



Mobile Medical Applications: Navigating Regulatory, Profitability, and Patentability

September 22, 2016

Market Observations

- Digital Health - Patient & Consumer Experience; Wellness, Personalized Health, Big Data Analytics
- 2015
 - Over 150 M&A transactions in Digital Health Space
 - \$4.5B invested in Digital Health Companies
 - 5 IPOs including Fitbit & Teladoc
- 2016 (as of August 2016)
 - \$3.9B invested
 - Over 65% of Deal Volume in Early Stage Companies

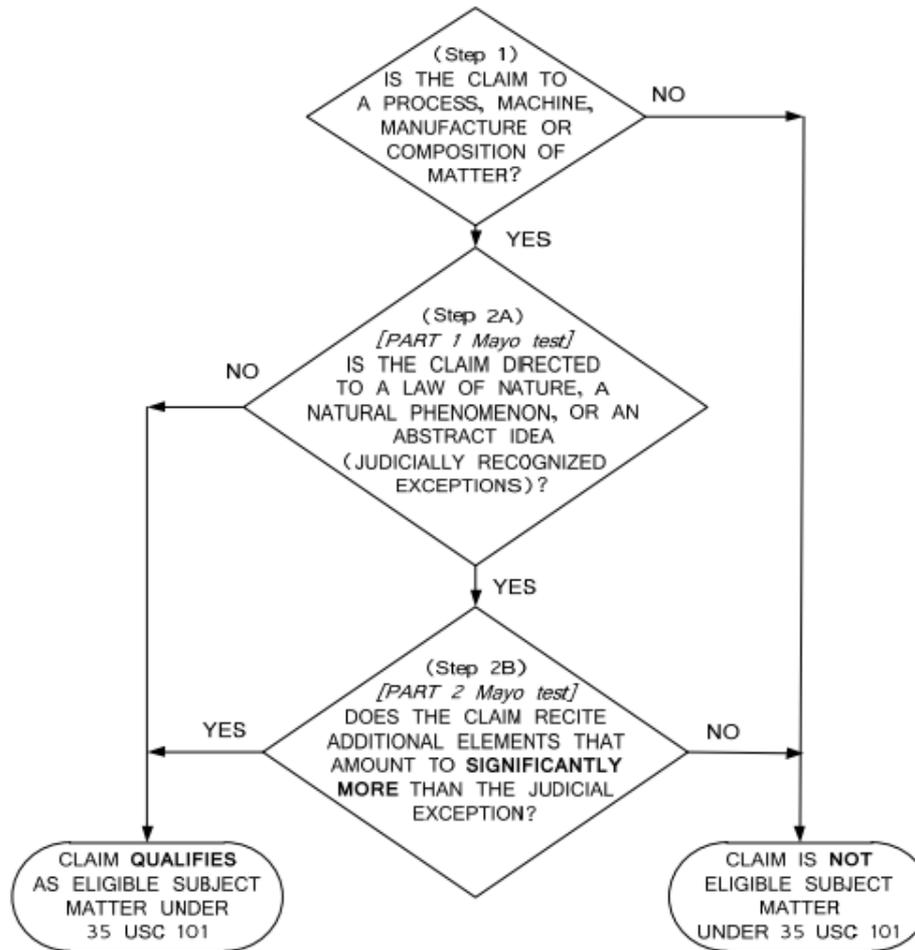
Source: Ropes & Gray Podcast:

<https://www.ropesgray.com/newsroom/alerts/2016/August/Digital-Health-Pulse-Regulatory-and-Transactional-Developments.aspx>

Disruptive Forces

- Rapid Market Changes
 - Ability to collect data, process & apply learning to data
 - Technology & tools for monitoring lifestyle & health
- Factors for Success
 - Market acceptance of products
 - Address legal & regulatory hurdles
 - Data & privacy security
 - Value proposition
- Legal
 - Regulatory Issues (Federal & State level)
 - Demise of patent protection

Alice Corp. v. CLS Bank International (2014)



