Morgan Lewis

PROTECTING DIGITAL HEALTH INTELLECTUAL PROPERTY

TECHNOLOGY MAY-RATHON

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About Morgan Lewis Tech May-rathon

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This year is our 6th annual May-rathon and we are offering more than 15 in-person and virtual events.

Recordings of all of our tech May-rathon programs can be found at https://www.morganlewis.com/topics/technology-may-rathon

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Welcome

Hello and thank you for joining us for this event in our Technology May-rathon series.

For more information about our upcoming Technology May-rathon events, please visit the Morgan Lewis website.

This event is audio listen only, so feedback and questions will not be taken verbally. We will have interactive Q&A capabilities that are available throughout the webinar. The Q&A tab is located on the bottom right hand side of your screen. Please type your questions in the space provided and click Send.

Participation in this webinar is mandatory for all attendees who requested CLE credit. We will provide the CLE code at the end of the presentation.

We would appreciate any feedback you have on today's presentation, and any other topics we should consider adding to our curriculum.

With that out of the way, let's begin.

General Overview

- Introduction to Digital Health
- Digital Health Judicial Landscape
- Patent Prosecution Strategies in view of Judicial Landscape
  - USPTO Art Group Shopping
  - Map Invention onto a USPTO Guideline Example of a Patentable Claim
- Digital Health Litigation

INTRODUCTION TO DIGITAL HEALTH - WHAT IS DIGITAL HEALTH?

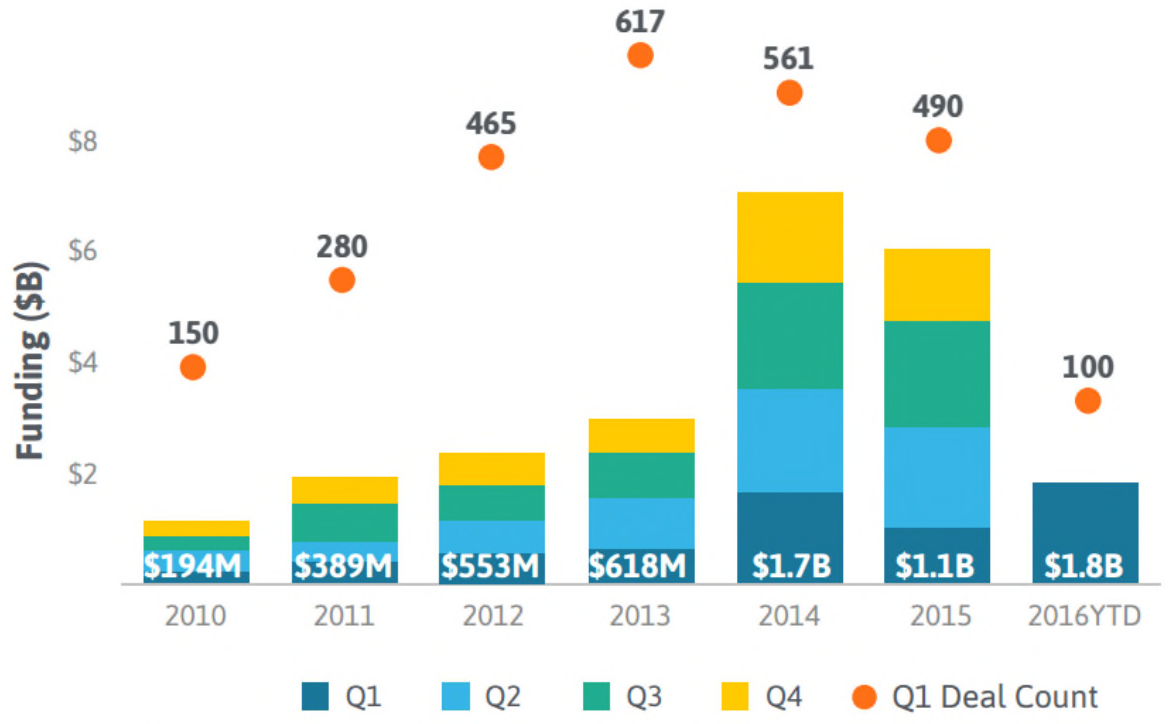
What is Digital Health?

- The use of technology to address the health problems and challenges faced by patients, doctors, and those in the healthcare field.
- Multifaceted practice:
  - Health IT
  - mHealth (mobile health)
  - **Health and Wellness Apps**
  - Big Data
  - Telehealth/Connected Health
  - Medical Imaging
  - EMR/HER
  - eHealth
  - Personal Genomics
  - Health 2.0/Social Media

Digital Health Funding Overview

Digital Health Funding Snapshot Year Over Year (2016 YTD)

2016 starts off with a record setting $1.8B quarter. While 22% of that funding was directed to the insurance upstart, Oscar Health, the remaining funding was distributed in increasingly mature rounds.



Source: StartUp Health Insights | startuphealth.com/insights Note: Report based on public data on seed, venture, corporate venture and private equity funding only through March 30, 2016.

2016 Active Markets in Digital Health

The **Top 10 Most Active Markets** of **2016**

Big data / analytics is the most active market, partially due to Flatiron's $175M raise, increasing 42% over Q1 2015. Average deal sizes fluctuate substantially based on the market.

