



Morgan Lewis

**THE LIFE SCIENCES  
GROWTH SERIES**

**JAPAN**

1 December 2021

# **Patenting Digital Therapies – Crossroad of Life Science and Technology**

**Morgan Lewis**

# Presenters



**Janice H. Logan**



**Brett A. Lovejoy**

**Morgan Lewis**

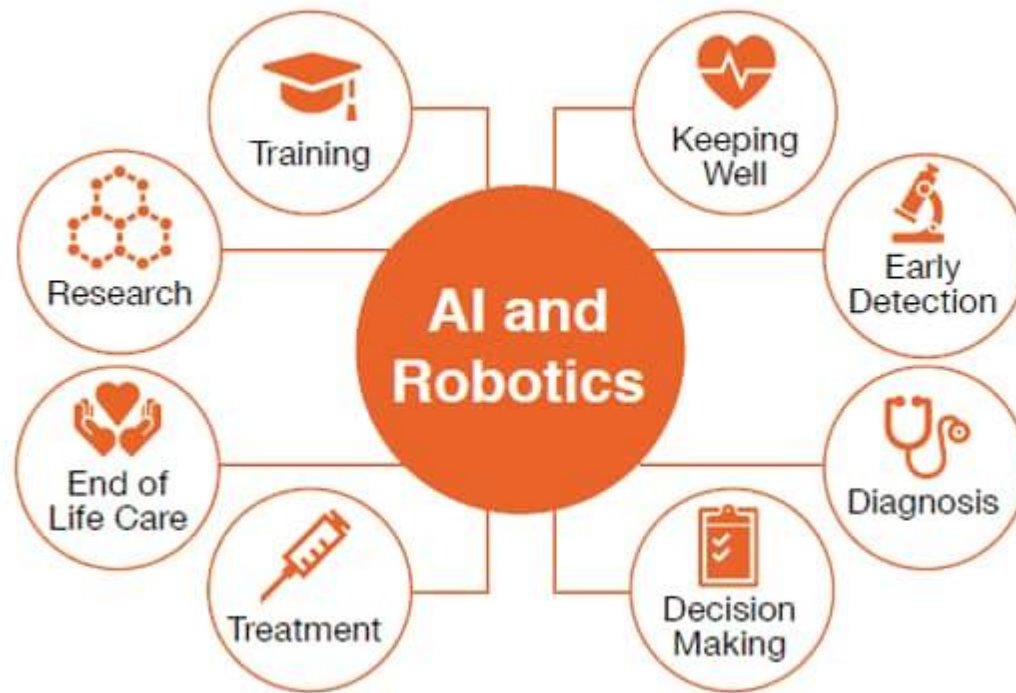
# Overview

- Current Trends in Digital Therapy
- Patentable Subject Matter in U.S.
- Exemplary Patents

# Trends in Digital Therapy

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# Trends in Adoption of AI in Healthcare



Source – PwC, “AI and robotics are transforming healthcare”

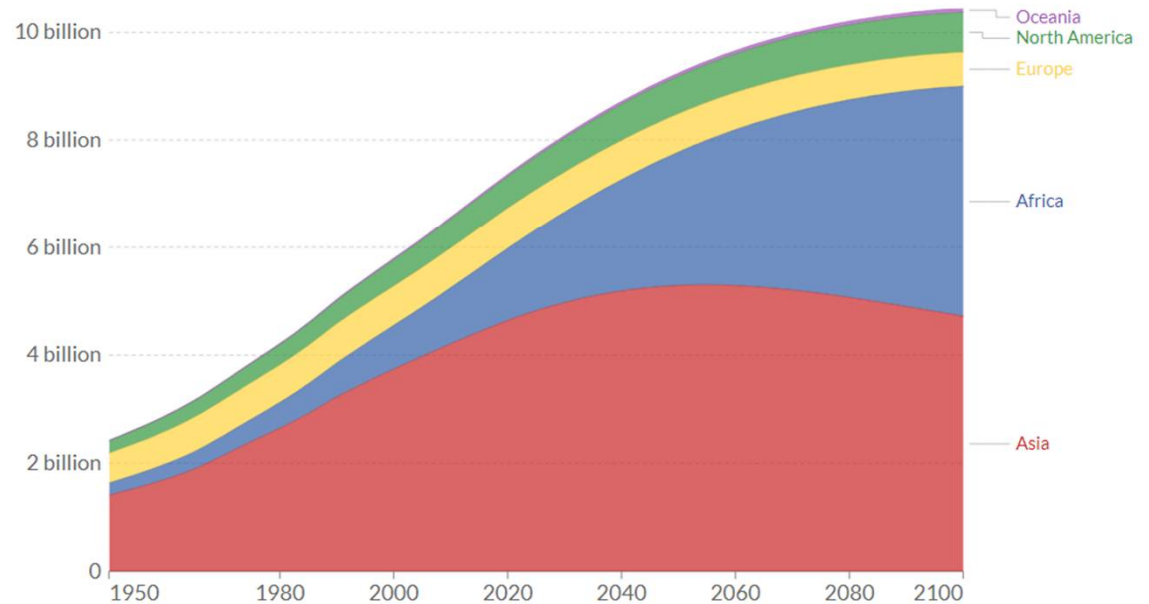
# The Global Population is Growing and Aging

- By 2030, 1 in 6 people in the world will be aged 60 years or over.
- By 2050, the world's population of people aged 60 years and older will double (2.1 billion).
- The number of persons aged 80 years or older is expected to triple between 2020 and 2050 to reach 426 million.

World population by region, 1950 to 2100

Projected population to 2100 is based on the UN's medium population scenario.

□ Relative

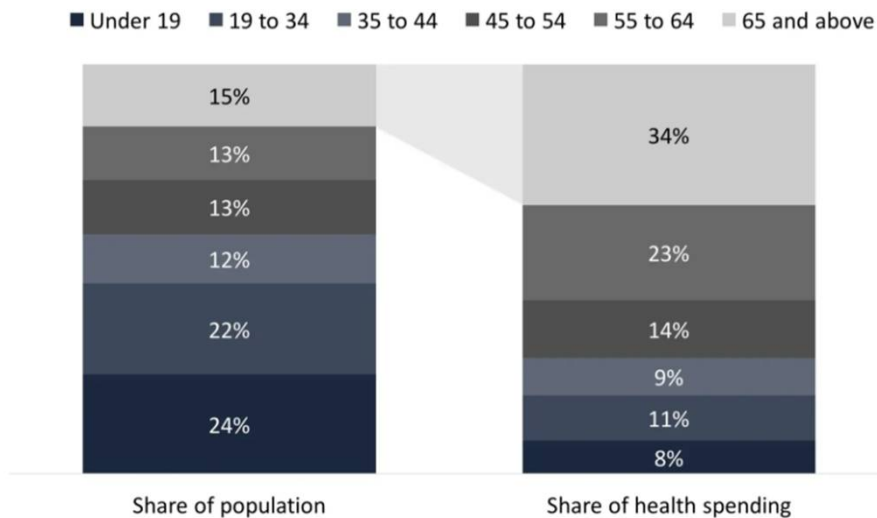


Our World  
in Data

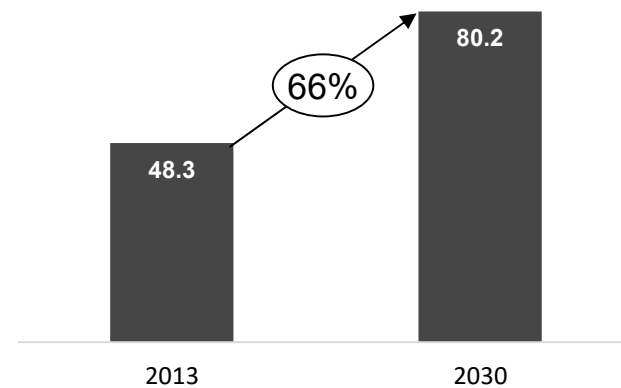
Sources – World Health Organization; United Nations