Test Applied – Federal Courts & USPTO

- **Step 1**: Determine whether the claims at issue are directed to a patent-ineligible exception?
 - Characterization of the claims at too high a level of abstraction
 - Examiners gloss claims broadly, divorced from context and details
 - Examiners quote entire claim as abstract idea
 - Often disembowels the claim
 - Examiners routinely ignore non-preemption argument
- **Step 2** - Consider the elements of each claim both individually and as a whole to determine whether the claims recite “significantly more” (transform the nature)
 - Nothing of the claim left over that could constitute “something more”
 - Burden on Patentee to prove eligibility

Subject Matter Ineligibility Statistics

- Federal Courts
 - Invalidity Findings about 70% Overall
 - 90% @ Federal Circuit (45/50)
 - 66% @ District Courts (187/282)
 - 68% Motion on Pleadings (128/188)
- Federal Courts By Patent Class
 - 67% Software patents invalid (195/293)
 - 79% Business method patents invalid (105/133)
- PTAB
 - 97% CBM Final (89/92)

Source: *Alice Storm in the Dog Days of Summer*:

<http://www.bilskiblog.com/blog/2016/09/alicestorm-in-the-dog-days-of-summer.html> (Sept. 7, 2016)

Effects in USPTO

- Rejections Based on Alice (§ 101)
 - Over 36,000 published applications rejected
 - 5,000 abandoned
- Tech Center For Art Unit Technologies - Business Crypto, Business Processing, Price Reservations, E-Shopping, Finance & Banking, Health Care, Incentive Programs, Operations Research, POS Accounting
 - 89% on average Non-Final & Final Rejections
 - 2% difference between Non-Final & Final Rejections
 - 8% average allowance rate

Source: *Two Years After Alice: A Survey of the Impact of a "Minor Case" (Part 2)*,
<http://www.bilskiblog.com/blog/2016/06/two-years-after-alice-a-survey-of-the-impact-of-a-minor-case-part-2.html>

Notable CAFC Cases

- 5 out of 50 pro- § 101 decisions since the U.S. Supreme Court's landmark holding in *Alice v. CLS Bank* (June 2014)
 - *DDR Holdings, LLC v. Hotels.com, L.P.* (December 2014)
 - *Enfish, LLC v. Microsoft Corp.* (May 2016)
 - *BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC* (June 2016)
 - *Rapid Litigation Management Ltd. v. Cellzdirect, Inc.* (July 2016)
 - *McRO Inc. v. Bandai Namco Games America Inc.* (Sept. 13, 2016)

DDR Holdings Takeaways

- Finding of eligibility at step 2
- The claims are patentable “because they do not merely recite the performance of **some business practice known from the pre- Internet world** along with the requirement to perform it on the Internet.”
- “Instead, the claimed solution is necessarily rooted in computer technology in order to **overcome a problem specifically arising in the realm of computer networks.**”

Enfish Takeaways

- “We do not read *Alice* to broadly hold that all improvements in computer-related technology are inherently abstract and, therefore, must be considered at step two.”
- *“In this case . . . the plain focus of the claims is on **an improvement** to computer functionality itself not on economic or other tasks for which a computer is used in its ordinary capacity.”*
- Claims directed to **improvements** in computer operations may be patent eligible - can demonstrate that the claim does not recite a concept to previously identified abstract ideas
- Patent Eligibility can be found at Step 1

Bascom Takeaways

- Eligibility found at Step 2
- In performing an analysis of a claim for patent eligible subject matter, it is insufficient to analyze each limitation of the claim in isolation.
- “[t]he inventive concept inquiry requires more than recognizing that each claim element, by itself, was known in the art. As is the case here, an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces.”

McRO Takeaways

- Claims which focus on a specific means or method **that improves** the relevant **technology** may be patentable.
 - The prior art process even if automated by rules, would not be within the scope of the claims at issue
- Claims which are directed to a result or effect that itself is an abstract idea and merely invokes generic processes and machinery are not.
- Courts must avoid oversimplifying the claims and must NOT ignore claim requirements and specific, claimed features in both step one and step two
- Non-preemption offers another way of doing “streamlined eligibility analysis”