	Market	Total Raised YTD	Deal Count	Average Deal Size
1	Big Data / Analytics	$286M	8	$35.7M
2	Medical Device	$198M	11	$17.9M
3	Patient / Consumer Experience	$195M	20	$9.8M
4	Personalized Health / Quantified-Self	$162M	11	$14.7M
5	Wellness	$141M	8	$17.7M
6	Workflow	$132M	17	$7.8M
7	Clinical Decision Support	$109M	8	$13.6M
8	E-commerce*	$102M	5	$16.9M
9	Population Health	$26M	5	$5.2M
10	50Plus	$6M	2	$2.9M

*Excludes outliers: $400M Oscar

Source: StartUp Health Insights | startuphealth.com/insights Note: Report based on public data on seed, venture, corporate venture and private equity funding only through March 30, 2016. © 2016 StartUp Health LLC

DIGITAL HEALTH JUDICIAL LANDSCAPE

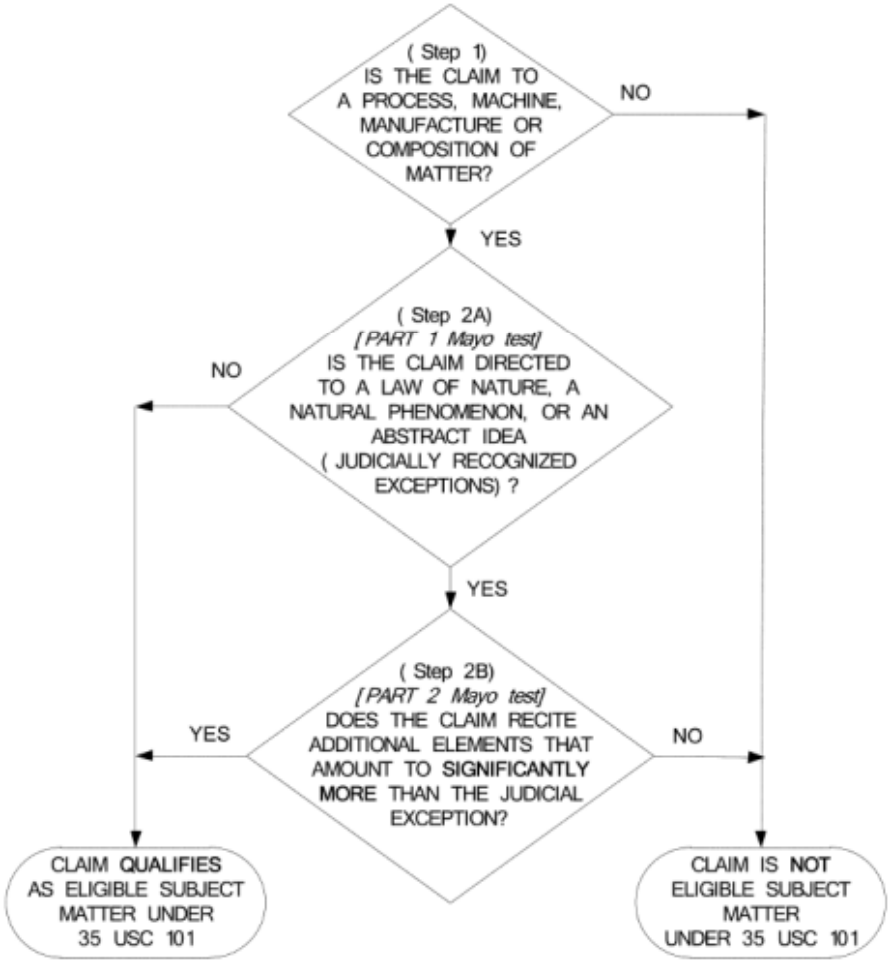
- ***MAYO COLLABORATIVE SERVS. V. PROMETHEUS LABS., INC.***
  - 132 S. Ct. 1289, (2012)
- ***ARIOSA DIAGNOSTICS INC. V. SEQUENOM, INC.***
  - 788 F.3d 1371 (Fed. Cir. 2015)
- ***ALICE CORP. PTY. V. CLS BANK INT'L***
  - 134 S. Ct. 2347, (2014)
- ***EXERGEN CORPORATION V. KAZ USA, INC.***
  - 2016 WL 1181658, (D. Mass.)

Mayo v. Prometheus

- Invention: Established a threshold level of dosage to determine the right level of metabolites to administer of thiopurine drugs in treatment of autoimmune diseases.
  - Using metabolites to treat autoimmune diseases was already known to those in the art
  - However, determining the right dosage amount was unknown.
- Is this patentable?
  - Because the methods for determining the threshold level are already well known in the art, this is simply telling doctors to engage in well-understood, conventional activity previously used by scientists in the field.
- Unanimous Supreme Court decision: the personalized method dosing process is not patentable because the process is *effectively* an unpatentable law of nature.
  - 1) A newly discovered law of nature is not patentable
  - 2) the application of newly discovered laws of nature are also unpatentable if the application relies on elements that are already well-known in the art

Mayo v. Prometheus Flowchart

USPTO "2014 Interim Guidance on Patent Subject Matter Eligibility"



Ariosa Diagnostics, Inc. v. Sequenom, Inc.

- Patent-in-Suit: U.S. No. 6,258, 540 "Non-invasive prenatal diagnosis"
  - An early pregnancy test, that tests fetal genetic conditions while avoiding dangerous or invasive techniques that are riskier to the mother and the fetus, using a method of testing cell-free-fetal DNA (cffDNA) which was discovered to exist in a pregnant mother's blood plasma
  - Technicians can test a pregnant mother's blood sample, keep the non-cellular portion, amplify the genetic material, and identify the maternal DNA.
- Is this patentable subject matter?

Case History: *Ariosa v. Sequenom*

- District Court:
  - The ’540 patent was not directed to patentable subject matter, because the only “inventive” component of the process is to apply a well-understood process to paternally inherited cffDNA, a natural phenomenon.
- On Appeal at the Federal Circuit:
  - Federal Circuit held it is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon.
  - Not transformative in application: Because the method steps were well-understood, the method of detecting the paternally inherited cffDNA is not new and useful.

Sequenom Inc. Petition for Writ of Certiorari

- Sequenom Inc. filed a petition for Writ of Certiorari in the Supreme Court of the United States of America challenging the Federal Circuit decision
  - Sequenom argues the language of *Mayo* invalidates an otherwise plainly meritorious invention.
  - **Question Presented:**
    - Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

Alice Corp. v. CLS Bank International

- Alice Corporation owned patents on electronic methods and computer programs for financial-trading systems; the trades between two parties were to exchange payment are settled via a third party in a way that reduces "settlement risk"
  - U.S. Patent No. 5,970,479 "Methods and Apparatus Relating to the Formulation and Trading of Risk Management Contracts"
  - U.S. Patent No. 6,912,510 "Methods of Exchanging an Obligation"
  - U.S. Patent No. 7,149,720 "Systems for Exchanging an Obligation"
  - U.S. Patent No. 7,725,375 "Systems and Computer Program Products for Exchanging an Obligation"

Alice Corp. v. CLS Bank International

- Supreme Court unanimously invalidated the patent
- Expanded on the two-part test from *Mayo* for determining whether claims are directed to an abstract idea and thus are unpatentable:
  - (i) Determine whether the claim is directed to a patent-ineligible concept (judicial exception) and, if it is,
  - (ii) examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application (significantly more).