# The Demand for Healthcare is Rising

US Seniors Account For The Largest Portion Of Healthcare Spending



Global Healthcare Workforce  
Estimated Health Worker Demand (in M)

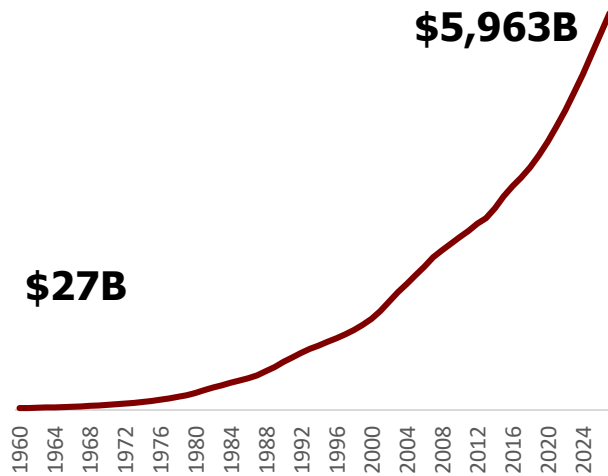


Sources – Insider; World Health Organization

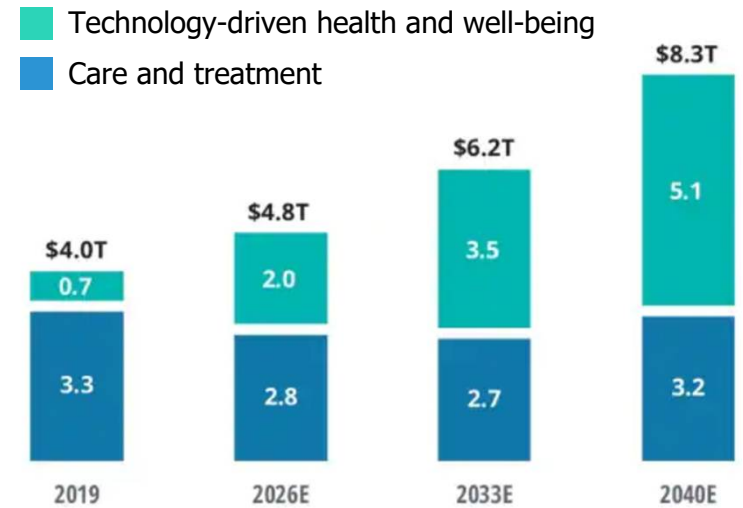


# Healthcare Spending is Rising . . . but Focus may Shift

U.S. Healthcare Spending  
National Health Expenditure Forecast



U.S. Healthcare Spending  
Projected Shift in Healthcare Focus



Sources – Centers for Medicare and Medicaid Services; Deloitte

# Recent Major Deals



**IPO September '19 (NASDAQ:  
TXG at \$39/share)**

Provides next generation sequencing (NGS) kits and tools for analyzing resulting NGS data using artificial intelligence



**Raised \$200M Series G-2 in Dec. '20**  
Uses artificial intelligence to analyze clinical, genomic, and transcriptomic data to advance precision medicine, matching patients with targeted therapies



**Raised \$123M in August '20**  
Deciphering human disease using an AI-drug discovery portfolio



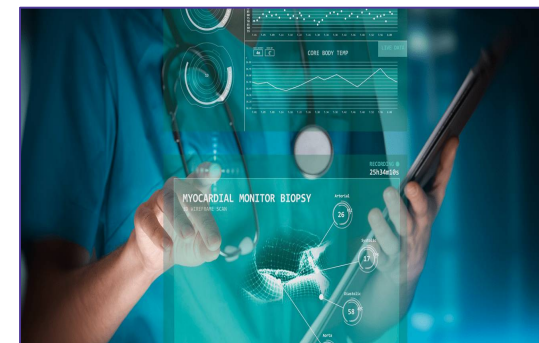
**Acquired by Illumina in August  
2021 for \$7.1 B**  
Earlier stage cancer detection using machine learning



**Raised \$22M in October '20**  
Mental health biotechnology and digital service company bringing innovative solutions to personalized mental healthcare and wellness through genetic testing

# AI in Healthcare: U.S.

- 90% of U.S. Hospitals and Insurance companies will implement some type of AI System by 2025
  - **Examples of AI Systems:** Medical image analysis, digital image processing, pattern recognition solutions, machine learning platforms, automated patient guidance and engagement solutions
- Increased adoption of AI will depend on:
  - Innovators' ability to decrease cost and improve accuracy of technology such as natural language processing, big data and cognitive technologies
  - Trust and acceptance of AI tools from healthcare professionals and patients



# Patentable Subject Matter in U.S.

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## Four Statutory Categories

- 35 U.S.C. § 101
  - Whoever invents or discovers any new and **useful process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
- The courts have interpreted the categories to ***exclude***:
  - “Laws of nature, natural phenomena, and abstract ideas”
  - These three terms are typically used by the courts to cover the basic tools of scientific and technological work, such as scientific principles, naturally occurring phenomena, mental processes, and mathematical algorithms.
  - Called “Judicial Exceptions”

# Judicial Exceptions

- Law of Nature
  - Naturally occurring correlation
  - A method of determining effective dosage of insulin using a correlation between insulin and blood glucose level (Mayo)
- Natural Phenomena or Product
  - An isolated DNA probe (Myriad)
- Abstract Ideas
  - A method for managing the risk cost (Bilski)
  - A method of exchanging obligation (Alice Corp)



# 101 Roller Coaster



- ***Bilski v. USPTO (2010)***

- Method of hedging energy trades claiming only an abstract idea is not a patent-eligible matter

- ***Mayo v. Prometheus (2012)***

- Diagnostic method reciting [“law of nature” + “well-known, routine, conventional”] steps is not a patent-eligible matter

- Patentable subject matter requires **“something more”**

- ***Association for Molecular Pathology v. Myriad (2013)***

- Removal of introns (cDNA) represents “something more” and is patent-eligible

- An “isolated” sequence (DNA, RNA, protein) is not necessarily patentable subject matter

