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SILICON VALLEY **FIRST CUP OF COFFEE** SEMINAR SERIES

UPCOMING SEMINARS:

Artificial Intelligence (AI) Boot Camp

- | | |
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| January 12 | Computer-Implemented Inventions in Biotechnology and Healthcare, Patentability from European and US Perspective |
| January 13 | M&A and Investment into AI Companies |
| January 19 | AI in Healthcare, An Overview of Key FDA Policies and Developments |
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- February 2 The Ethics of Artificial Intelligence for the Legal Profession
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- February 4 Patents for MedTech AI: Opportunities and Pitfalls
- February 9 IP Landscape of AI Hardware Startups
- February 11 AI in Digital Advisory Offerings: Regulatory Considerations
- February 16 Bias Issues and AI
- February 25 The Risks of Bias and Errors in AI-Enabled Decision-Making

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PATENTS FOR MEDTECH AI: OPPORTUNITIES AND PITFALLS

Steven J. Frank
and Andrew J. Gray IV

February 4, 2021

Presenters



Steven J. Frank

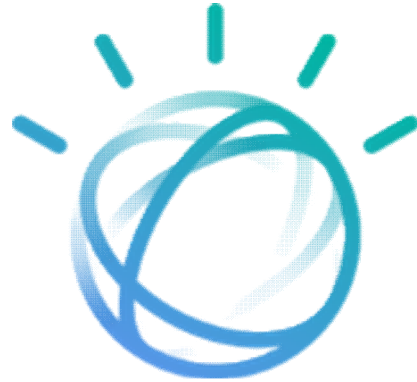


Andrew J. Gray IV

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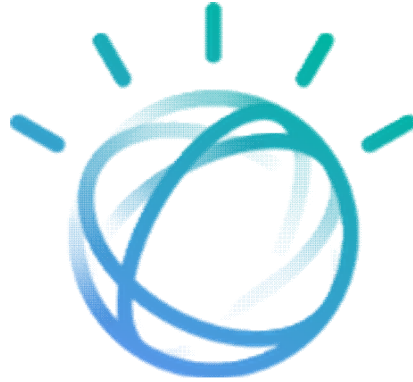


Artificial Intelligence in Medicine: Examples



IBM Watson

Artificial Intelligence in Medicine: Examples



IBM Watson

- Clinical decision support
- Automated ingestion of medical literature
- Patient data mining
- Learning and inference

Artificial Intelligence in Medicine: Examples



IBM Watson

Artificial Intelligence in Medicine: Examples



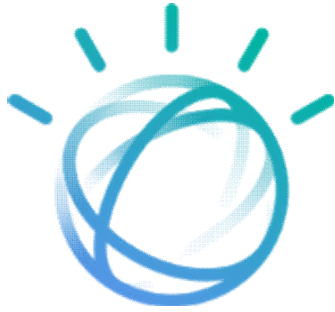
IBM Watson



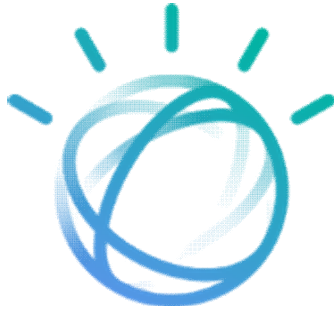
“How artificial intelligence is changing drug discovery”

Nature, May 30, 2018

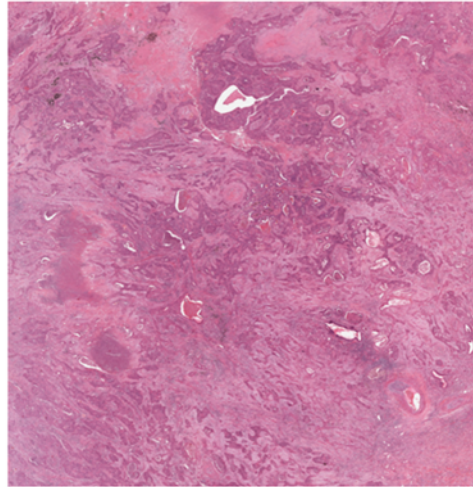
Artificial Intelligence in Medicine: Examples



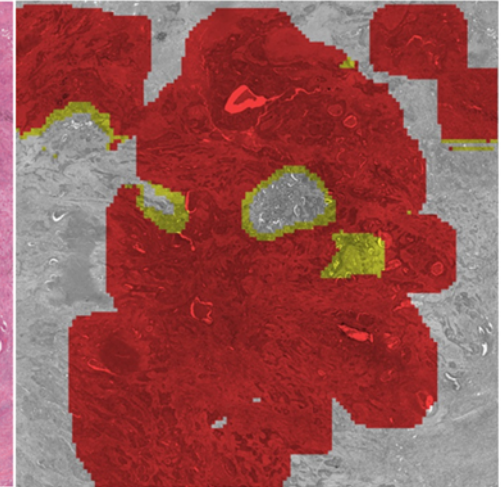
Artificial Intelligence in Medicine: Examples



AI in Medical Imaging



Biopsy



Tumor Probability Map

Why AI is Proliferating in MedTech

- **In fact, AI is very widespread in medtech, and keeps growing**
 - **Competitors look for an edge**
 - **Capability: e.g., robotic surgery, Apple's ECG app, personalized medicine**
 - **Economic: e.g., automate data collection and entry of physician notes**
 - **Investors demand an "AI strategy"**
 - **Maintain parity with state of the art**
 - **Avoid liability**
 - **Resolve ambiguous cases**
 - **Improve monitoring**

Patenting Medtech AI: The Usual Challenges

- **Utility**
- **Novelty**
- **Unobviousness**



The Eligibility Elephant



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(Slip Opinion)

OCTOBER TERM, 2013

1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

ALICE CORPORATION PTY. LTD. v. CLS BANK
INTERNATIONAL ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

No. 13–298. Argued March 31, 2014—Decided June 19, 2014

Petitioner Alice Corporation is the assignee of several patents that disclose a scheme for mitigating “settlement risk,” i.e., the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the patent claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The patents in suit claim (1) a method for exchanging financial obligations, (2) a computer system configured to carry out the method for exchanging obligations, and (3) a computer-readable medium containing program code for performing the method of exchanging obligations.