Alice Corp. v. CLS Bank International

- Considerations that have been found to render a claim significantly more than the judicial exception:
  - **Improvement to another technical field**
  - **Adding unconventional steps that confine the claim to a particular application**
  - **Meaningful limitations beyond those that generally link the judicial exception to a particular technical environment**
  - **A new combination of conventional steps where the individual steps were known but the ordered combination was not known (*Diehr*)**
  - **Transformation of a particular article**

Exergen Corporation v. Kaz USA, Inc.

- U.S. Patent Nos. 6,292, 685 and 7,787,938 "Temporal Artery Temperature Detector"
  - non-invasive methods and devices for accurately determining a person's deep body temperature by taking measurements of the skin temperature over an artery, preferably the temporal artery.
- Plaintiff brought suit for infringement
- Defendant moved for summary judgment of invalidity with respect to certain claims in two patents.

Exergen Corp. v. Kaz USA

- Citing *Mayo* and *Alice,* the court analyzed the invention for an "inventive concept":
  - Exergen's "body temperature detector" built on two previously known but unrelated natural laws or phenomena—the absence of arteriovenous anastomoses (AVAs) that would create a relatively constant blood flow in certain arteries close to the skin surface, including the temporal artery, and the principles of thermodynamics embodied by the heat transfer equations disclosed in the patents
- Here, the claims avoided the pitfalls of *Alice* and *Mayo*:
  - the claims, as asserted, do not attempt to appropriate or cordon off the development by others of ideas based on either or both of these principles, citing *Alice*, 134 S.Ct. at 2354–2355
  - The claims do not simply state a law of nature and say "apply it," citing *Mayo*, 132 S.Ct. at 1294
- **Held: Patent claims directed to patentable subject matter**

Exergen Corp. v. Kaz USA Continued

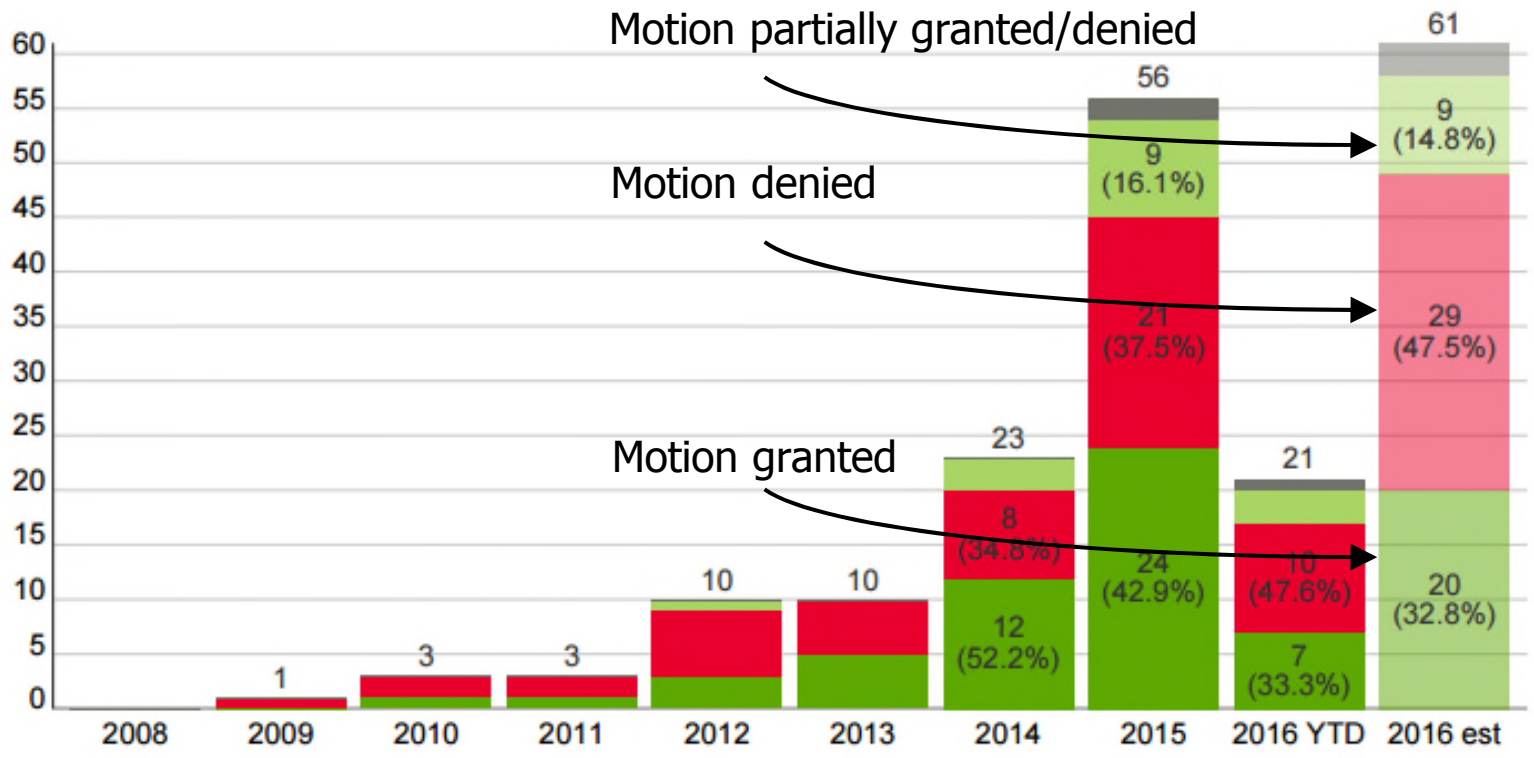
- The teaching in this case, it should be emphasized, is not that novel combinations of natural phenomena are patentable without more, although they might possibly be in some circumstances.
- Rather ***Mayo*** requires that a second question be asked: What else is there in the claims besides the recitation of laws of nature?
  - The asserted claims each recite a subset of three additional steps—moving while (laterally) scanning, obtaining a peak temperature reading, and obtaining at least three readings per second
  - Although well-known generally in the field of thermochemistry, there is **no evidence in the record that these steps were "well-understood, routine, [or] conventional[ly]" used to detect arterial temperature beneath the skin before the introduction of Exergen's invention.**