- ***Alice Corp. v. CLS Bank International (2014)***

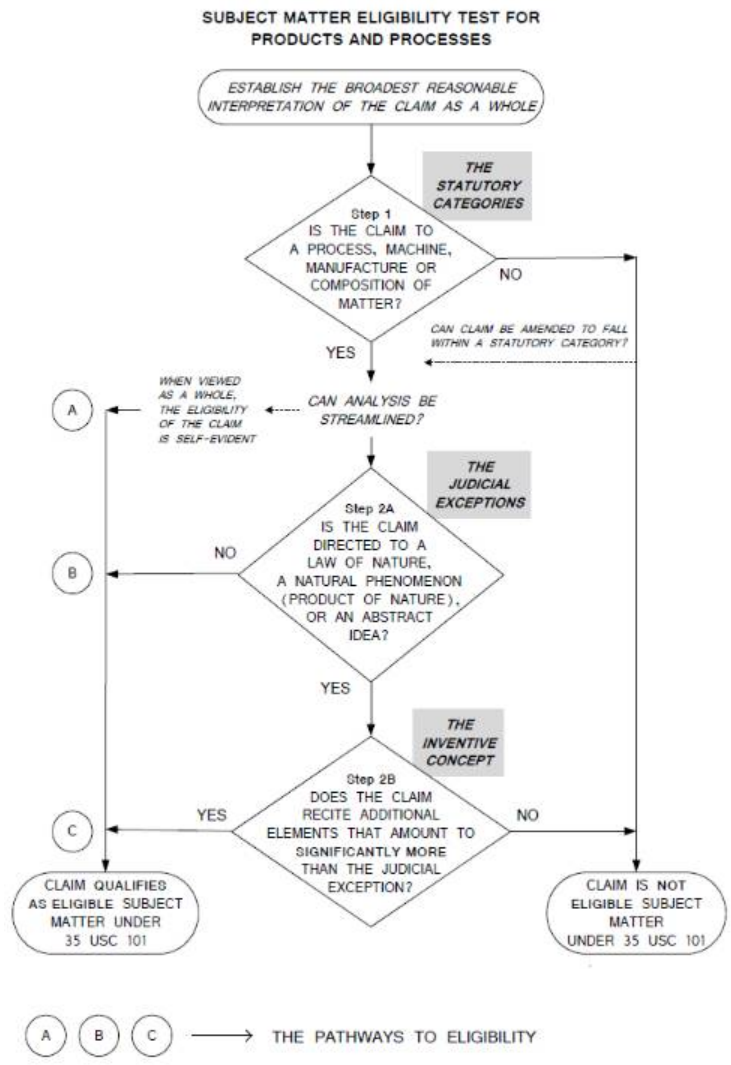
- A computer-implemented, electronic escrow service for facilitating financial transactions is an abstract idea ineligible for patent protection

- Merely adding “a generic computer to perform generic computer functions” does not make an otherwise abstract idea patentable

- Court did not elaborate on what is an abstract idea



# USPTO Guideline

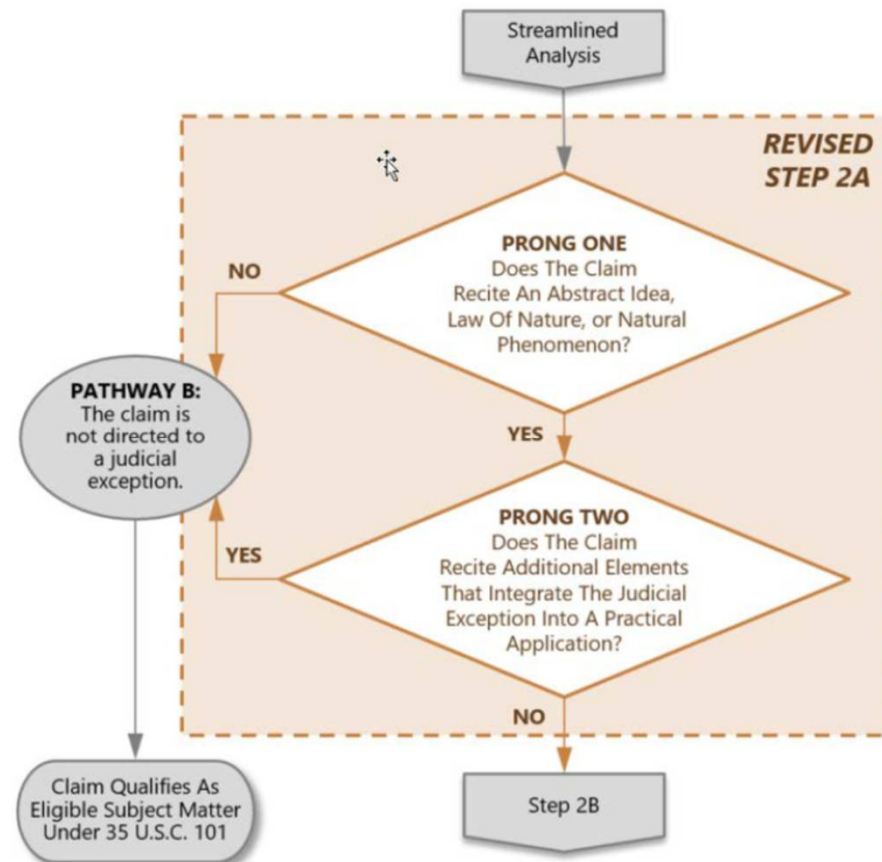


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# Step 2A: Two Prong Inquiry

The 2019 Revised Patent Subject Matter Eligibility Guidance (issued January 7, 2019)



# Step 2A, Prong Two: Consideration indicating integration

## 1. to a different state or thing

- Example 1 USPTO guideline: Gunpowder comprising: an intimate finely-ground mixture of 75% potassium nitrate, 15% charcoal and 10% sulfur.

## 2. Treatment

- *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*, 887 F.3d 1117 (Fed Cir. 2018): Practical application of the natural relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation to treat schizophrenia are not merely the recognition of those relationships.

## 3. TECHNICAL Improvement

- *Enfish LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016): Improvement in the functioning of a computer in self referential data table
- *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016)
- *Visual Memory LLC v. Nvidia Corp.*, 867 F.3d 1253 (Fed. Cir. 2017): enhanced computer memory system
- *Finjan, Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299 (Fed Cir. 2017); *Trading Technologies Int'l v. CQG Inc.*, 675 Fed. Appx. 1001 (Fed Cir. 2017)
- *Exergen Corp. v. Kaz USA, Inc.*, 725 Fed. Appx. 959 (Fed Cir. 2018): “unconventional” to use temperature scanning technology to measure arterial temperature beneath the skin
- *Ancora Tech, Inc. v. HTC America, Inc.*, 908 F.3d 1343 (Fed Cir. 2018); *SRI Int'l Inc. v. Cisco Systems Inc.*, 930 F.3d 1295 (Fed Cir. 2019)

