101 Ineligibility

USPTO's Medical Device Partnership Meeting

September 16, 2014

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Mayo v. Prometheus

Representative Claim 1 of US 6,355,623:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Mayo v. Prometheus

- **District Court (Mar. 2008)** – Granted SJ that Prometheus method claims invalid under 35 U.S.C. §101 as claiming natural laws/phenomena, i.e., natural correlations.
- **CAFC I (Sept. 2009)** – Reversed, held claims pass Machine or Transformation test.
- **SCOTUS I (June 2010)** – GVR CAFC I in view of *Bilski v. Kappos*.
- **CAFC II (Dec. 2010)** – Again held claims pass Machine or Transformation test.

Mayo v. Prometheus

- **SCOTUS II (March 20, 2012)**
  - Reversed CAFC II and held Prometheus claims directed to laws of nature and invalid under §101 (132 S.Ct. 1289).
  - "If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."

Mayo v. Prometheus

- Simply appending conventional steps to laws of nature, natural phenomena, and abstract ideas does not confer patent eligibility.
  - Pre-solution activity = post-solution activity

- CAFC II transformation analysis is irrelevant.
  - Administering – refers to relevant audience
  - Determining – well-understood, routine, conventional pre-solution activity
  - Wherein – informs one of natural law

Mayo/Myriad Guidance

- http://www.uspto.gov/patents/announce/myriad-mayo.jsp
- http://www.uspto.gov/patents/law/comments/myriad-mayo_guidance_comments.jsp

CAFC I – CLS Bank v. Alice

- CAFC I - Reversed DDC, system, method and media claims not drawn to mere abstract ideas.
- "Patent eligibility must be evaluated based on what the claims recite, not merely on the ideas upon which they are premised."
- Interpreted shadow records of method claim as requiring computer implementation which is integral to the method.

CAFC II – CLS Bank v. Alice

- Rehearing en banc:
  - What test to determine whether a computer-implemented invention is a patent ineligible "abstract idea"; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?
  - In assessing patent eligibility of a computer-implemented invention, should it matter whether the claimed invention is a method, system, or storage medium; and should such be considered equivalent for 101 purposes?
- Held: Claims ineligible as being directed to an abstract idea.

SCOTUS – CLS Bank v. Alice

- Affirmed Federal Circuit
  - Claims ineligible as merely requiring generic computer implementation fails to transform an abstract idea into a patent-eligible invention.
- Citing Mayo, SCOTUS stated that the test is:
  - (1) Whether the claims are directed to a law of nature, natural phenomenon, or an abstract idea, then
  - (2) Whether the elements of the claim both individually and as an ordered combination transform the nature of the claim in to a patent-eligible application.
- General Computer Implementation akin to Conventional Steps of Mayo

Alice Guidance

- Only directed to claims involving abstract ideas.
- Supersedes Bilski Guidance
- Two-Part Test:
  - (1) Determine whether the claim is directed to an abstract idea;
  - (2) Do the claim elements, either individually or in combination add something “significantly more” than the abstract idea itself?

Alice Guidance Issues

- What is an abstract idea? How is an abstract idea different from a law of nature or a natural phenomenon?
- What is significantly more?
- Need detailed examples

- http://www.uspto.gov/patents/law/comments/alice_2014_comments.jsp

Medical Devices – Alice

- What test to determine whether a medical device-invention is a patent ineligible "law of nature or abstract idea"; and when, if ever, does the presence of device structure in a claim lend patent eligibility to an otherwise patent-ineligible law of nature or abstract idea?
- In assessing patent eligibility of a medical device-implemented invention, should it matter whether the claimed invention is a method, system, or device; and should such be considered equivalent for §101 purposes?

Medical Devices – Alice

- A method of health care delivery comprising:
  - delivering medical treatment to a patient via a medical treatment apparatus,
  - subjectively querying the patient via a health care treatment device associated with the medical treatment apparatus, wherein the step of subjectively querying the patient includes querying the patient about at least one of the following: patient's mental health and well being, quality of life, degrees of pain, and views on success of therapy,
  - accepting responses to those subjective queries,
  - correlating the responses to those subjective queries with operating conditions of the medical treatment apparatus so as to monitor at least one of the treatment of the patient and operation of the medical treatment apparatus.

Medical Devices – Mayo

- 1. A method for calculating a current sensitivity of a subject to administration of an anesthetic drug during surgery, said method comprising the steps of:
  - changing an infusion rate of the drug by a calibration amount during surgery for calibration, in addition to a therapeutic infusion of the drug;
  - detecting a change in an entropy signal in response to the infusion rate change; and
  - determining a current sensitivity of the subject to the drug based on the change in the entropy signal wherein the current sensitivity has a value defined by a ratio comprising the change in the entropy signal and the change in the infusion rate.
- 2. The method of claim 1, and further adjusting a delivery rate of the drug based on the current sensitivity of the subject.

Mayo v. Prometheus

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Suggestions

- Practitioners need to stay current on 101 developments in all technologies and comment on the effect in their given area of expertise.
- USPTO should create one webpage where all 101 guidance materials and information are provided.
- USPTO should set forth in one place/webpage claims it rejects under section 101, and claims it allows following a rejection under section 101.

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