Post *Alice* Outcomes:

Motion Success

DocketNavigator analytics

Type of court document	Motion to Dismiss -- Failure to State a Claim, OR Motion for Judgment on the Pleadings
Legal issue	Unpatentable Subject Matter (35 USC § 101) (and no subcategories)



PATENT PROSECUTION STRATEGIES IN VIEW OF JUDICIAL LANDSCAPE

- ***USPTO ART GROUP SHOPPING***
  - *1631 Art group versus conventional Data Processing Art Groups*
- ***MAP INVENTION ONTO A USPTO GUIDELINE EXAMPLE OF A PATENTABLE CLAIM***
  - *Transmission of Stock Quotes*
  - *Rubber Manufacturing*
  - *Diagnosing and Treating Julitis*
- ***ANALYZE CLAIMS ALLOWED BY YOUR EXAMINER IN OTHER CASES AND ARGUMENTS MADE IN SUCH CASES***
- ***HOLD TELEPHONIC EXAMINER INTERVIEWS TO REACH AGREEMENT***
- ***APPEAL CASE IF EXAMINER IS UNREASONABLE***

USPTO Art Group Shopping

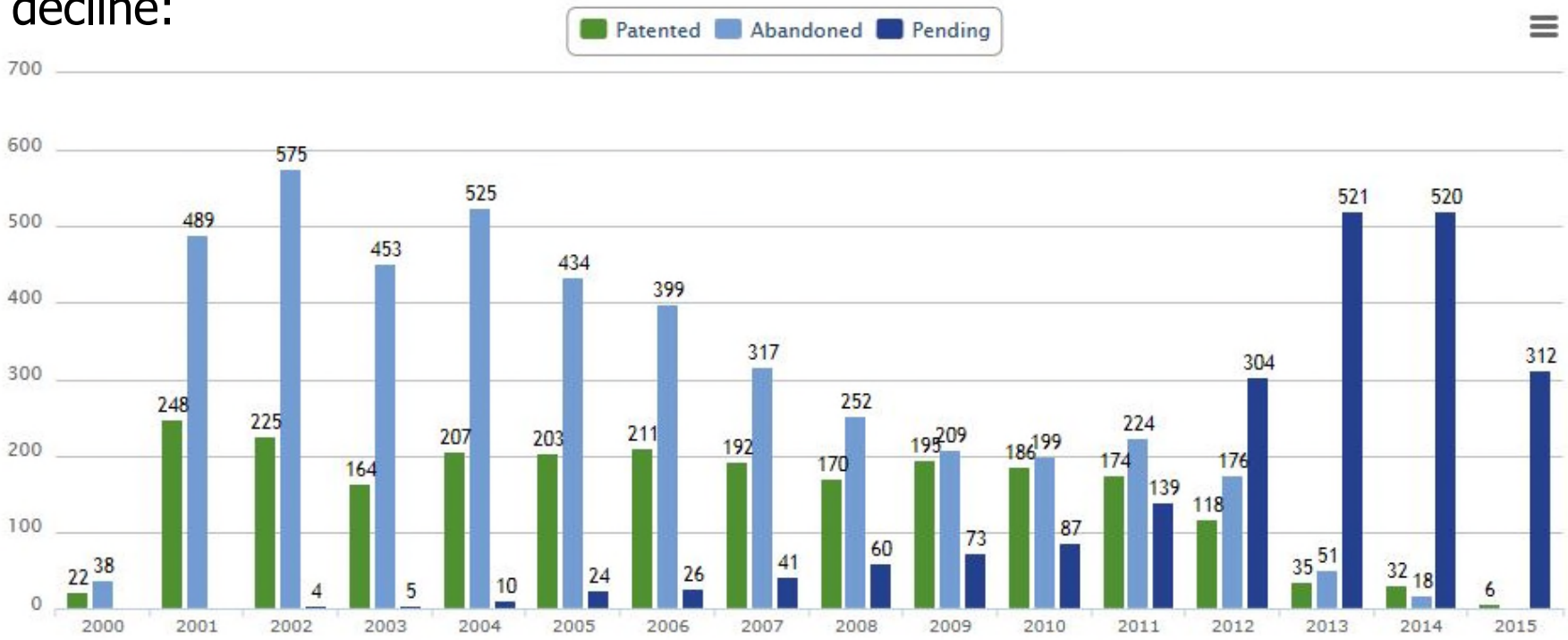
- The USPTO has used *Alice* as a basis to make 35 U.S.C. § 101 (unpatentable subject matter) rejections.
- Since *Alice*, the number § 101 rejections at the USPTO has increased, but these rejections are not uniformly applied across art groups

