

#### When Biology and High Tech Collide: Strategies for Protecting IP in Emerging Medical and Life Science Technologies

March 20, 2024





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These materials have been prepared solely for educational and entertainment purposes to contribute to the understanding of intellectual property law. These materials reflect only the personal views of the authors and are not individualized legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.



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### **Discussion Topics**

Attitudes regarding IP rights

Portfolio development strategies

Use of AI/ML with life science technologies

Partnerships and investments

**Enablement considerations** 



"If you know the enemy and know yourself, you need not fear the result of a hundred battles."

— Sun Tzu, The Art of War





### Art Units focused on the Digital Health Technologies

- Tech Center 3600 Business Method Art Units
  - AUs 3626, 3686 (Healthcare)
- Tech Center 2120+ Computer Architecture and Software Art Units
  - AUs 2120+ (AI and Simulation/Modeling)
    - AU 2129 Artificial Intelligence
    - AU 2123 Modelling and Simulation



### **Statistics of Art Units Examining Digital Health Apps**

Art Unit	Allowance Rate	Appeal Rate	Appeal Win Rate	Percent of appealed cases decided by Board	101 rejections	112 Rejections
3626	32.4%	13.2%	42.4%	49.4%	75.8%	51.6%
3686	45.8%	14.1%	53%	41.4%	73.7%	40.3%
2129 (AI)	79.6%	5.8%	71.2%	21.5%	49.5%	36.2%
2123 (Modeling and Simulation)	66.7%	7.6%	61.8%	32.9%	50.7%	52.8%
2121	71.1%	5.5%	68.5%	22.9%	27.5%	36.08%
2122	71.1%	6%	66.9%	27.3%	44.8%	22.0%
2124	78.3%	4.9%	66.4%	37.3%	43.2%	29.2%
2125	79.7%	3.7%	60.8%	34.5%	26.4%	41.5%
2126	71.8%	5.7%	55.2%	42.6%	33.0%	35.2%
2127	76.2%	6.2%	58.4%	35.1%	34.1%	40.3%
2128	64.3%	8.6%	53.6%	43.8%	54.5%	43.5%





## Helpful Guidance for AI/ML Inventions

- USPTO
  - AI/ML Inferencing
    - Ex Parte Hannun, 2018-003323 (Apr. 1, 2019) (PTAB Informative)
  - AI/ML Training
    - Example 39: Methods of Training a Neural Network for Facial Detection

https://www.uspto.gov/sites/default/files/documents/ 101 examples 37to42 20190107.pdf

- Federal Circuit
  - In re: Board of Trustees of Stanford, 991 F.3d 1245 (2021)



# AI/ML - Guidance from the USPTO

Ex Parte Hannun, 2018-003323 (Apr. 1, 2019) (PTAB Informative)

#### ELIGIBLE

11. A computer-implemented method for transcribing speech comprising:

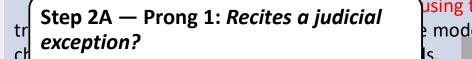
receiving an input audio from a user;

normalizing the input audio to make a total power of the input audio consistent with a set of training samples used to train a trained neural network model;

generating a jitter set of audio files from the normalized input audio by translating the normalized input audio by one or more time values;

for each audio file from the jitter set of audio files, which includes the normalized input audio: generating a set of spectrogram frames for each audio file;

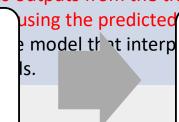
inputting the audio file along with a context of spectrogram frames into a trained neural network; obtaining predicted character probabilities outputs from the trained neural network; and