Respondents (together, CLS Bank), who operate a global network that facilitates currency transactions, filed suit against petitioner, arguing that the patent claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. After *Bilski v. Kappos*, 561 U. S. 593, was decided, the District Court held that all of the claims were ineligible for patent protection under 35 U. S. C. §101 because they are directed to an abstract idea. The en banc Federal Circuit affirmed.

Held: Because the claims are drawn to a patent-ineligible abstract idea, they are not patent eligible under §101. Pp. 5–17.

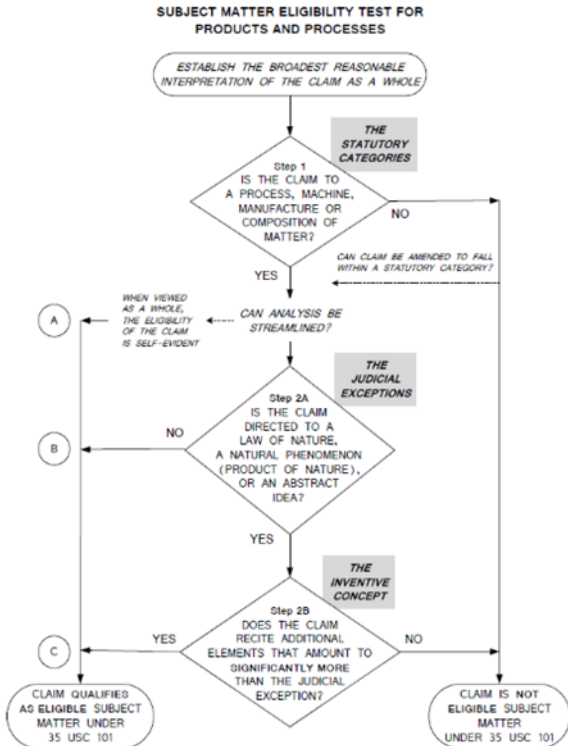
(a) The Court has long held that §101, which defines the subject matter eligible for patent protection, contains an implicit exception for “[l]aws of nature, natural phenomena, and abstract ideas.” *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U. S. _____. In applying the §101 exception, this Court must distinguish patents that claim the “buildin[g] block[s]” of human ingenuity, which are ineligible for patent protection, from those that integrate

*Patent lawyers have
upped their meds ...*



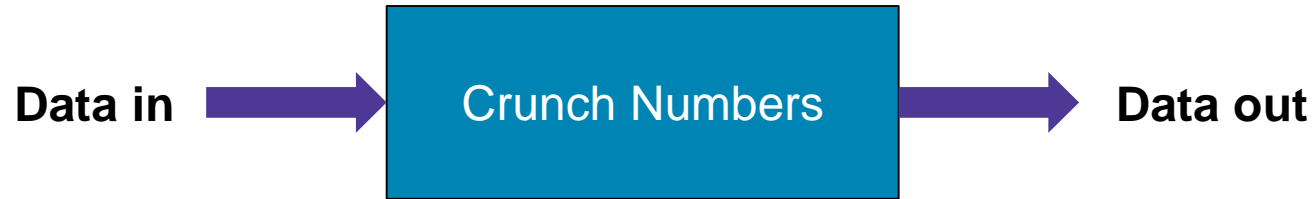
Artificial Intelligence in Medicine: Examples

- Numerous, sometimes conflicting and often arbitrary criteria



- MPEP §2016
- Determine whether the claims are directed to an abstract idea, a law of nature or a natural phenomenon (i.e., a judicial exception)
- If so, determine whether the claim recites additional elements that amount to “significantly more”
- Additional criteria
 - Pre-emption
 - “Well-understood, routine, conventional activity”
 - “Mental processes”