Percent of all Actions with § 101 Rejections

	Jan-12	Oct-12	Aug-13	May-14	Jul-14	Feb-15	Mar-15	Apr-15	May-15
1600 – Bio, Genes & O. Chem.	6.81%	8.02%	8.73%	12.93%	13.55%	13.99%	10.89%	12.41%	11.86%
1700 – Chemical Material Eng.	2.54%	2.55%	2.02%	2.02%	2.12%	2.11%	2.59%	2.01%	2.04%
2100 – Computer Architecture	20.12%	25.44%	17.20%	15.97%	16.51%	15.76%	10.69%	16.97%	12.44%
2400 -Networks, Video	18.83%	18.24%	12.02%	10.20%	10.22%	10.47%	9.09%	12.08%	10.95%
2600 - Communications	12.07%	10.69%	9.30%	8.28%	7.57%	7.84%	2.71%	7.79%	6.50%
2800 – Semicon., Elect. Opti.	3.27%	3.40%	2.24%	2.00%	2.25%	2.85%	2.39%	3.17%	3.40%
3600 – Trans, Const., Biz Methods	12.79%	12.15%	11.29%	10.90%	28.03%	42.38%	28.70%	32.59%	31.43%
3700 - Mechanical Eng. & Manuf.	4.89%	4.90%	3.97%	4.60%	5.51%	8.08%	6.21%	6.70%	5.78%

USPTO Art Group Shopping

- A prominent art group for digital health applications is the 1631 art group – "Data Processing: Measuring, Calibrating, Testing"
- The number of applications granted by the 1631 art group is on the decline:

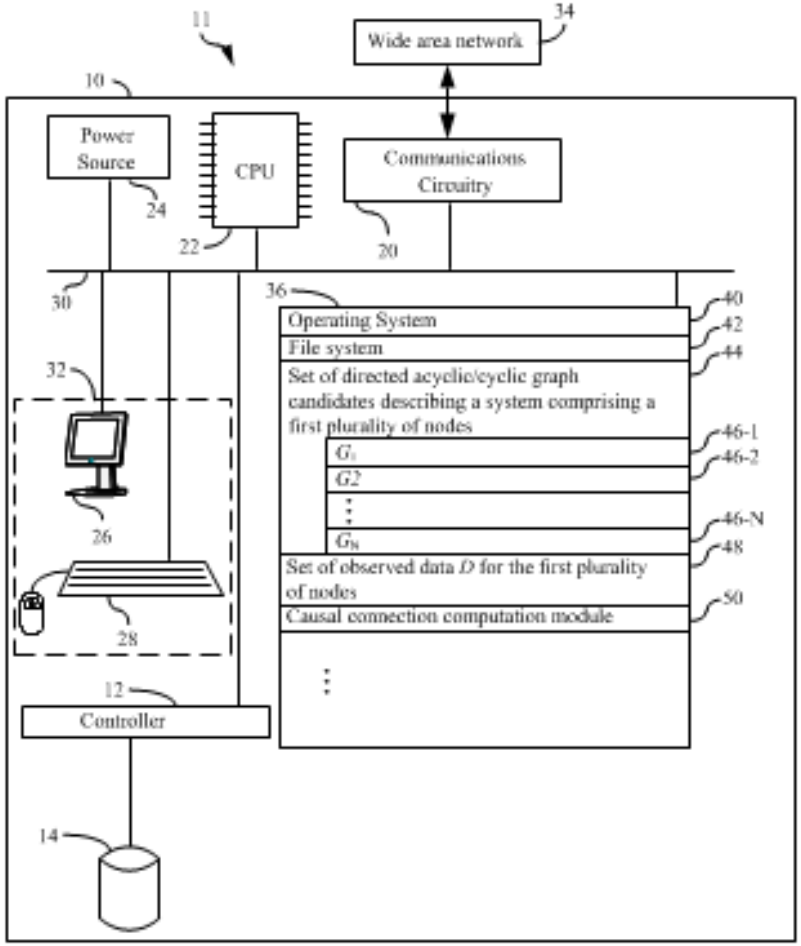


USPTO Art Group Shopping

- Given the disparate application of *Alice* across USPTO art units, art group shopping is advisable, particularly in view of the strict application of *Alice* guidelines in the 1631 Art Group where many digital health applications land
- Frame patent application from a computer science perspective, with diagrams of computer system and de-emphasis of biological components in abstract and claims of patent application in order to have application routed to a 2100 art group such as 2123 instead of a 1600 art group
- Once in an art group, roll out as necessary from the specification elements that do not narrow claims:
  - E.g.) upon entry into software art group (2100), add dependent claims directed to biological markers etc.
  - E.g.) conversely, upon entry into a bioinformatics art group (1600), add dependent claims directed to non-obvious sensor requirements, hardware requirements for data processing etc.

USPTO Art Group Shopping - software patent

WO2016/036958 A1
Published 10 March 2016



1. A method of perturbing a system, the method comprising:
at a computer system comprising hardware memory and one or more hardware processors:
(A) obtaining a set of directed acyclic/cyclic graph candidates $\{G_1, \ldots, G_N\}$ for the system, wherein
N is a positive integer greater than 1, and
each respective directed acyclic/cyclic graph candidate G_i in at least a subset of $\{G_1, \ldots, G_N\}$ includes one or more causal relationships […] and wherein two or more nodes in each respective directed acyclic/cyclic graph candidate G_i in at least a subset of $\{G_1, \ldots, G_N\}$ are Markov equivalent;
(B) obtaining observed data *D* […]

USPTO Art Group Shopping - software patent

- *Enfish LLC v. Microsoft Corp*., Fed. Cir. 2015-1244, May 12, 2016
- Reversed a lower court's decision that two database patents asserted against Microsoft Corp. are invalid under Alice, finding that they are not directed to abstract ideas
- Claims directed to format for a database "self-referential table"
- "Nor do we think that claims directed to software, as opposed to hardware, are inherently abstract and therefore only properly analyzed at the second step of the *Alice* analysis. Software can make non-abstract improvements to computer technology just as hardware improvements can"
- "we find that claims at issue in this appeal are not directed to an abstract idea within the meaning of *Alice*. Rather, they are directed to a specific improvement to the way computers operate, embodied in the self-referential table."