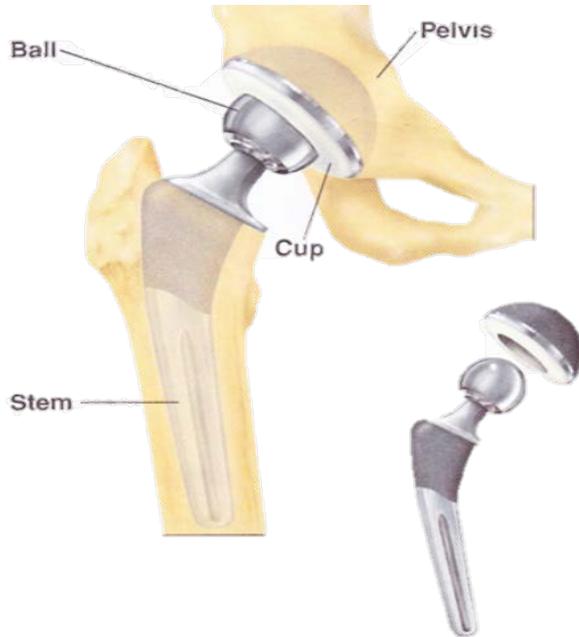
USPTO Guidelines

- May 2016 Memo to Examiner's:
 - Address the eligibility of every claim as a whole using the 2-step analysis
 - Step 1: Identify the judicial exception by referring to what is recited
 - How exception corresponds to concept that courts have identified as an abstract idea
 - Don't go beyond what courts have identified
 - Address Applicant's Challenge to identification of Abstract idea
 - Point to Case in which Abstract idea was identified
 - Step 2: identify additional elements beyond judicial exception
 - Explain why additional elements ***individually and as a combination*** do not result in significantly more than the judicial exception

Some Considerations

- Do the claims call on a computer to do what has routinely been done previously [**not eligible**]?
- While involving conventional pieces, do the claims define a non-conventional and non-generic arrangement [**may be eligible**]?
- Do the claims recite a means or method that provides an improvement to the *device* [**eligible**]?
- Do the claims focus on a specific means or method that improves the relevant *technology* [**eligible**], or, are they directed to a result or effect that merely invokes generic processes and machinery [**not eligible**]?
- Are the claims limited to a specific means or method to achieve a result [**eligible**] or do the claims preempt all means or methods to achieve such result [**not eligible**]?

Case Study #1 – Hip Replacement



Subject Matter Ineligible – Case Study # 1

A method comprising:

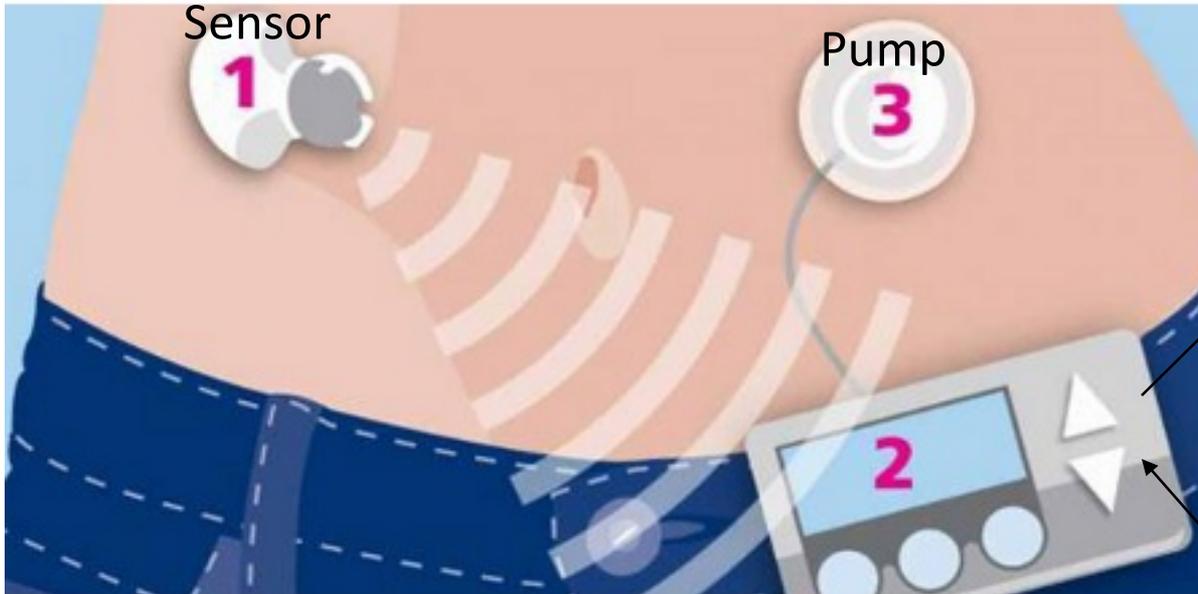
- receiving first diet and activity information via a user interface of a device from a user prior to a hip replacement surgery;
- receiving second diet and activity information via a user interface of the device from the user after the hip replacement surgery;
- communicating the first and second diet and activity information from the device via a network; and
- setting and communicating via the device one or more activity goals based on the received first and second diet and activity information.