Toast Under *Alice*



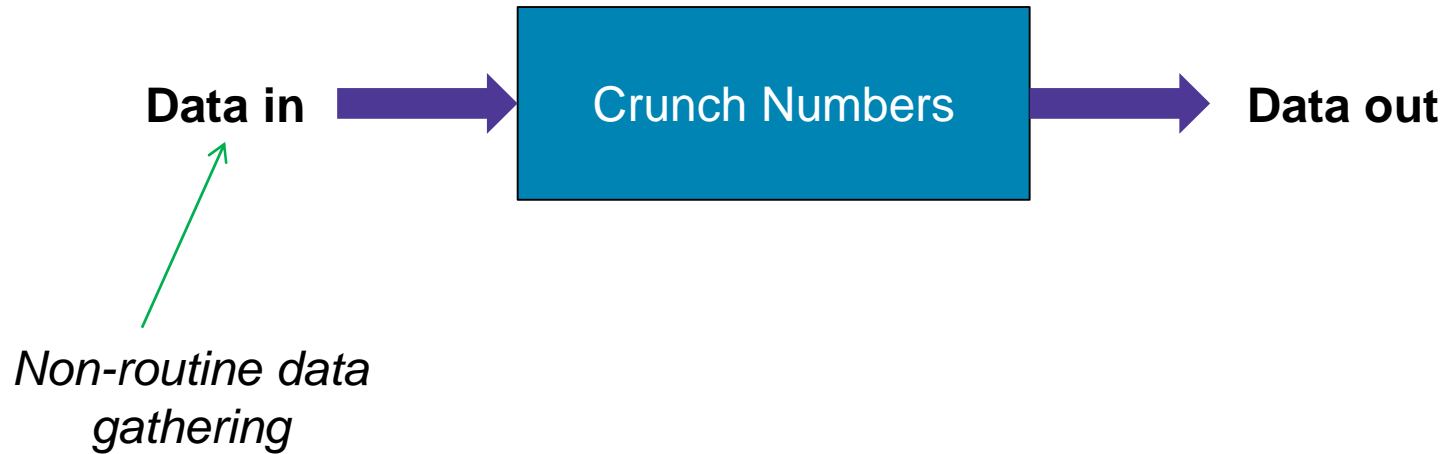
Appeasing Alice



We shall say “Ni” to you ... if you do not appease us!

Monty Python and the Holy Grail (1975)

Appeasing Alice



Appeasing Alice

(19) **United States**

(12) **Patent Application Publication**

LEVY et al.

(10) **Pub. No.: US 2019/0307427 A1**

(43) **Pub. Date: Oct. 10, 2019**

(54) **PRECEDENT-BASED ULTRASOUND
FOCUSING**

(71) Applicant: **INSIGHTEC, LTD.**, Tirat Carmel (IL)

(72) Inventors: **Yoav LEVY**, Hinanit (IL); **Eyal ZADICARIO**, Tel Aviv-Yafo (IL);
Talia AMAR, Tirat Carmel (IL)

(21) Appl. No.: **16/314,808**

(22) PCT Filed: **Jul. 14, 2017**

(86) PCT No.: **PCT/IB2017/001029**

§ 371 (c)(1),

(2) Date: **Jan. 2, 2019**

Related U.S. Application Data

(60) Provisional application No. 62/362,151, filed on Jul. 14, 2016.

Publication Classification

(51) **Int. Cl.**
A61B 8/08 (2006.01)
A61B 8/00 (2006.01)
A61B 6/00 (2006.01)

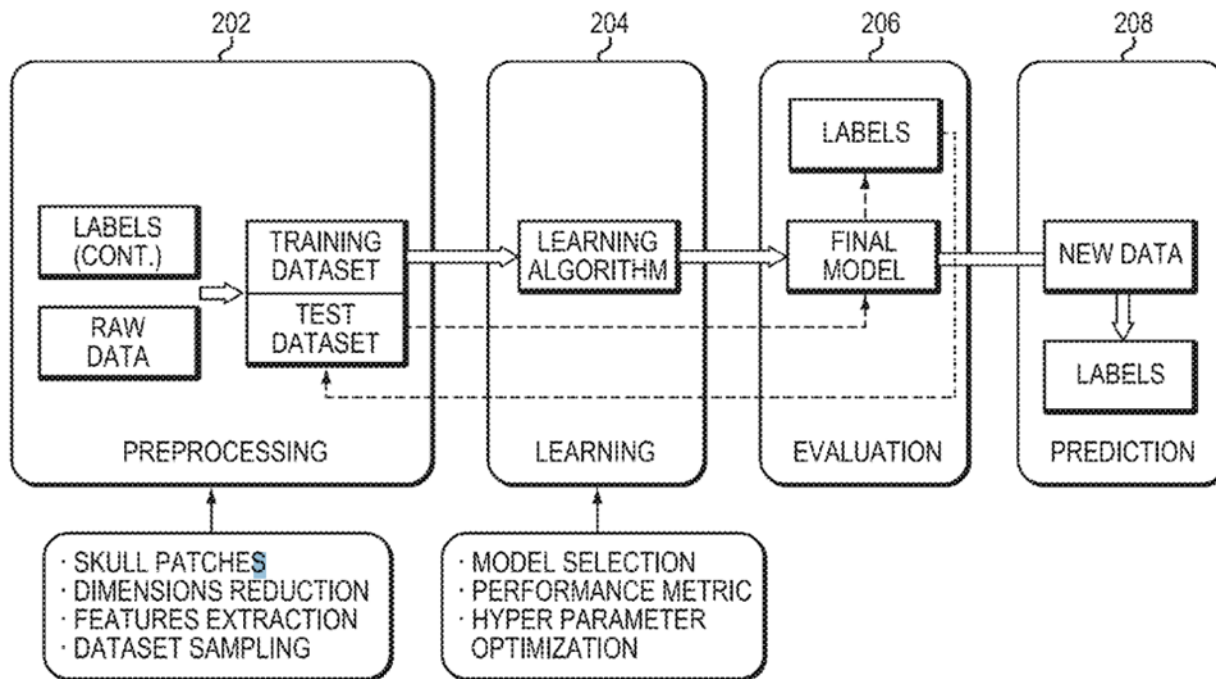
(52) **U.S. CL.**

CPC *A61B 8/5269* (2013.01); *A61B 8/0808*
(2013.01); *A61B 8/4416* (2013.01); *A61B*
8/4488 (2013.01); *A61B 2090/374* (2016.02);
A61B 8/5253 (2013.01); *A61B 8/5261*
(2013.01); *A61B 8/58* (2013.01); *A61B 8/54*
(2013.01); *A61B 6/5217* (2013.01)

(57) **ABSTRACT**

Various approaches for operating an ultrasound transducer having multiple transducer elements include acquiring one or more measurements of anatomical regions through which ultrasound waves emitted from the transducer elements travel; for each of the anatomical regions, determining values of characteristics based at least in part on the measurement(s); computationally predicting aberrations of the ultrasound waves traveling through the anatomical regions by using the first values as input to a predictor that has been computationally trained to predict ultrasound aberrations based on values of the characteristics; and driving the transducer elements to compensate for the predicted aberrations.