## 4. Particular machine or manufacture integral to claims, Beyond general linking

- *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343 (Fed. Cir. 2017): Tied to a particular machine or manufacture using sensors to more efficiently track object on moving platform
- *Data Engine Tech. LLC v. Google LLC*, 906 F.3d 999 (Fed Cir. 2018): Meaningful tie to a particular technology of 3d machines
- *Core Wireless Licensing v. LG Elecs. Inc.*, 880 F.3d 1356 (Fed Cir. 2018): GUI for mobile devices that displays commonly accessed data on main menu
- *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014)

# Practical Application of Law Of Nature Is Patentable

## **1. Method of Diagnosing**

- Directed to Law of Nature
- *Mayo v. Prometheus*, 566 U.S. 66 (2012)
- *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert denied*
- *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019)

## **2. Method of Treatment**

- **Not** Directed to Law of Nature
- *Vanda Pharm, Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)
- *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019)
- *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347, (Fed. Cir. 2019)

## **3. Method of Preparation**

- **Not** Directed to Law of Nature
- *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016)
- *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 952 F.3d 1367 (Fed. Cir. 2020)(*en banc* denied)

***Ariosa Diagnostics, Inc. v. Sequenom, Inc.,  
788 F.3d 1371 (Fed. Cir. 2015), cert denied***



A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises  
obtaining a non-cellular fraction of the blood sample  
amplifying a paternally inherited nucleic acid from the non-cellular fraction and  
performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal  
nucleic acid.

- **Not significantly more** because the method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cell free fetal DNA (cffDNA).
  - Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful.
  - The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.
    - just because a discovery is groundbreaking, innovative or brilliant does not by itself satisfy §101.

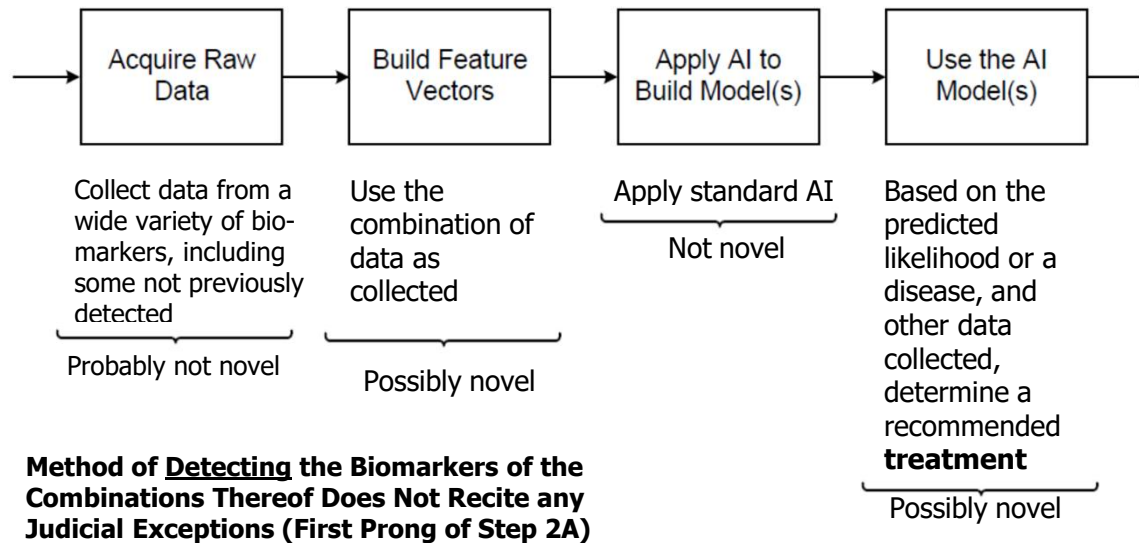
# ***Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 952 F.3d 1367 (Fed. Cir. 2020)(*en banc* denied)**

A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:

- (a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;
- (b) **producing a fraction** of the DNA extracted in (a) by:
  - (i) size discrimination of
  - (ii) selectively removing the DNA fragments greater than approximately 500 base pairs, wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and
- (c) analyzing a genetic locus in the fraction of DNA produced in (b).

- **"[t]his is not a diagnostic case. And it is not a method of treatment case. It is a method of preparation case."**

# Hypothetical Example

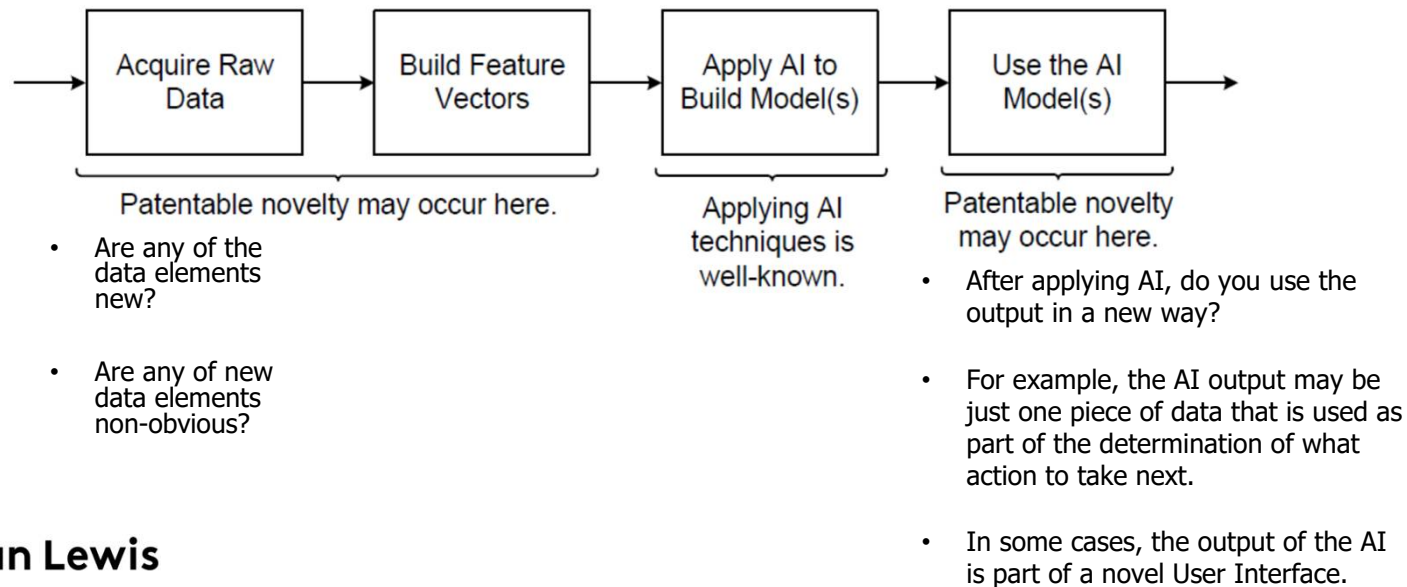


**Method of Treatment is Practical Application of Judicial Exceptions (Second Prong of Step 2A)**

- Issue of Indirect Infringement

# Digital Therapy that Uses Artificial Intelligence

- Have the raw data elements been combined in new ways?
- Simple Boolean combinations of data elements can be handled by the AI engine, but there are many types of calculation that are beyond what current AI engines can do.