Subject Matter Eligible? – Case Study # 1

A method comprising:

- receiving first diet and activity information via a user interface of a device from a user prior to a hip replacement surgery;
- receiving second diet and activity information via a user interface of the device from the user after the hip replacement surgery;
- communicating the first and second diet and activity information from the device via a network; and
- setting and communicating via the device one or more activity goals ***based on application of an L&A algorithm to the received first and second diet and activity information.***

Case Study #2 – Artificial Pancreas



Subject Matter Ineligible – Case Study # 2

A method for controlling a dosage of insulin to a patient, comprising:

- receiving from a continuous glucose monitor a series of data points indicative of a glucose level in the patient over time;
- receiving from a patient at a user interface data indicative of a meal event;
- determining a current glucose level of the patient and a rate of change of the glucose level based on the series of data points;
- determining an amount of insulin to be administered based on the current glucose level, the rate of change of the glucose level and the meal event data.

Subject Matter Eligible? – Case Study # 2

A method for controlling a dosage of insulin to a patient, comprising:

- receiving from a continuous glucose monitor a series of data points indicative of a glucose level in the patient over time;
- receiving from a patient at a user interface data indicative of a meal event;
- determining a current glucose level of the patient and a rate of change of the glucose level based on the series of data points;
- determining an amount of insulin to be administered ***based on an L&A predictive algorithm that is a function of*** the current glucose level, the rate of change of the glucose level and the meal event data; and
- **providing a signal to an insulin pump indicating the dosage of insulin to be provided to the patient.**

U.S. Pat. 9,439,602 – “Alert System for Hypo and Hyperglycemic Prevention Based on Clinical Risk”

1. A system for communicating glycemic risk to a patient, comprising:

a continuous glucose monitoring device that generates a series of data points indicative of a glucose level in the patient; and

processing circuitry configured to iteratively:

calculate a glucose level and a rate of change of the glucose level based on the series of data points;

determine a dynamic risk score based a nonlinear transformation that converts the current glucose level and the rate of change of the current glucose level to a dynamic risk score; and

select a color from a color scale based on the dynamic risk score, the color scale comprising a plurality of colors, each color indicative of one of a plurality of risk levels of the patient; and

display, on a user interface, the current glucose level, the rate of change, and the color indicative of one of a plurality of risk levels of the patient so that glycemic risk is communicated.