Appeasing Alice



Appeasing Alice

39. An ultrasound system comprising:
- an **ultrasound transducer** comprising a plurality of transducer elements;
 - a **measuring system** for acquiring a first series of measurements of a plurality of first anatomical regions through which the ultrasound waves emitted from the transducer elements will travel; and
 - a processor configured to:
 - determine first values of a plurality of characteristics **based at least in part on the measurements**;
 - execute a predictor that has been computationally trained to predict ultrasound aberrations **based on values of the characteristics**;
 - use the first values as input to the executing predictor, whereby the predictor predicts first aberrations of the ultrasound waves traveling through the first anatomical regions; and
 - drive the transducer elements to compensate for the predicted aberrations.

Appeasing Alice

Data preprocessing

Data in

Crunch Numbers

Data out

*Non-routine data
gathering*

Appeasing Alice

(12) **United States Patent**
Yu

(10) **Patent No.:** **US 10,832,406 B2**

(15) **Date of Patent:** **Nov. 10, 2020**

(54) **QUA
AND
NET**

(57)

ABSTRACT

Histological images are preprocessed and classified among pathology states using a neural network. In preprocessing, the digital image is electronically partitioned into a grid of identically sized, overlapping subimages, and images are selected for analysis based on a parameter such as density.

(71) Appli

(72) Inven

(73) Assig

(*) Notic

(21) Appl. No.: 16/179,101

(22) Filed: **Nov. 2, 2018**

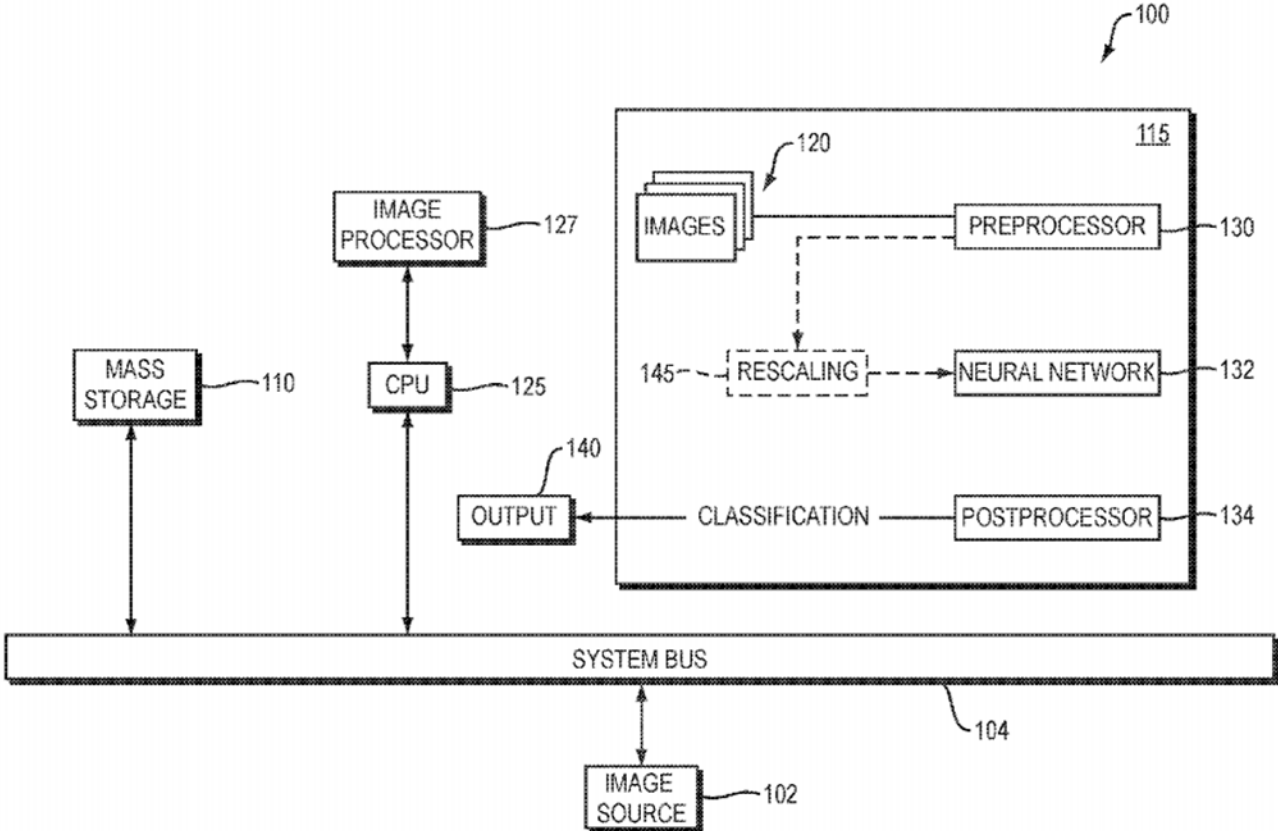
See application file for complete search history.

