



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

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FINNEGAN

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Your Presenters

Emily Gardel, Ph.D., J.D.

Associate Director, Patent Attorney II, Dyno Therapeutics

Sylvia Georges Evangelinos, Ph.D., J.D.

Head R&D IP for Neuroscience and Discovery Sciences, Novartis

Leslie Grab, Ph.D., J.D.

Vice President, Corporate Legal, BigHat Biosciences

Aaron Capron

Partner, Finnegan

Jeffrey Smyth

Partner, Finnegan

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

Step 2A — Prong 1: *Recites a judicial exception?*

- No
 - Cannot practically be performed in the human mind

using the predicted
the model that interp
s.

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

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 . . . 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 . . . using the first training set;

creating a set of digital non-facial

images that are

training the

Step 2A — Prong 1: *Recites a judicial exception?*

- No
 - Cannot practically be performed in the human mind
 - Mathematical concepts are not recited in the claim

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 re-computation of the set of parameters comprising local recombination rates and mutation rates contained within the data structure;

repeatedly randomly modifying at least one of the imputed initial haplotype phases in the set of imputed haplotype phases to

Step 2A — Prong 1: Provides a Technical Application?

Yes

- Claim 1 is drawn to “a computerized method for inferring haplotype phase in a collection of unrelated individuals”
- Abstract idea directed to a computerized method for inferring haplotype phase using statistical modeling for

Step 2B — Provides an inventive concept?

No

- Steps of receiving, extracting, and storing data amount to well-known, routine, and conventional steps taken when executing a mathematical algorithm on a regular computer.
- The written description further illustrates that the mathematical steps performed and the data received are conventional and well understood in the prior art.
- Therefore, the claim is **ineligible**

Step 2B — Provides an inventive concept?

data, imputing an initial predicted haplotype phase in a computer memory, and repeatedly randomly modifying at least one of the imputed initial haplotype phases to provide a predicted haplotype phase. The claimed advance provides a technical application.

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

Digital Health - Guidance from the USPTO

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 network-based non-transitory storage devices.

Step 2A exception

Yes

- Claim
- intera
- "cont
- transi

Step 2B — Provides an inventive concept?

No

- Claim as a whole merely applies concept of updating records in a computer environment
- "Thus, even when viewed as a whole, nothing in the claim adds significantly more (*i.e.*, **an inventive concept**) to the abstract idea."
- Therefore, the claim is **ineligible**

Step 2: Practical Application?

and "network-based non-transitory
merely invoked as tools to perform an
records update process
ing abstract idea on a generic
practical application of the recited

Digital Health - Guidance from the USPTO

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 non-transitory 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) **converting, by a content server, the non-standardized updated information into the standardized format,**

- d) ~~storing the standardized updated information about the patient's condition in the collection of medical records in~~

Step 2A — Prong 1: *Recites a judicial exception?*

Yes

- Still directed to a method for organizing human activity

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

• Yes

- The additional elements (highlighted) provide a specific improvement over prior art “by allowing remote users to share information in real time in a standardized format regardless of the format in which the information was input . . .”

Digital Health - Guidance from the USPTO

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 animal specific information with animal

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Step 2B — Provides an inventive concept?

- No
- Displaying and monitoring information are well known
- “Thus, even when viewed as a whole, nothing in the claim adds significantly more (*i.e.*, **an inventive concept**) to the abstract idea.”
- Therefore, the claim is **ineligible**

Prong 2: Practical application?

W is too generic
to the computer technology
elements (*i.e.*, livestock interface and
component) do not more than
the mental processes

Digital Health - Guidance from the USPTO

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 exhibiting an aberrant behavioral pattern indicative of grass tetany.

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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 information provided by the judicial control an outside component (i.e., ser) to dispense feed in a particular

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

Questions?