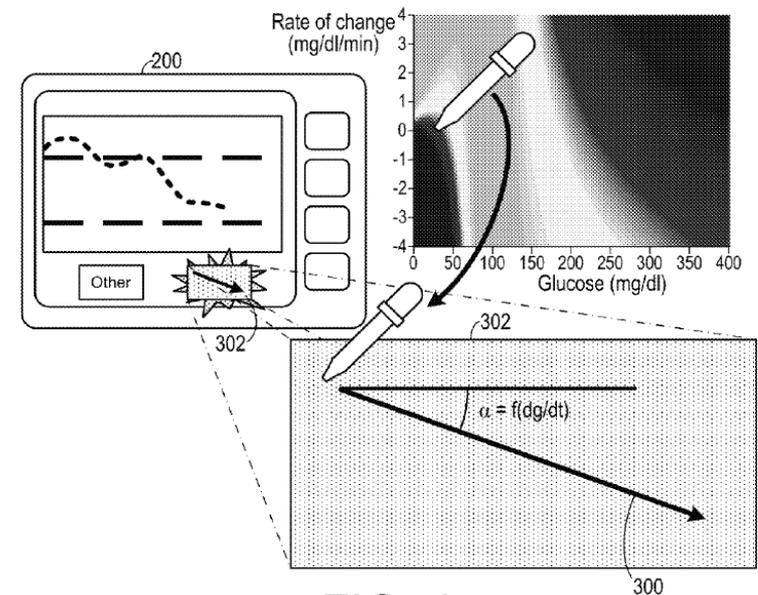
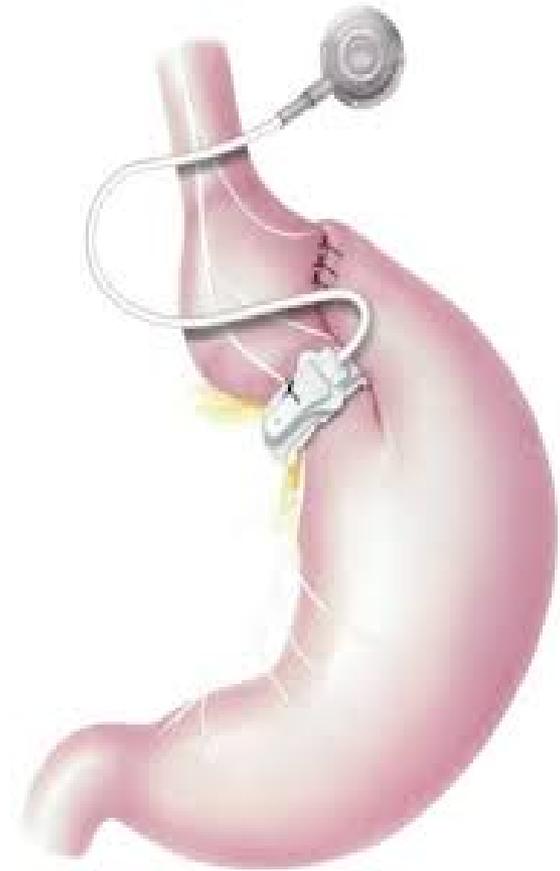


FIG. 4

Case Study #3 – Gastric Band



Not Subject Matter Eligible – Example 3

A computer-implemented method, comprising:

- receiving data from a sensor coupled to a gastric band implanted in a patient;
- providing the sensor data to the patient via a graphical user interface;
- communicating the sensor data by the device via a network;
- determining a drug dosage recommendation for the patient based on the sensor data;
- providing the drug dosage recommendation to the patient via a graphical user interface.

Subject Matter Eligible? – Example 3

A method for processing acoustic sensor data from a gastric band sensor, comprising:

- receiving **acoustic sensor data** from a sensor coupled to a gastric band implanted in a patient;
- **filtering the acoustic sensor data to isolate gastric blood flow information**;
- communicating the **gastric blood flow information** by a user interface;
- determining the drug dosage recommendation for the patient as a **function of the gastric blood flow** information;
- providing the drug dosage recommendation to the patient via a graphical user interface.

Practice Tips

- Watch the Courts
- Get Technical in Drafting the Patent Application
 - Describe in as much detail as possible
 - Real Flow Charts
 - Describe from views of 1) client 2) server 3) system/architecture
 - Describe tangible components, results, the device, hardware alternatives
 - Describe the specific rules that are applied to data to solve a particular problem.
 - overall architecture of the rule framework

Practice Tips

- Tell a Compelling Story in the Specification
 - Play up the **Improvements/Advantages** over what was done previously
 - Play up the distinctions between Man & Machine
 - identify differences between the automated computer process and a manually implemented version of the process
 - Discuss any obstacles overcome by automating the process
- Narrow the Claims
 - Should recite specific means or method that achieves the desired result, **that improves** the relevant technology
 - Independent claims recite the rules that are used (@ genus level)
 - Dependent claims recite the specific (@species) level
 - File multiple applications in parallel with narrow claims so that the sum of the parts equals the whole