- 🗹 No
  - Cannot practically be performed in the human mind



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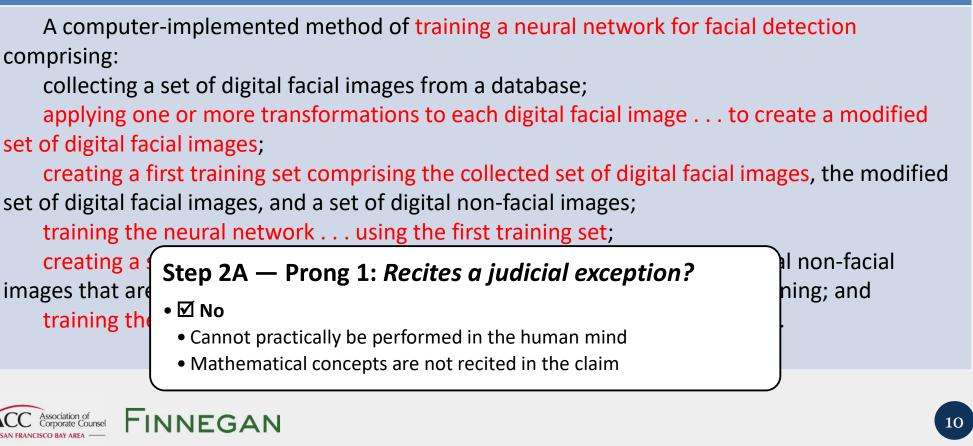
Step 2A — Prong 2: *Practical Application?* 

- 🗹 Yes
  - Moreover, improvement to the technical field of speech recognition

# AI/ML - Guidance from the USPTO

Example 39: Methods of Training a Neural Network for Facial Detection

#### ELIGIBLE



# **AI/ML- Guidance from the Federal Circuit**

In re: Board of Trustees of Stanford, 991 F.3d 1245 (2021)

#### INELIGIBLE

Claim 1 - A computerized method for inferring haplotype phase in a collection of unrelated individuals, comprising:

receiving genotype data describing human genotypes for a plurality of individuals and storing the genotype data on a memory of a computer system;

imputing an initial haplotype phase for each individual in the plurality of individuals based on a statistical model and storing the initial haplotype phase for each individual in the plurality of individuals on a computer system...;

#### building a data structure describing a Hidden Markov Model, where the data structure contains:

a set of imputed haplotype phases comprising the imputed initial haplotype phases for each individual in the plurality of individuals; a set of parameters comprising local recombination rates and mutation rates;

wherein any change to the set of imputed haplotype phases contained within the data structure automatically results in recomputation of the set of parameters comprising local recombination rates and mutation rates contained within the data structure;

at least one of the imputed initial haplotype photos in the set of imputed h

a	Step 2A — Prong 1:		oplication?
d	⊠Yes	Step 2B — Provides an inventive concept?	
s h	<ul> <li>Claim 1 is drawn to "a haplotype phase in a c</li> <li>Abstract idea directed statistical modeling fo</li> </ul>	Steps of receiving, extracting, and storing data amount to well-known, routine, and	data, imputing an initial predicted haplotype phase t in a computer memory ation not enough aimed advance provides type phase
- SAN	Association of Corporate Counsel	INEGAN	

### Helpful Guidance for Digital Health Inventions

- USPTO
  - Example 42 directed to Network-based Patient Management System

https://www.uspto.gov/sites/default/files/documents/ 101 examples 37to42 20190107.pdf

- Example 46 - directed to Livestock Management

https://www.uspto.gov/sites/default/files/documents/ peg\_oct\_2019\_app1.pdf

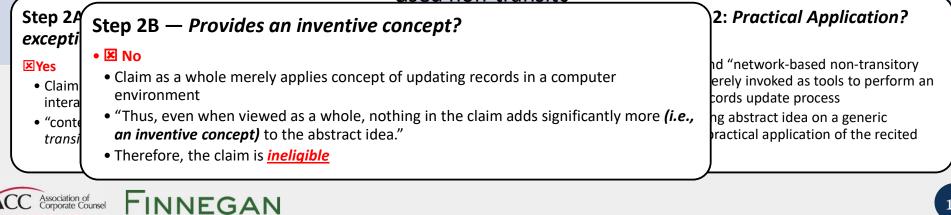


Example 42: Network-based Patient Management System

#### INELIGIBLE

Claim 2 - A method comprising:

- a) storing information about a patient's condition in a plurality of network-based non-transitory storage devices having a collection of medical records stored thereon;
- b) providing access, by a content server, to users so that any one of the users can update the information about the patient's condition in the collection of medical records, and
- c) storing the updated information about the patient's condition in the collection of medical records in the plurality of potwork based non-transitory storage devices