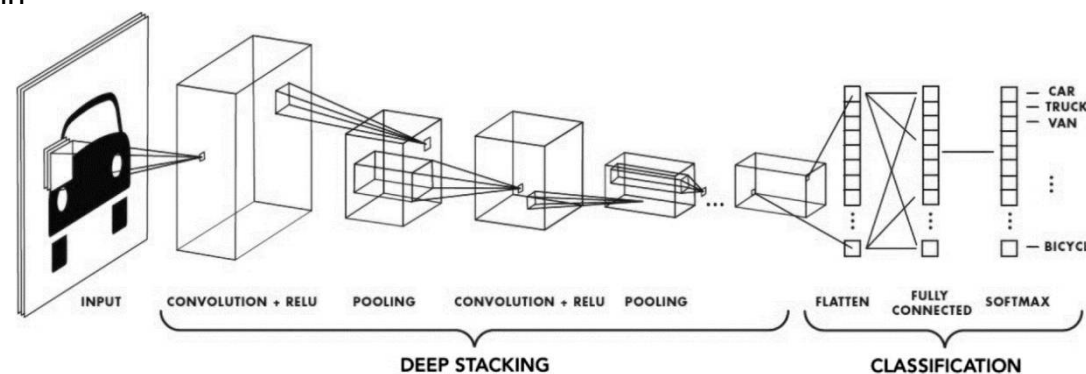
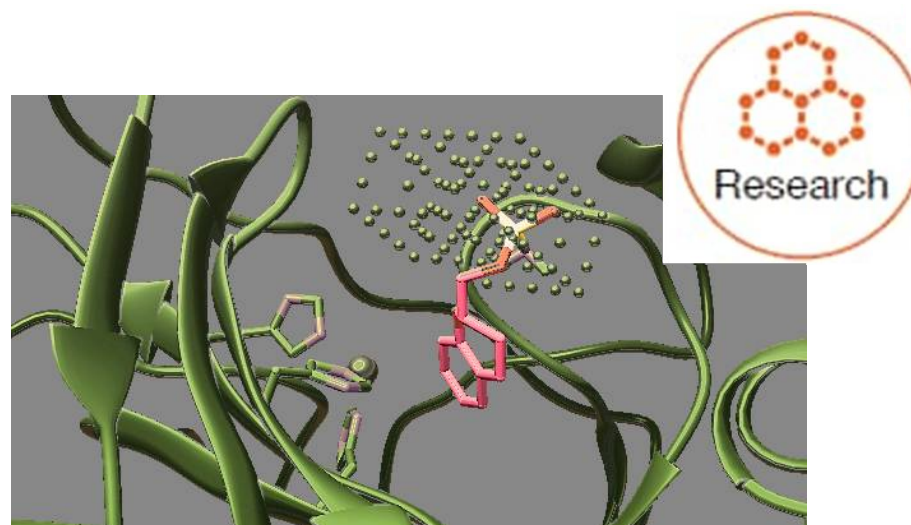
# Exemplary Patents

Morgan Lewis





- Founded in 2012
  - Based in San Francisco, CA
  - ~200 employees
  - Total Funding: USD \$176 million
- Patented use of deep neural networks for structure-based drug design
- CEO: Abraham Heifets, Ph.D.
  - Formerly at the University of Toronto
  - Created SCRIPDB database and LigAlign protein analysis tool
- 17 investors
  - E.g., B Capital Group, Monsanto Growth Ventures, Y Combinator, Khosla Ventures, DFJ
- 200 academic collaborations
  - e.g., Dana Farber Cancer Institute, Tulane, Stanford, and Duke University)



# U.S. 10,002,312 • Atomwise



(12) **United States Patent**  
Heifets et al.

(10) **Patent No.:** US 10,002,312 B2  
(45) **Date of Patent:** \*Jun. 19, 2018

(54) **SYSTEMS AND METHODS FOR APPLYING A CONVOLUTIONAL NETWORK TO SPATIAL DATA**

(58) **Field of Classification Search**  
None  
See application file for complete search history.

(71) Applicant: **Atomwise Inc.**, San Francisco, CA (US)

(56) **References Cited**

(72) Inventors: **Abraham Samuel Heifets**, San Francisco, CA (US); **Izhar Wallach**, Tel-Mond (IL); **Michael Dzamba**, San Francisco, CA (US)

U.S. PATENT DOCUMENTS

9,190,053 B2 11/2015 Penn et al.  
9,202,144 B2 12/2015 Wang et al.  
(Continued)

(73) Assignee: **Atomwise Inc.**, San Francisco, CA (US)

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WO WO 2015/168774 A1 11/2015

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 186 days.  
This patent is subject to a terminal disclaimer.

OTHER PUBLICATIONS

Chae, Myong-Ho, et al. "Predicting protein complex geometries with a neural network." *Proteins: Structure, Function, and Bioinformatics* 78.4 (2010): 1026-1039. 14 pages.\*

(Continued)

(21) Appl. No.: **15/187,018**

(22) Filed: **Jun. 20, 2016**

*Primary Examiner* — Ryan P Potts  
(74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius LLP

(65) **Prior Publication Data**

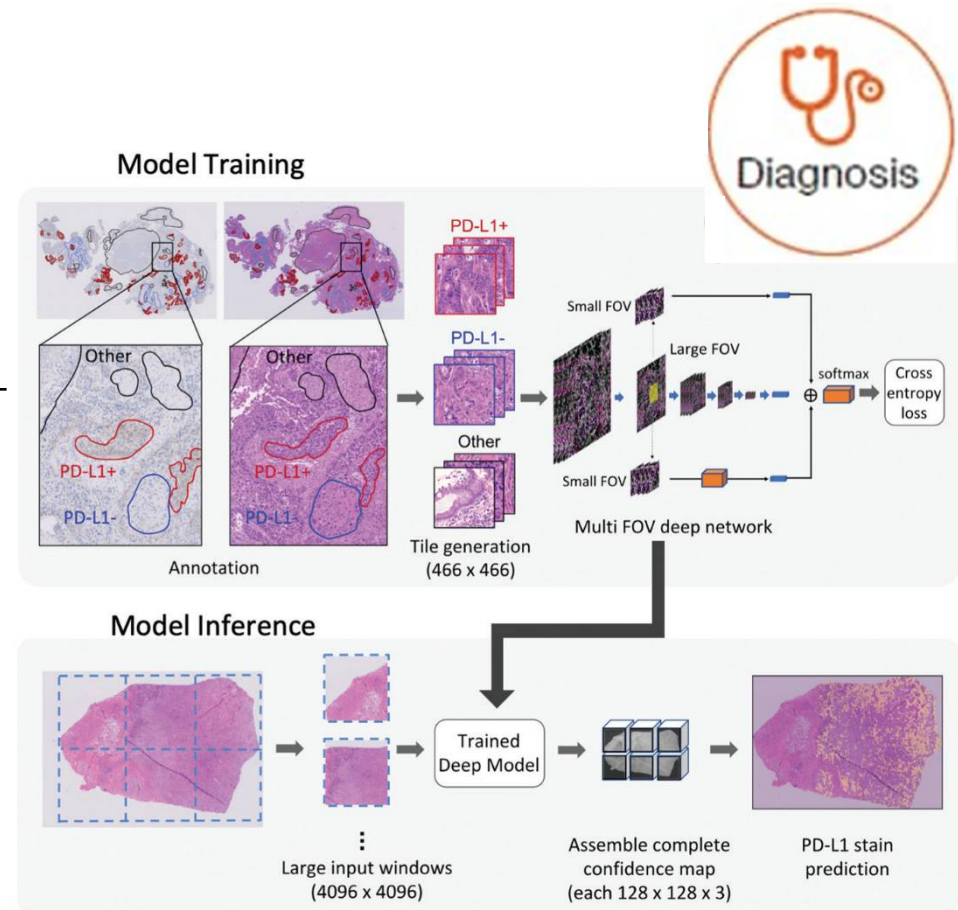
1. A computer system for characterization of a test object using spatial data, the computer system comprising: at least one processor; and memory addressable by the at least one processor, the memory storing at least one program for execution by the at least one processor, the at least program comprising instructions for:

. . .  
(D) inputting [a] plurality of vectors to a network architecture that includes an input layer for sequentially receiving the plurality of vectors, a plurality of convolutional layers, and a scorer

. . .  
(F) using the plurality of scores to characterize [a] test object

# TEMPUS

- Founded in 2015
  - Based in Chicago, IL
  - Valuation: USD \$8B
- Developed multiple genomic profiling platforms for precision oncology and clinical trial matching, including xT (solid tumor-normal matched), xF (liquid biopsy), xE (whole exome), and xG (germline). Using machine learning, data from these platforms is integrated with (i) clinical data, (ii) imaging data, and (iii) in vitro disease modeling data to improve clinical decision making.
- CEO and Founder: Eric Lefkofsky
  - American billionaire businessman
  - Founder of Groupon
  - Managing director of Lightbank
- Has raised about \$1.05 billion in venture capital
  - e.g., Baillie Gifford, Franklin Templeton, Google, Novo Holdings, and New Enterprise Associates



# U.S. 11,145,416 • Tempus



(12) **United States Patent**  
**Hafez et al.**

(10) **Patent No.:** US 11,145,416 B1  
 (45) **Date of Patent:** Oct. 12, 2021

(54) **PREDICTING LIKELIHOOD AND SITE OF METASTASIS FROM PATIENT RECORDS**

(71) Applicant: **Tempus Labs, Inc.**, Chicago, IL (US)

(72) Inventors: **Ashraf Hafez**, Woodinville, WA (US);  
**Martin Christian Stumpe**, Belmont, CA (US); **Nike Beaubier**, Chicago, IL (US); **Daniel Neems**, Evanston, IL (US); **Caroline Epstein**, Chicago, IL (US); **Adrian William George Lange**, La Grange, IL (US)

(73) Assignee: **Tempus Labs, Inc.**, Chicago, IL (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 17/227,120

(22) Filed: **Apr. 9, 2021**

**Related U.S. Application Data**

(56) **References Cited**

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2014/0127708 A1\* 5/2014 Muraca ..... G01N 33/57434 435/7.1

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 WO WO 2019/152788 A1 8/2019  
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Akagi, Ichiro, et al. "Combination of Protein Coding and Noncoding Gene Expression as a Robust Prognostic Classifier in Stage I Lung Adenocarcinoma", American Association for Cancer Research, 73 (13), Jul. 1, 2013, pp. 3821-3832.

(Continued)

*Primary Examiner* — Neal Sereboff  
 (74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius LLP

1. A method for predicting metastasis of a colorectal cancer in a subject, comprising:
  - at a computer system . . .
  - (A) obtaining [sequence reads] for a plurality of RNA molecules from a sample of the cancer . . .
  - (B) determining, . . . a plurality of data elements for the subject's cancer comprising: a first set of sequence features comprising relative abundance values for the expression of a plurality of at least 30 genes in the sample of the cancer obtained from the subject,
  - (C) applying, . . . one or more models that are collectively trained to provide a respective one or more indications of whether the cancer will metastasize in the subject, thereby predicting whether the cancer will metastasize; and
  - (D) generating a clinical report . . .

# U.S. 10,975,445 • Tempus

(12) **United States Patent**  
Venkat et al.

(10) **Patent No.:** US 10,975,445 B2  
(45) **Date of Patent:** Apr. 13, 2021

(54) **INTEGRATED MACHINE-LEARNING FRAMEWORK TO ESTIMATE HOMOLOGOUS RECOMBINATION DEFICIENCY**

(71) Applicant: **Tempus Labs, Inc.**, Chicago, IL (US)

(72) Inventors: **Aarti Venkat**, Chicago, IL (US); **Jerod Parsons**, Chicago, IL (US); **Joshua S K Bell**, Chicago, IL (US); **Catherine Igartua**, Chicago, IL (US); **Yilin Zhang**, Wilmette, IL (US); **Ameen Salahudeen**, Oak Park, IL (US); **Verónica Sánchez Freire**, Chicago, IL (US); **Robert Tell**, Chicago, IL (US)

(73) Assignee: **Tempus Labs, Inc.**, Chicago, IL (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(51) **Int. Cl.**  
*C12Q 1/6886* (2018.01)  
*G16B 40/00* (2019.01)  
*G16B 20/00* (2019.01)  
*G06N 3/02* (2006.01)  
*G16B 50/30* (2019.01)  
*G06F 17/18* (2006.01)

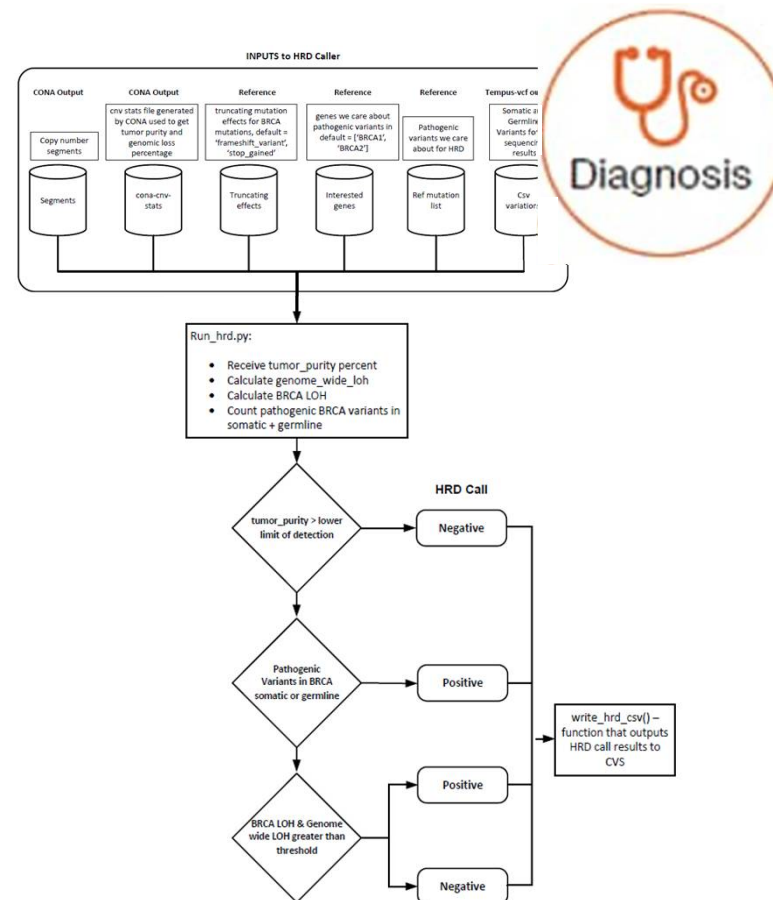
(52) **U.S. Cl.**  
CPC ..... *C12Q 1/6886* (2013.01); *G06F 17/18*

