may not be known by programmers
  - Drafting an enabling disclosure can be a challenge
    - Don't want to include source code
    - Don't necessarily understand how the system arrives at answers
  - Particularly challenging for confidential data (proteins / DNA / compounds)
    - Need to enable how to make and use claimed system, but don't want to describe particular compounds
- Solution generally is to disclose as much as possible, short of confidential information
- As AI becomes more widely used, enablement will require less information because POSA will be more knowledgeable



## Section 101 Analysis Overview

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- Step 1: Is claim as a whole is directed to a process, machine, manufacture, or composition of matter?
  - AI claims generally pass Step 1
- Step 2A:
  - Prong 1: Does the claim recite a judicial exception?
    - Abstract idea, law of nature, or natural phenomenon
    - Abstract ideas include mathematical concepts, mental processes, organizing human activity
  - Prong 2: Even if claim recites a judicial exception, is the judicial exception integrated into a practical application?
- Step 2B: Do the claims recite an inventive concept?
  - significantly more than the judicial exception

## Section 101 Issues – USPTO Guidance, Example 39

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### USPTO Section 101 Guidance - 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.

# USPTO Section 101 Guidelines – Example 39 Analysis

Step	Analysis
1: Statutory Category?	<b>Yes.</b> The claim recites a series of steps and, therefore, is a process.
2A - Prong 1: Judicial Exception Recited?	<b>No.</b> The claim does not recite any of the judicial exceptions enumerated in the 2019 PEG. For instance, the claim does not recite any mathematical relationships, formulas, or calculations. While some of the limitations may be based on mathematical concepts, the mathematical concepts are not recited in the claims. Further, the claim does not recite a mental process because the steps are not practically performed in the human mind. Finally, the claim does not recite any method of organizing human activity such as a fundamental economic concept or managing interactions between people. Thus, the claim is <b>eligible</b> because it does not recite a judicial exception.
2A - Prong 2: Integrated into a Practical Application?	<b>N/A.</b>
2B: Claim provides an Inventive Concept?	<b>N/A.</b>

# Overcoming Section 101 Rejections

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- Include claim elements that emphasize the practical applications of the AI system
  - Discoveries of important proteins which bind to particular therapeutic receptors
  - Discoveries of small molecules which can affect a disease state
  - Demonstrate better clinical trial outcomes by stratifying data
  - Show correlations between certain treatments and improved patient outcomes
- Input data processing and training innovations seem to meet Section 101 requirements more easily than improvements in the AI processing
- Improved neural network data structures (configuration of networks) seem to meet Section 101
- Improved methods for calculating loss (feedback loop) seem to meet Section 101
- Does the new AI system include elements that are not a well-understood, routine, or conventional activity?

# Challenges With Applying Section 101 to AI inventions

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- Health Discovery Corp. v. Intel Corp.
  - Judge Alan D. Albright, 6:20-cv-666-ADA (W.D. Tex. Dec. 27, 2021)
  - J. Albright explains in great detail the history and challenges of section 101 application to AI type inventions
    - Applied unevenly across software technologies
  - J. Albright found that two patents claiming machine learning systems to help discover patterns in gene data were unpatentable under 35 U.S.C. § 101
  - Court found the claims only improved a known mathematical analysis
    - “a mathematical idea can be novel and even a ‘groundbreaking’ advance and still not be patent eligible”
  - AI inventions are patentable where the claims are directed to “improving an existing technological or computer functionality”

# The Future - AI is better than you think (ChatGPT)

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**Input:** *Draft a patent claim on a robot that makes pancakes*

**Output:**

1. A pancake-making robot comprising:
  - a) a base platform;
  - b) a cooking surface mounted on said base platform;
  - c) a batter dispenser mounted on said base platform, said batter dispenser configured to dispense pancake batter onto said cooking surface;
  - d) a cooking mechanism configured to flip and cook the pancake batter on said cooking surface; and
  - e) a control system comprising a processor and memory configured to control the operation of said batter dispenser and said cooking mechanism.
  
2. The pancake-making robot of claim 1, wherein said batter dispenser comprises a hopper for holding pancake batter, and a dispensing mechanism configured to release a predetermined amount of batter onto said cooking surface.
  
3. The pancake-making robot of claim 1, wherein said cooking mechanism comprises a spatula for flipping the pancake, and a heating element for cooking the pancake.

QUESTIONS?