(56)

References Cited

U.S. PATENT DOCUMENTS

Appeasing Alice



Appeasing Alice

What is claimed is:

1. A pathology classification system comprising:
a processor;

a computer memory for storing a digital image of tissue to be analyzed, the digital image comprising an $m \times n$ array of pixels, where m and n are non-zero integers;
an image preprocessor, executed by the processor and configured to (i) partition the digital image into a grid of identically sized, overlapping subimages thereof, each of the subimages comprising an $o \times p$ array of pixels that includes pixels from a subimage adjacent thereto along a single overlap dimension, where o and p are non-zero integers and

$$\frac{o \times p}{m \times n} \leq 0.01,$$

(ii) compute an average pixel density for each of the subimages, and (iii) select q subimages with densities higher than the densities of the other subimages, where q is a non-zero integer equal to or greater than 10;

a neural network, executed by the processor and configured to receive the q selected subimages as feature vectors and classify the selected subimages among pathology states; and

a postprocessing module, executed by the processor and configured to aggregate the subimage classifications and classify tissue among a plurality of types within the pathology states.

Appeasing Alice

Data preprocessing

Data in

Crunch Numbers

Data out

**Novel hardware
or AI algorithm**

*Non-routine data
gathering*

Appeasing Alice

- A non-generic piece of hardware
 - A specialized source of data, or doing something physical with the output
 - E.g., a computer plus *a sequencer* (data in)
 - A computer plus a DNA synthesizer
- Something that enhances the operation, functionality or efficiency of the computer
 - *Enfish* case: “self-referential database”
 - Court said the claimed improvement provided for “faster searching of data than with the relational model,” “more efficient storage” of certain types of data, and “more flexibility in configuring the database.”

Appeasing Alice

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

(10) **Patent No.:** **US 9,558,321 B2**
(45) **Date of Patent:** **Jan. 31, 2017**

(54) **SYSTEMS AND METHODS FOR SMART TOOLS IN SEQUENCE PIPELINES**

(56) **References Cited**

(71) Applicant: **Seven Bridges Genomics Inc.**,
Cambridge, MA (US)

U.S. PATENT DOCUMENTS

5,583,024 A 12/1996 McElroy et al.
5,674,713 A 10/1997 McElroy et al.

What is claimed is:

1. A system for genomic analysis, the system comprising: a processor coupled to a memory operable to cause the system to:

present to a user a plurality of **genomic tools** organized into a bioinformatics pipeline, wherein at least a first one of the genomic tools comprises an executable and a wrapper script;
receive instructions from the user and sequence data, wherein the instructions call for the sequence data to be analyzed by the **bioinformatics pipeline**;
initiate the executable of the first genomic tool of the bioinformatics pipeline; and

modify, using the wrapper script, the bioinformatics pipeline to replace the first genomic tool of the bioinformatics pipeline with an alternative genomic tool, wherein the wrapper script modifies the bioinformatics pipeline by:

receiving an error from the executable of the first genomic tool;
identifying the alternative genomic tool that is consistent with the user instructions and the data being passed; and
initiating an executable of the alternative genomic tool, wherein the alternative genomic tool avoids the error.

Another example ...

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

(10) **Patent No.:** **US 9,519,650 B2**

(45) **Date of Patent:** **Dec. 13, 2016**

(54) **SYSTEMS AND METHODS FOR GENETIC
DATA COMPRESSION**

(75) Inventors: **Christoph Lange**, Cambridge, MA
(US); **Dandi Qiao**, Boston, MA (US)

(73) Assignee: **PRESIDENT AND FELLOWS OF
HARVARD COLLEGE**, Cambridge,
MA (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,253,264 B1 * 6/2001 Sebastian G06T 9/005
341/107
8,340,914 B2 * 12/2012 Gatewood H03M 7/3084
702/19

(Continued)

FOREIGN PATENT DOCUMENTS

Another example ...

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

(10) **Patent No.:** **US 9,519,650 B2**

(45) **Date of Patent:** **Dec. 13, 2016**

(54) **SYSTEMS AND METHODS FOR GENETIC
DATA COMPRESSION**

(56)