Example 42: Network-based Patient Management System

#### ELIGIBLE

Claim 1 - A method comprising:

a) storing information in a standardized format about a patient's condition in a plurality of network-based nontransitory storage devices having a collection of medical records stored thereon;

b) providing remote access, by a content server, to users over a network so that any one of the users can update the information about the patient's condition in the collection of medical records, and in real time through a graphical user interface, wherein the one of the users provides the updated information in a non-standardized format dependent on the hardware and software platform used by the one of the users;

c) <u>converting, by a content server, the non-standardized updated information into the standardized format</u>,

	d) staring the standardized undeted information about the patient's predition in the collection of medical records in							
the	Step 2A — Prong 1: Recites a judicial	<del>e devices</del> standardi	Step 2A — Prong 2: <i>Practical Application?</i>					
	exception?	the updated inforn	• 🗹 Yes					
<u>co</u>	⊠Yes	<u>een</u> n <u>d</u>	<ul> <li>The additional elements (highlighted) provide a</li> </ul>					
•	<ul> <li>Still directed to a method for organizing human activity</li> </ul>	<u>er the</u> <u>er net</u>	specific improvement over prior art "by allowing remote users to share information in real time in a					
<u>im</u>	activity		standardized format regardless of the format in					
		) (	which the information was input"					



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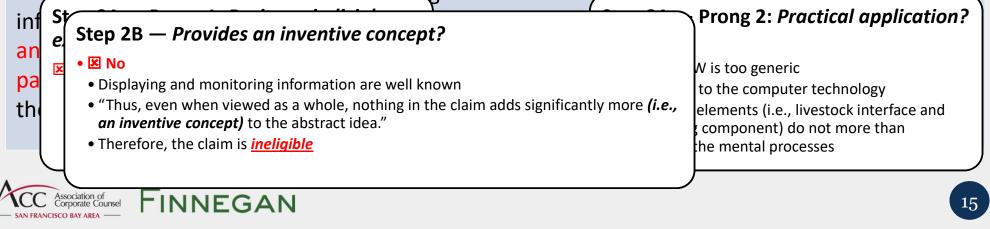
Example 46: Livestock Management

#### INELIGIBLE

Claim 1 - A system for monitoring health and activity in dairy livestock animals comprising: **a memory**; **a display**; **and a processor** coupled to the memory programmed with executable instructions, the instructions including:

a livestock interface for obtaining animal-specific information [comprising] animal identification data and at least one of body position data, body temperature data, feeding behavior data, and movement pattern data; and

a monitoring component for (a) comparing the obtained apimal coocific information with animal



Example 46: Livestock Management

#### ELIGIBLE

Claim 2 - The system of claim 1, wherein the system further comprises:

a feed dispenser . . . is operable to dispense individualized amounts of feed and optional supplements, and

wherein the monitoring component is further configured for (d) automatically sending a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the analysis results for the animal indicate that the animal is subjective and encoded and minerals mixed with feed when the analysis results for the animal indicate that the animal

is exhibiting an aborrant hobavioral nattorn indicative of grass totany

St
 ex
 USPTO Practice Note — the claim itself did not encompass actually dispensing the minerals, so the USPTO stated that there is no limitation that could invoke the "particular treatment or prophylaxis" consideration by the *Ino* case.

#### Prong 2: Practical application?

d) "adds a meaningful limitation" by nformation provided by the judicial control an outside component (i.e., ser) to dispense feed in a particular

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### **Prosecution Tips: Electrical/Computer Technology**

#### General Tips for Avoiding/Overcoming a §101 Rejection

- How you describe and claim your invention matters
- Build in a "practical application"—tech problem and solution
- Capture aspects of solution in the claims
- Avoid the terms "routine," "well-understood," "conventional"
- Model claims off claims held eligible by courts

#### **General Tips for Working with Examiners:**

- Review their statistics to understand tendencies
- If appropriate, consider going the appeal route
- Present issues in conformance with MPEP
- Interviews: show improvements in action