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Bonadio, et al. "Homologous recombination deficiency in ovarian cancer: a review of its epidemiology and management," *Clinics*, pp. 1-6 (2018).  
Chang, et al. "Homologous recombination deficiency (HRD) by BROCA-HR and survival outcomes after surgery for patients (pts) with pancreatic adenocarcinoma (PC): A single institution experience," *Journal of Clinical Oncology*, 38, No. 4, pp. 1-3 (Feb. 4, 2020).  
Coleman, et al. "Rucaparib maintenance treatment for recurrent ovarian carcinoma after response to platinum therapy (ARIEL3): a randomised, double-blind, placebo-controlled, phase 3 trial," *Lancet*. Author manuscript; available in PMC, pp. 1-26 (Apr. 16, 2018).  
Criscuolo, et al. "New combinatorial strategies to improve the PARP inhibitors efficacy in the urothelial bladder Cancer treatment," *Journal of Experimental & Clinical Cancer Research*, pp. 1-9 (2019).  
Davies, et al. "HRDetect is a predictor of BRCA1 and BRCA2 deficiency based on mutational-signatures," *Nat. Med.*, pp. 1-28  
Hoppe, et al. "Biomarkers for Homologous Recombination Deficiency in Cancer," *JNCI J Natl Cancer Inst* 110 (7), pp. 704-713 (May 18, 2018).

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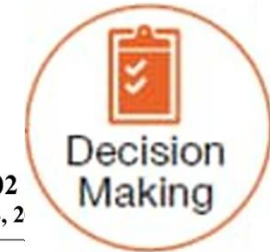
*Primary Examiner* — Jerry Lin  
(74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius LLP





(12) **United States Patent**  
Blasetto et al.

(10) **Patent No.:** US 10,325,678 B2  
(45) **Date of Patent:** \*Jun. 18, 2019



## Technology-Assisted Self-Selection of Candidates for Nonprescription Statin Therapy

Steven  
Sara Tr  
Paul M

### NEWS • Daily News Could an App Replace Statin

### Prescribing by Doctors?

### In AstraZeneca-Sponsored Study, Digital App Corrects OTC Statin Self-Selection Problem

Study Also Could Improve Chances In US To Switch Drugs For Other Chronic Conditions  
by **Mi** September 07, 2021 | 4 min read

### Web app for self-prescription of statins 96% concordant with physician reviewers

Written  
Eileen

Malcol **Cardiology**today

By Scott Buzby

Perspective from Joseph S. Alpert, MD

+ ADD TOPIC TO EMAIL ALERTS



(12) **United States Patent**  
Blasetto et al.

(10) **Patent No.:** US 10,600,502  
(45) **Date of Patent:** Mar. 24, 2

(12) **United States Patent**  
Blasetto et al.

(10) **Patent No.:** US 10,910,091 B2  
(45) **Date of Patent:** Feb. 2, 2021

(12) **United States Patent**  
Blasetto et al.

(10) **Patent No.:** US 11,031,104 B2  
(45) **Date of Patent:** \*Jun. 8, 2021

(54) **SYSTEMS AND METHODS FOR DISPENSING A STATIN MEDICATION OVER THE COUNTER**

Applicant: AstraZeneca UK Ltd., London England (GB)

Inventors: James Blasetto, Chadds Ford, PA (US); Judy Firor, Landenberg, PA (US); David Guiga, West Chester, PA (US); William Mongan, Malvern, PA (US); Robert Prybolsky, West Chester, PA (US); Richard L. Skelly, Flourtown, PA (US)

ASTRAZENECA UK LTD., London (GB)

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

No.: 16/791,745

(58) **Field of Classification Search**  
None  
See application file for complete search history.

(56) **References Cited**  
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(Continued)  
*Primary Examiner* — Devin C Hein  
(74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius LLP; Brett A. Lovejoy; Andrew J. Antczak

## U.S. 11,031,104 • AstraZeneca



1. A method of managing cholesterol in a human subject . . . comprising:
  - a) receiving a request from the subject for the statin pharmaceutical composition, at a computer system . . .
  - b) providing a survey for obtaining a plurality of survey results from the subject . . .
  - c) receiving the plurality of survey results . . .
  - d) applying an algorithm to the plurality of survey results. . . wherein the algorithm:
    - i) runs all or a portion of the plurality of survey results against a plurality of filters, wherein, when a respective filter in the plurality of filters is fired, the process is terminated or the subject is provided with a warning corresponding to the respective filter, and wherein the plurality of filters comprises . . .
    - ii) obtains, when the process is not terminated, acknowledgment from the subject for each warning issued to the subject by any filter in the plurality of filters, and
    - iii) proceeds with the process when (1) the process is not already terminated by the firing of a filter in the plurality of filters and (2) the subject has acknowledged each warning associated with each filter in the plurality of filters that was fired and that is associated with a warning, wherein the process further comprises:
      - storing an indication in a subject profile of a re-order for the statin pharmaceutical composition,
      - communicating an over the counter drug facts label for the statin pharmaceutical composition to the subject, and
      - authorizing, upon confirmation from the subject that the over the counter drug facts label has been received and read, a provision of the statin pharmaceutical composition to the subject; and
  - e) administering the statin pharmaceutical composition to the human subject, upon authorization of the provision, to manage cholesterol in the human subject.



- Partnering with Beta Bionics on diabetes management with iLet®, a closed-loop insulin delivery system leveraging machine-learning algorithms to better maintain glucose levels within target ranges.