References Cited

(75) Inventors: **Christoph Lang**
(US); Dandi Qia

(73) Assignee: **PRESIDENT AND
FACULTY OF HARVARD COLLEGE,
CAMBRIDGE, MA (US)**

*Compression is
something computers
do!*

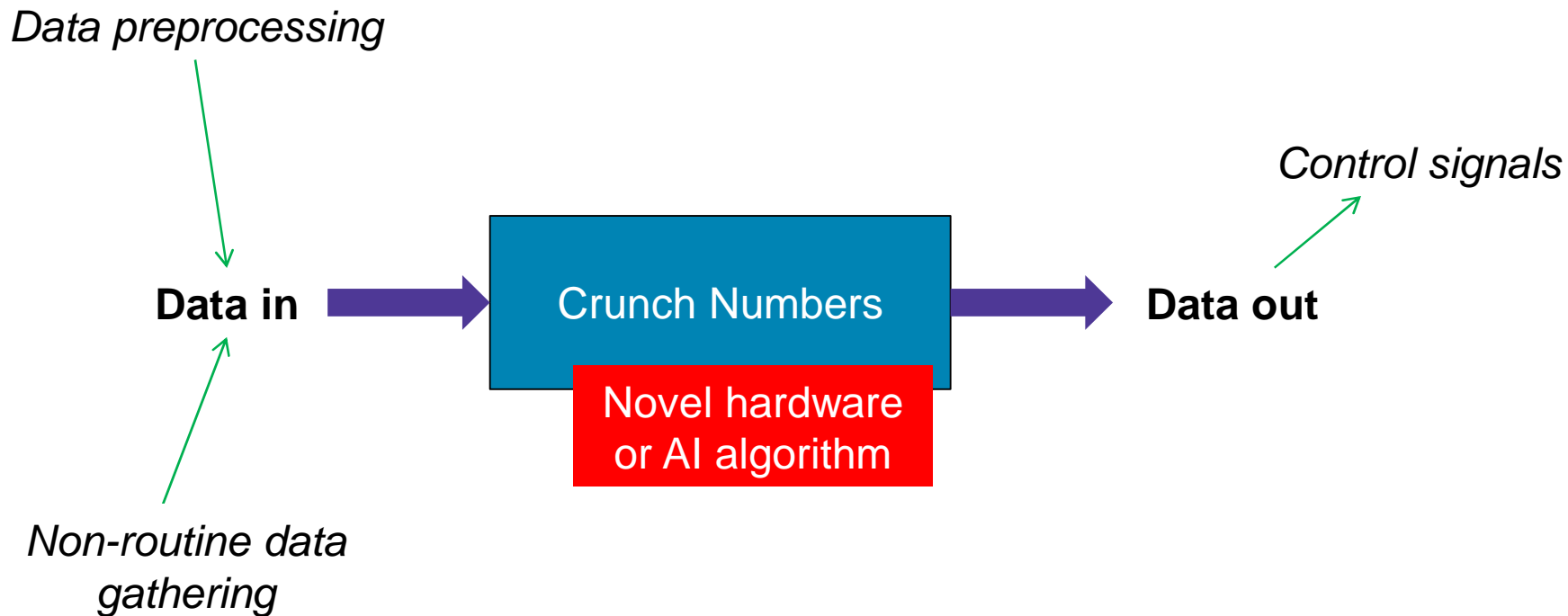
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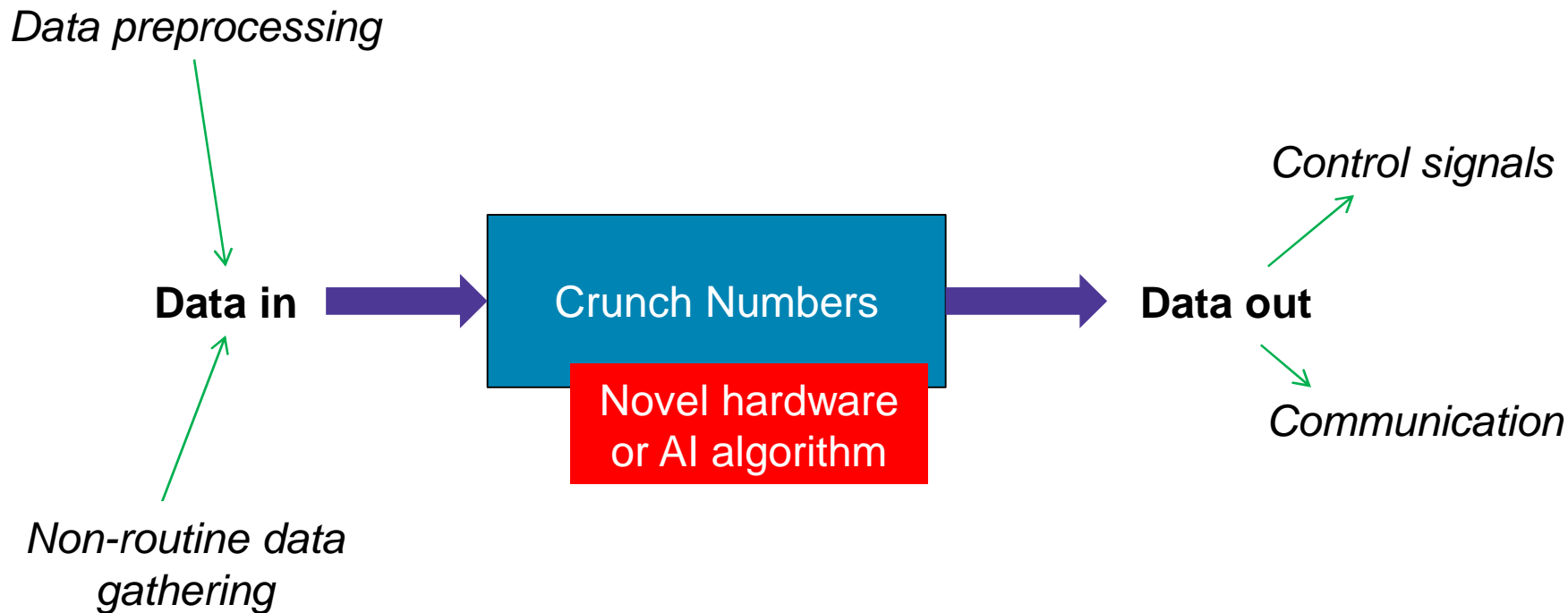
Appeasing Alice



Appeasing Alice: Back to that InSightec application ...

39. An ultrasound system comprising:
- an ultrasound transducer comprising a plurality of transducer elements;
 - a measuring system for acquiring a first series of measurements of a plurality of first anatomical regions through which the ultrasound waves emitted from the transducer elements will travel; and
 - a processor configured to:
 - determine first values of a plurality of characteristics based at least in part on the measurements;
 - execute a predictor that has been computationally trained to predict ultrasound aberrations based on values of the characteristics;
 - use the first values as input to the executing predictor, whereby the predictor predicts first aberrations of the ultrasound waves traveling through the first anatomical regions; and
 - drive the transducer elements to compensate for the predicted aberrations.