Map Invention onto a USPTO Guideline Example of a Patentable Claim

- *Examples: Nature-Based Products* (NBP), issued December 16, 2014 (Examples NBP-1 through NBP-10)
- *Examples: Abstract Ideas* (AI), issued January 27, 2015 (Examples AI-1 through AI-8)
- *Computer Based Training & CBT Slides* (CBT), issued March 6, 2016 (Examples CBT1 and CBT-2)
- *July 2015 Update Appendix 1: Examples*, issued July 30, 2015 (Examples 21 through 27)
- *Subject Matter Eligibility Examples: Life Sciences*, issued May 4, 2016 (Examples 28 through 33)
- "it would be acceptable for applicants to cite an example in support of an argument for finding eligibility in an appropriate factual situation"

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 21

- Example 21 of the July 2015 Update Appendix 1 of the *2014 Interim Guidance Matter Eligibility*, based upon the 35 U.S.C. § 101 analysis in *Google Inc. v. Simpleair, Inc.*, Covered Business Method Case No. CBM 2014-00170 (Jan. 22, 2015)
- The example claim recites a series of acts for distributing stock quotes to selected remote devices
- The recited steps of comparing and organizing data for transmission are a mental process and thus abstract.
- The recited claim recites the additional limitations such as using a transmission server to store subscriber preferences, transmitting a stock quote alert from the transmission server over a data channel to a wireless device, and providing a stock viewer application that causes the stock quote alert to display on the subscriber computer
- It was found that these additional limitations, although conventional in their own right, **when viewed as an ordered combination**, would make the claim patentable because they **do more than generally link the use of the abstract idea** (the general concept of organizing and comparing data) **to the Internet**, because they solve an Internet-centric problem with a claimed solution that is necessarily rooted in computer technology

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 21

- Example 21: Claim 2 (patentable ordered combination of conventional components):

2. A method of distributing stock quotes over a network to a remote subscriber computer, the method comprising:

providing a stock viewer application to a subscriber for installation on the remote subscriber computer;

receiving stock quotes at **a transmission server** sent from a data source over the Internet, **the transmission server comprising a microprocessor and a memory that stores the remote subscriber's preferences** for information format, destination address, specified stock price values, and transmission schedule, wherein the microprocessor

filters the received stock quotes by comparing the received stock quotes to the specified stock price values;

generates a stock quote alert from the filtered stock quotes that contains a stock name, stock price and a universal resource locator (URL), which specifies the location of the data source;

formats the stock quote alert into data blocks according to said information format; and

transmits the formatted stock quote alert over a wireless communication channel to a wireless device associated with a subscriber based upon the destination address and transmission schedule,

wherein **the alert activates the stock viewer application to cause the stock quote alert to display on the remote subscriber computer and to enable connection via the URL to the data source over the Internet when the wireless device is locally connected to the remote subscriber computer and the remote subscriber computer comes online**.

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 25

- Example 25 of the July 2015 Update Appendix 1 of the *2014 Interim Guidance Matter Eligibility*, based upon the 35 U.S.C. § 101 analysis in *Diamond v. Diehr*, 450 U.S. 175 (1981)
- The invention improves upon conventional molding processes by constantly measuring actual temperature in a rubber mold using a thermocouple, and automatically feeding these measurements into a standard computer that repeatedly recalculates cure time using the Arrhenius equation. The Arrhenius equation had long been used to calculate the rubbermolding cure time.
- The recited mathematical relationship and the claim limitations of performing repetitive calculations and comparisons between the calculated time and the elapsed time are all deemed abstract.
- However, the **combination of all the steps taken together**, including the constant temperature determination of the mold, the repetitive calculations and comparisons, and the opening of a press based on the calculations, **amount to significantly more than** simply calculating the mold time using the Arrhenius equation because the claim does not merely recite the equation in isolation, but integrates these ideas into the molding process.
- The additional steps specifically relate to the particular variables used, how the variables are gathered, the process by which the rubber is molded and cured, and how the result of the cure time calculation is used. The totality of the steps act in concert to **improve another technical field**, specifically the field of precision rubber molding, by controlling the operation of the mold.

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 25

- Example 25 of the July 2015 Update Appendix 1 of the *2014 Interim Guidance Matter Eligibility*, based upon the 35 U.S.C. § 101 analysis in *Diamond v. Diehr*, 450 U.S. 175 (1981):

1. A method of operating a rubber-molding press for precision molded compounds withthe aid of a digital computer, comprising:

providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press,

initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

constantly providing the computer with the temperature (Z),

repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is ln v = CZ+x, where v is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

opening the press automatically when a said comparison indicates equivalence.