# U.S. 10,930,382 and EP 3 479 266 B1

## Novo Nordisk



(12) <b>United States Patent</b> Bengtsson et al.	(10) <b>Patent No.:</b> US 10,930,382 B2 (45) <b>Date of Patent:</b> Feb. 23, 2021
(54) <b>SYSTEMS AND METHODS FOR ANALYSIS OF INSULIN REGIMEN ADHERENCE DATA</b>	(58) <b>Field of Classification Search</b> CPC ..... G06Q 50/22-24 See application file for complete search history.
(71) Applicant: Novo Nordisk A/S, Bagsvaerd (DK)	(56) <b>References Cited</b>
(7) 	(11) <b>EP 3 479 266 B1</b>
<b>EUROPEAN PATENT SPECIFICATION</b>	
(45) Date of publication and mention of the grant of the patent: <b>02.06.2021 Bulletin 2021/22</b>	(51) Int Cl.: <b>G16H 20/10<sup>(2018.01)</sup> G16H 50/20<sup>(2018.01)</sup></b> <b>G16H 20/17<sup>(2018.01)</sup></b>
(21) Application number: <b>17734277.1</b>	(86) International application number: <b>PCT/EP2017/065383</b>
(22) Date of filing: <b>22.06.2017</b>	(87) International publication number: <b>WO 2018/001854 (04.01.2018 Gazette 2018/01)</b>
(54) <b>SYSTEMS AND METHODS FOR ANALYSIS OF INSULIN REGIMEN ADHERENCE DATA</b> SYSTEME UND VERFAHREN ZUR ANALYSE VON INSULINDIÄT-EINHALTUNGSDATEN SYSTÈMES ET PROCÉDÉS POUR L'ANALYSE DE DONNÉES D'OBSERVANCE DE TRAITEMENT POSOLOGIQUE PAR INSULINE	

1. A device for monitoring adherence to a prescribed insulin medicament dosage regimen for a subject over time [programed to] perform a method of: obtaining a first data set, . . . comprising a plurality of metabolic events the subject engaged in . . . within a first period of time and each respective metabolic event . . . comprises (i) a timestamp . . . and (ii) a first characterization that is one of insulin regimen adherent and insulin regimen nonadherent, computing a plurality of primary adherence values . . . computed by dividing a number of insulin regimen adherent metabolic events by a total number of metabolic events . . . identifying a trend in adherence to the prescribed insulin medicament dosage regimen for the subject as a drop off in the plurality of primary adherence values or the plurality of secondary adherence values . . . reducing amounts of insulin medicament dosage . . . when the trend is identified; and communicating the plurality of primary adherence values . . . thereby monitoring adherence to the prescribed insulin medicament dosage regimen for the subject over time.



(12) **United States Patent**  
**Schecter**

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(45) **Date of Patent:** Jan. 5, 2021

(54) **SYSTEMS AND METHODS FOR OPTIMIZING MANAGEMENT OF PATIENTS WITH MEDICAL DEVICES AND MONITORING COMPLIANCE**

(52) **U.S. Cl.**  
CPC ..... *G16H 10/60* (2018.01); *G06Q 30/018* (2013.01); *G06Q 50/22* (2013.01); *A61B 5/0022* (2013.01); *A61B 5/0031* (2013.01); *A61B 5/7275* (2013.01)

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(58) **Field of Classification Search**  
None  
See application file for complete search history.

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(56) **References Cited**

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U.S. PATENT DOCUMENTS

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **15/780,890**

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(22) PCT Filed: **Dec. 2, 2016**

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(86) PCT No.: **PCT/US2016/064716**

§ 371 (c)(1),  
(2) Date: **Jun. 1, 2018**

*Primary Examiner* — Michael Tomaszewski  
(74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius LLP

1. A computer system for determining health care provider monitoring compliance [programed for]:
  - A) performing a first autonomous process [by] (i) measuring the respective data element . . . from a corresponding wireless signal transmitted by a corresponding cardiac implantable electronic medical device . . . (ii) interrogating the respective data element to (a) determine the condition of the corresponding cardiac implantable electronic medical device or to determine the condition of the corresponding subject . . . and (iii) recording . . . a corresponding first medical code . . .
  - B) performing a second autonomous process [by] (i) determining whether the first medical code has been recorded . . . (ii) advancing a compliance counter [or] (iii) advancing a noncompliance counter
  - C) comparing a compliance . . . and shortening the length of the epoch period when the compliance for the second plurality of subjects does not satisfy the compliance threshold, . . .
  - D) performing a third process [by] . . . (i) providing compliance information . . . , and (ii) providing a list of subjects . . . on the basis that they (a) share one or more characteristics and (b) the medical records of the subjects indicate they lack a specific therapy or a treatment that is a standard of care for subjects having the one or more characteristics.

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Using AI in Pharma R&D and Clinical Testing—Regulatory and Legal Issues for the US Landscape

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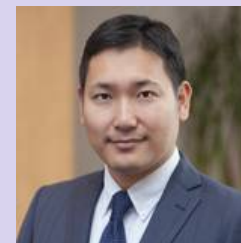
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# Coronavirus COVID-19 Resources

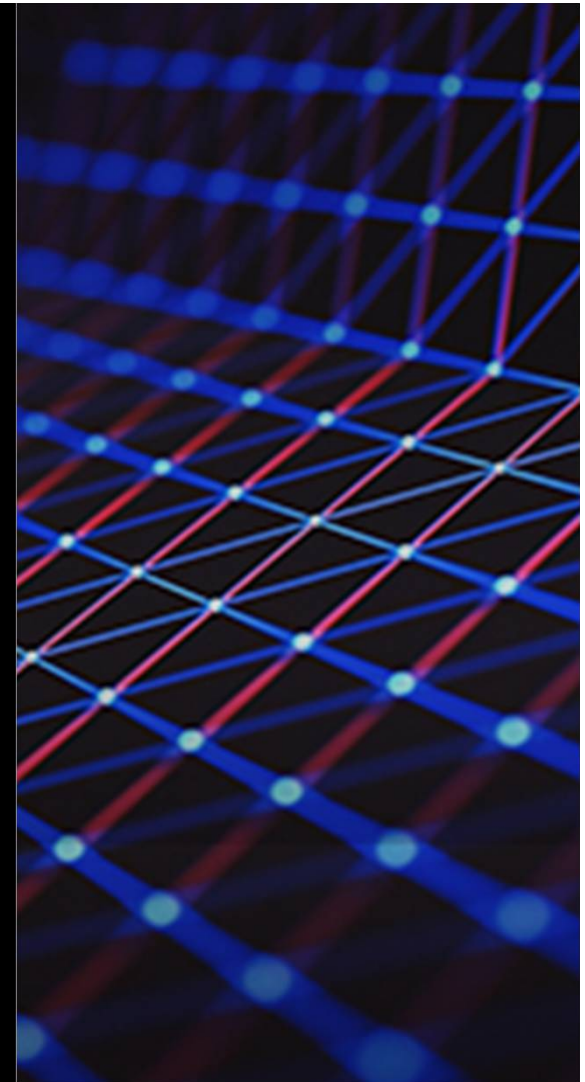
We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

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To help keep you on top of developments as they unfold, we also have launched a resource page on our website at

[www.morganlewis.com/  
topics/coronavirus-  
covid-19](http://www.morganlewis.com/topics/coronavirus-covid-19)

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to [subscribe](#) using the purple "Stay Up to Date" button.



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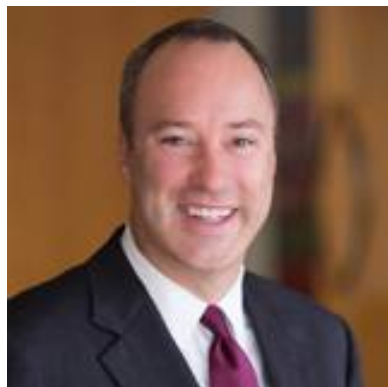
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