Appeasing Alice



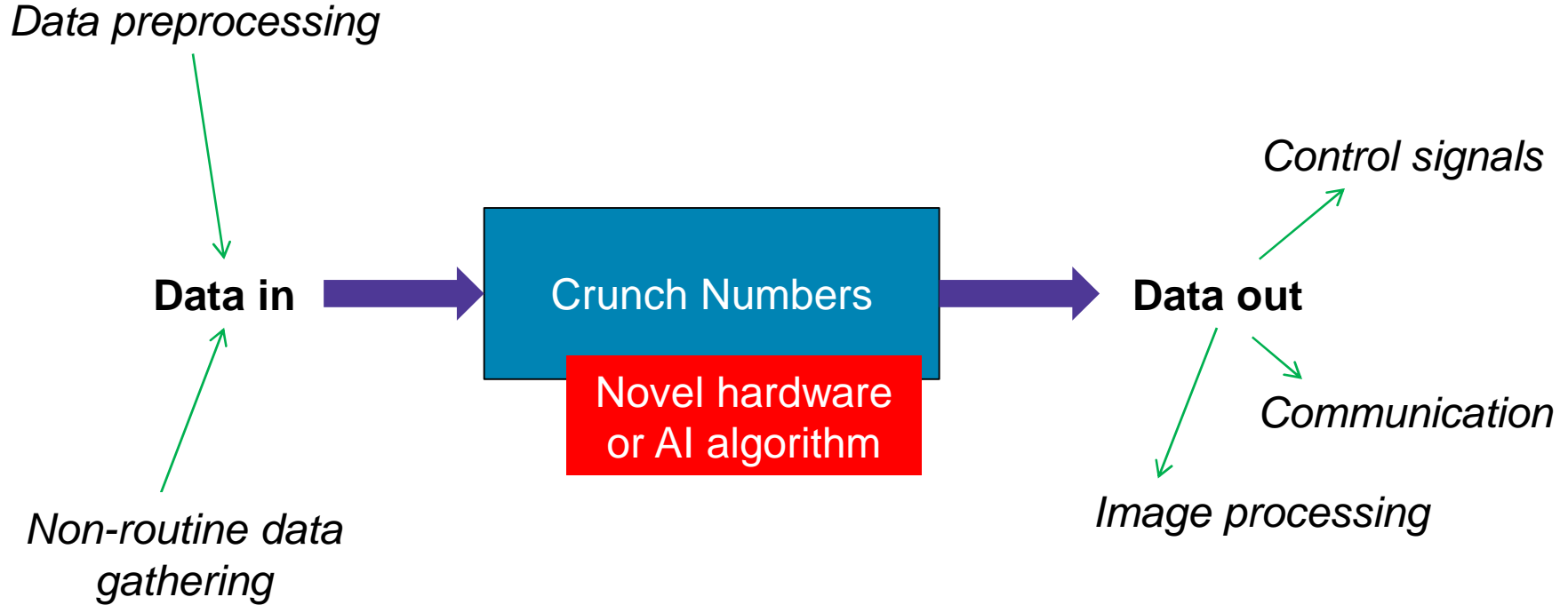
Artificial Intelligence in Medicine: Examples

From MPEP §2106:

Examples of claims that do not recite mental processes because they cannot be practically performed in the human mind include:

- a claim to a method for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals, where the claimed GPS receiver calculated pseudoranges that estimated the distance from the GPS receiver to a plurality of satellites, *SiRF Tech.*, 601 F.3d at 1331-33, 94 USPQ2d at 1616-17;
- a claim to detecting suspicious activity by using network monitors and analyzing network packets, *SRI Int'l*, 930 F.3d at 1304

Appeasing Alice



Appeasing Alice

More from MPEP §2106:

Examples of claims that do not recite mental processes because they cannot be practically performed in the human mind include:

- a claim to a method for rendering a halftone image of a digital image by comparing, pixel by pixel, the digital image against a blue noise mask, where the method required the manipulation of computer data structures (*e.g.*, the pixels of a digital image and a two-dimensional array known as a mask) and the output of a modified computer data structure (a halftoned digital image), *Research Corp. Techs.*, 627 F.3d at 868, 97 USPQ2d at 1280.

And Now for the Pitfalls ...

- **Defensive planning for *Alice* rejections**
 - **Often negotiation with the examiner is productive**
 - **You need fallback positions, described adequately in the spec**
 - **Detailed description of algorithm (necessary for enable and written description, too)**
 - **Hardware context**
 - **Data sources, uses of output**

And Now for the Pitfalls ...

- **Make sure the claims align with the client's business objectives throughout prosecution**
 - **What is the client selling?**
 - **An app using a trained neural network?**
 - **Claims to the trained neural network ...**
 - **Methods of training ...**
 - **Methods of gathering or synthesizing training data ...**
 - **Claims to the output (e.g., if it's an image) ...**
 - **Claims to what's done (or what customers might do) with the prediction ...**
 - **A device?**
 - **Services (e.g., SaaS model)?**
 - **Who are the competitors? What do they do and sell?**
- **Where's the novelty?**