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 29

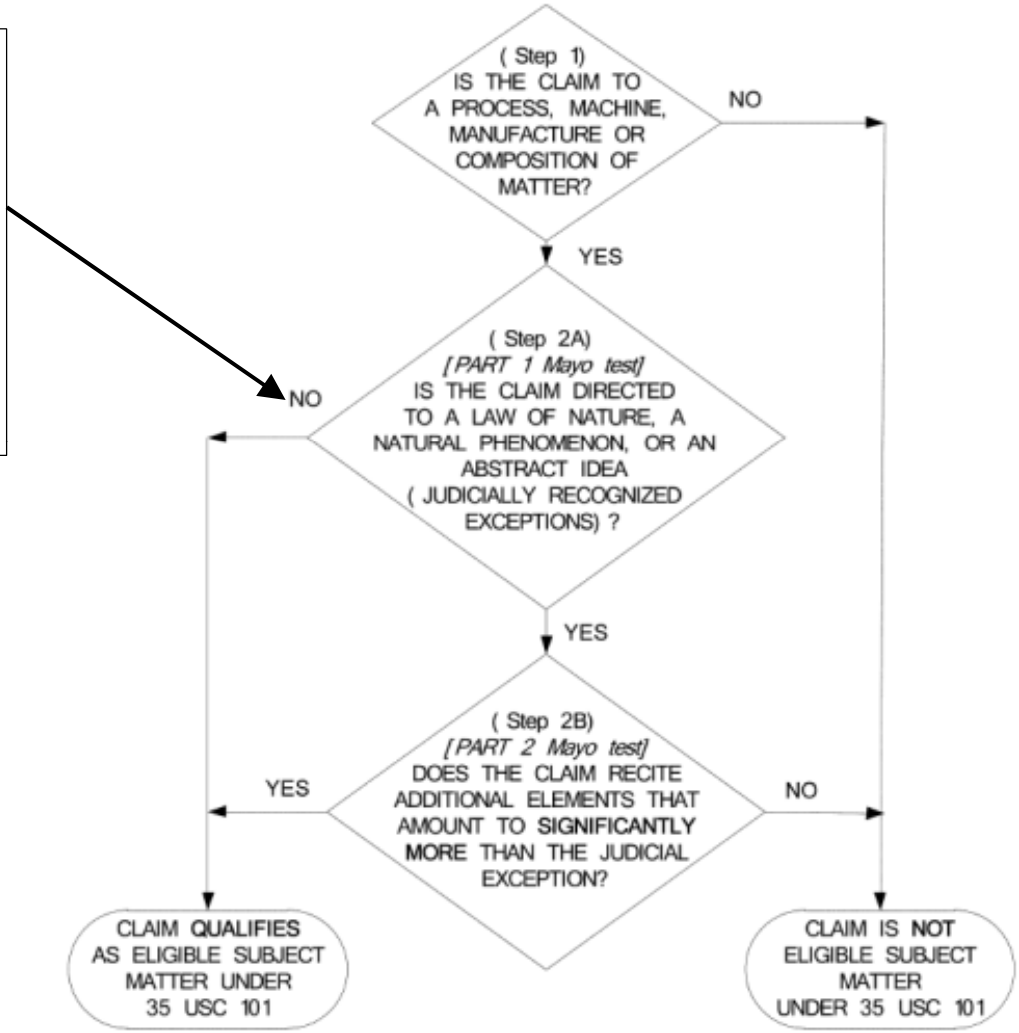
- Example 29 of the *Subject Matter Eligibility Examples: Life Sciences*, issued May 4, 2016
- Invention: discovery that the presence of the protein "JUL-1" in a person is indicative that the person has julitis. Julitis patients have JUL-1 in their plasma, skin, hair and nails, but this protein is not found in persons who do not have julitis.
- Applicant discloses detecting JUL-1 using anti-JUL-1 antibodies that may be naturally occurring (*e.g.*, a human anti-JUL-1 antibody isolated from a patient known to have julitis), or non-naturally occurring (*e.g.*, a porcine anti-JUL-1 antibody created by injecting pigs with JUL-1, or a specific monoclonal antibody named "mAb-D33" that was created by applicant).
- Prior to invention, the use of porcine antibodies in veterinary therapeutics was known to scientists in the field, but were not conventionally used to detect JUL-1.
- Hypothetical claim:

    1. A method of detecting JUL-1 in a patient, said method comprising:
        a. obtaining a plasma sample from a human patient; and
        b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

- Patent eligible: *Mayo v. Prometheus*, 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Accordingly, the claim is not directed to an exception (*Step 2A: NO*).

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 29

1. A method of detecting JUL-1 in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient; and
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.



Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 29

- Hypothetical claim:

> 2. A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

- Must do a Mayo step 2B analysis because of step "c" of claim 2.
- Detecting whether JUL-1 is present in the plasma sample merely instructs a scientist to use any detection technique with any generic anti-JUL-1 antibody. At this high level of generality, there is no meaningful limitation, such as a particular or unconventional machine or a transformation of a particular article, in this step that distinguishes it from well-understood, routine, and conventional data gathering activity
- Patent ineligible

Map Invention onto a USPTO Guideline Example of a Patentable Claim – Example 29

- Hypothetical claim:

> 3. A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a **porcine** anti-JUL-1 antibody and detecting binding between JUL-1 and the **porcine** antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

- Must do a Mayo step 2B analysis because of step "c" of claim 2.
- Step b requires detecting using a **porcine** anti-JUL-1 antibody. There is no evidence that porcine antibodies were routinely or conventionally used to detect human proteins such as JUL-1
- Patent eligible