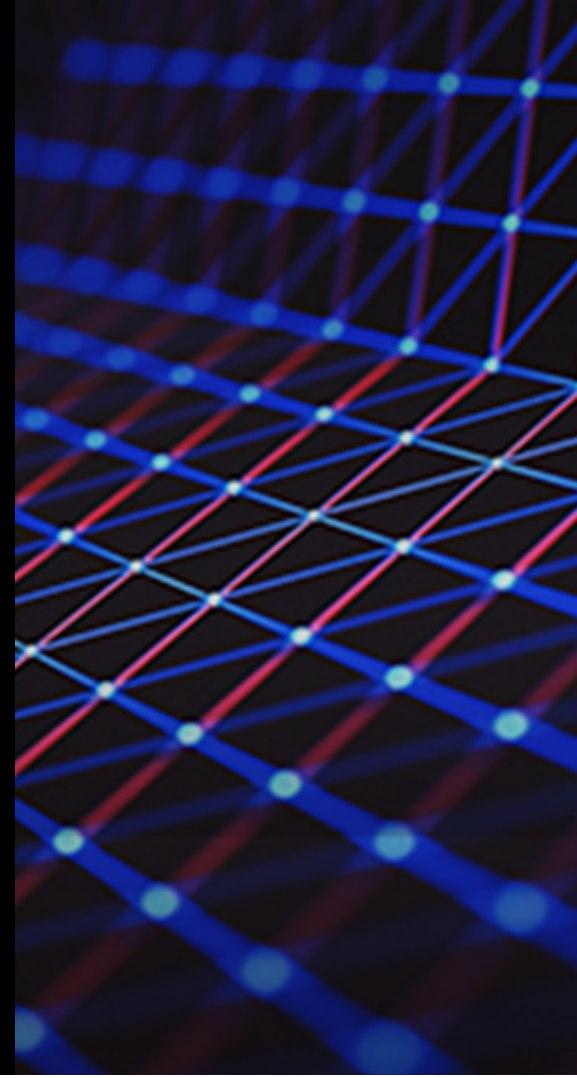
Coronavirus COVID-19 Resources

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

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.



Biography



Steven J. Frank

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Steven J. Frank focuses on advising clients in all areas of intellectual property and commercial technology law, with an emphasis on strategic IP transactions, patent prosecution, analysis of infringement and related issues, copyright questions, and the drafting and negotiation of agreements relating to the transfer or license of intellectual property. Steve has significant experience with general IP diligence, both in investment and M&A contexts, and has negotiated multimillion-dollar domestic and cross-border licenses as well as technology-transfer agreements involving leading universities and research institutions.

Biography



Andrew J. Gray IV

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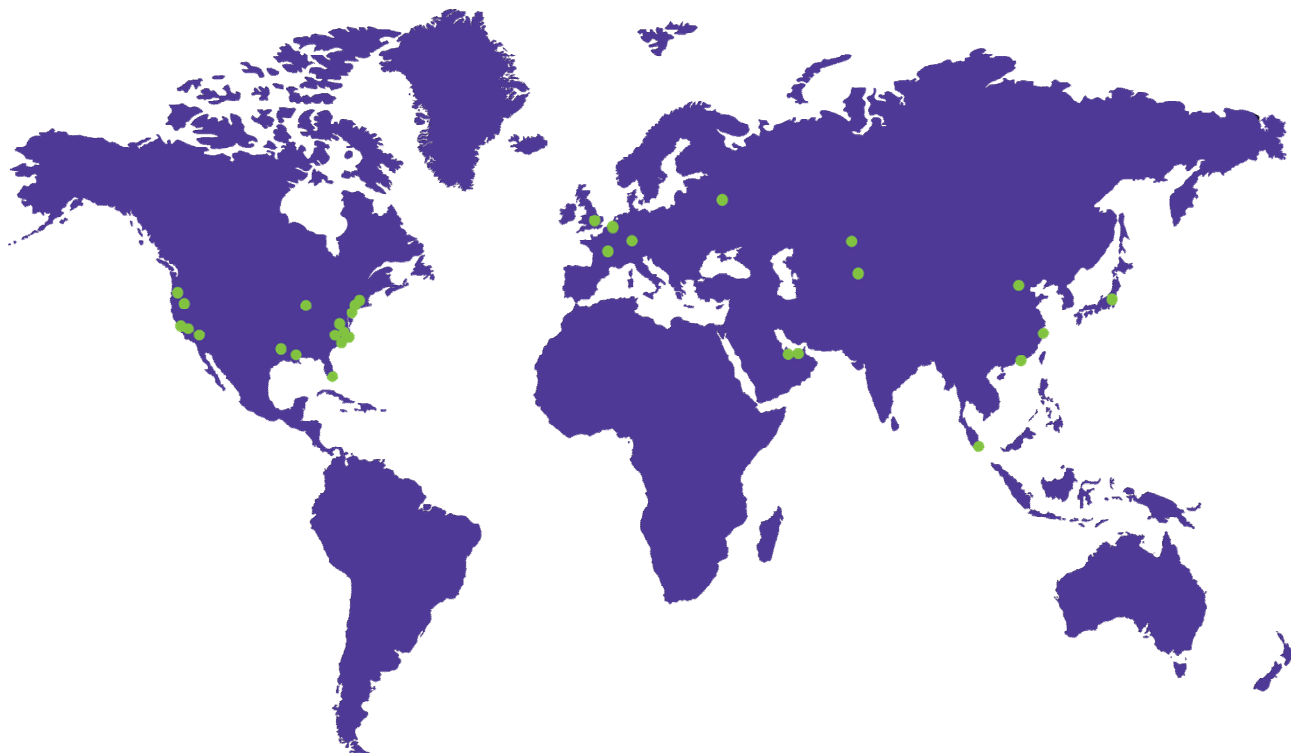
Serving as the leader of Morgan Lewis's semiconductor practice and as a member of the firm's fintech and technology practices, Andrew J. Gray IV concentrates his practice on intellectual property (IP) litigation and prosecution and on strategic IP counseling. Andrew advises both established companies and startups on Blockchain, cryptocurrency, computer, and Internet law issues, financing and transactional matters that involve technology firms, and the sale and licensing of technology. He represents clients in patent, trademark, copyright, and trade secret cases before state and federal trial and appellate courts throughout the United States, before the US Patent and Trademark Office's Patent Trial and Appeal Board, and before the US International Trade Commission.

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