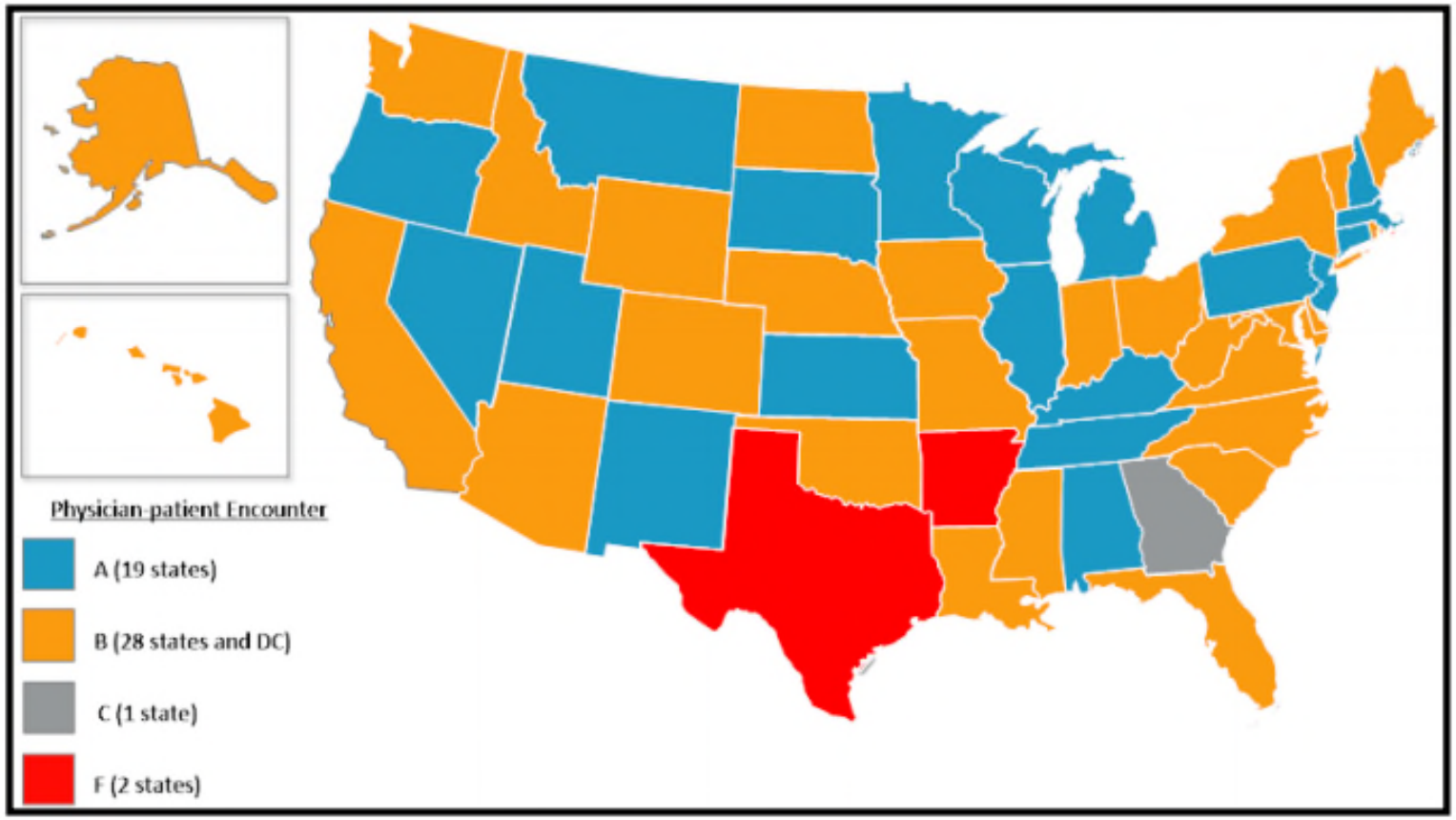
DIGITAL HEALTH LITIGATION

Telemedicine Regulation

- Examples of Telemedicine Companies
  - Teladoc
    - One of the largest telemedicine providers
    - Patients consult with doctors over the phone and receive a prescription
    - Generally no more than $40 per visit
    - Employers or insurers have deals with teledoc and can contact 24/7
    - Limits on what drugs can be prescribed (no opiates or lifestyle drugs, for example)
  - American Well
    - Utilizes an app interface
    - Users select from available physicians
    - Users then conference with doctors via video
  - Virtuwell
    - Patients fill out an online questionnaire "What do you think you have"
    - Questionnaire address 40-50 various questions
    - Nurse practitioner sends patients a treatment plan & prescription

Regulation of Telemedicine

State Ratings – Physician-Patient Encounter via Telemedicine



Source: American Telemedicine Association, M. http://www.americantelemed.org/policy/state-policy-resource-center

Teladoc Texas Litigation

- Teladoc filed a lawsuit against the Texas Medical Board for violations of antitrust law
  - Teladoc asserts the Texas Medical Board of artificially limiting supply of physicians & increasing prices.
  - Texas Medical Board drafted new rules in June 2015 mandating that only physicians who have seen patients in person may then see them remotely
- Teladoc secured a victory winning an injunction to stop Texas' latest proposed rules from taking effect
- In December 2015 a Judge denied the Texas Medical Board's request to dismiss the lawsuit
- In January 2016, the Texas Medical Board announced it plans to appeal the federal judge's decision

American Well Patent Litigation

- American Well is a telemedicine company that owns software which allows doctors to videoconference with patients
- American Well owns 25 patents and has 26 patent applications related to its technology
- Issued patents include:
  - 8,600,773 patent titled "Tracking the availability of service providers across multiple platforms,"
  - 8,510,130 patent titled "Documenting remote engagements," and
  - 8,719,047 patent titled "Patient directed integration of remotely stored medical information with a brokerage system."

American Well v. Teladoc Litigation

- Suit regards US Patent No. 7,590,550 titled "Connecting consumers with service providers."
  - related to the algorithms American Well uses to match patients with providers
  - Claim infringement of Claims 10, 11, 20 & 30.
- Claim 10 describes a computer implemented method comprising
  - "accessing a ***data repository that stores*** information pertaining to medical service providers, ***of the medical service providers for participating in a consultation; receiving in a*** computer,
  - ***indications that members of a pool of medical service providers have become presently available;***
  - ***receiving in the computer, a request from a consumer of services to consult with a medical service provider;***
  - ***identifying in the computer,channel between the consumer of services and the identified member of the pool."***
  - 550 Pat. Cl. 10. (emphasis in complaint)

Inter Partes Review

- What is Inter Partes Review
  - Trial proceeding conducted at the USPTO to review the patentability of patent claims
  - Only on grounds that can be raised under §102 (novelty) or §103 (obviousness)
  - Only on the basis of prior art: patents or printed publications
  - Limitations related to co-pending litigation
- Benefits of Inter Partes Review
  - Timely resolution – within 18 months
  - Cost reduction
  - "Broadest reasonable construction" of claims can be beneficial

Inter Partes Review of '550 Patent

- March of 2015, Teladoc filed a request for the PTAB to IPR of four claims within the '550 Patent.
- Argues that the claims of the '550 patent assert basic concepts of telemedicine.
  - require a consumer make a request to consult with a medical service provider, a computer identifies the available provider and establishes a real time communication channel between the consumer and provider, which are basic concepts of telemedicine – *Teladoc v. American Well,* IPR2015-00924
- Argues claims are obvious & anticipated in light of prior art
- PTAB denied review for obviousness, but granted review for anticipation.

Biography

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Brett Lovejoy advises clients on many aspects of intellectual property ownership and protection. Central to his practice is helping clients create patent portfolios. This includes writing, prosecuting patent applications in the United States, while coordinating clients' worldwide patent protection efforts. Brett also provides strategic counseling to his clients, conducts IP due diligence, and offers IP opinions.

Biography

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Angela M. Gandhi concentrates her practice on intellectual property matters, including litigation, prosecution, and enforcement. Angela represents clients in litigation matters in federal district court, federal courts of appeal, and administrative proceedings in the Trademark Trial and Appeal Board and International Trade Commission.

Thank You

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