Patentable Subject Matter in the US

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Overview

• 35 U.S.C. § 101

• *Mayo v. Prometheus* and ramifications

• Previews of coming attractions…
  – *Assoc. for Molecular Pathology v. Myriad*
  – *CLS Bank v. Alice Corp.*
• Whoever invents or discovers any new and useful
  – Process (process, art, or method)
  – Machine
  – Manufacture
  – Composition of matter
35 U.S.C. § 101

• Derived Exceptions
  – Fundamental Principles
    • Laws of nature
    • Natural phenomena
    • Abstract ideas
Mayo v. Prometheus
March 20, 2012
Process claims reciting laws of nature must contain sufficient additional features
Method of optimizing therapeutic efficacy:

- administering a thiopurine drug to a subject;
- determining the resulting metabolite level in the subject
- wherein a metabolite level:
  - $< X$ indicates a need to increase the dosage and
  - $> Y$ indicates a need to decrease the dosage
Prometheus

• History

  – Found eligible twice by Federal Circuit (CAFC)
    • administering and determining steps transformed the body
    • claims did not preempt a fundamental principle

  – Supreme Court (S. Ct.)
    • Claims did not add enough to avoid preempting a law of nature
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 $8 \times 10^8$ 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 $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.
wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ 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 $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

* * * *

“Prometheus’ patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.”
Overarching Analysis

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.
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

** * * *

First:
- “administering” simply refers to the relevant audience, doctors
- doctors used thiopurine drugs long before these claims
- “prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.’”
wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ 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 $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

* * *

Second:
• “wherein” clauses simply tell a doctor about the relevant natural laws
• these clauses tell the doctors about the laws while trusting them to use those laws appropriately
(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

* * *

Third:

• “determining” step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process desired.
  • methods for determining metabolite levels were well known in the art

• purely “conventional or obvious” “[pre]-solution activity” is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.
Fourth:
• “to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately.”

* * *

“To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.”
Prometheus

• Ramifications of *Prometheus*
  – claims involving other fundamental principles
  – already issued patent claims
  – pending and future applications
Previews

• *Myriad* - Genetics

• *CLS Bank* – Computer-implemented Business Methods
Myriad at the US Supreme Court (Again!)
April 15, 2013

Are Human Genes Patentable?
• History

– Dist. Ct. - all claims found patent ineligible

– CAFC reversed in part (twice) finding that:
  • composition claims to “isolated” DNA molecules cover patent eligible products of nature (molecules as claimed do not exist in nature);
  • method claim to screening potential cancer therapeutics via changes in cell growth rates is directed to a patent-eligible scientific principle; and
  • method claims to “comparing” or “analyzing” DNA sequences are patent ineligible – (no transformative steps)

– S. Ct.
  • Denied review of CAFC application of Prometheus to method of screening
• Claim 20 from US 5,747,282 is valid:
• Essentially it states, a method for screening potential cancer therapeutics which comprises:
  – (1) **growing** host cells *transformed* with an altered *BRCA1* gene in the presence or absence of a potential cancer therapeutic,
  – (2) **determining** the growth rate of the host cells with or without the potential therapeutic, and
  – (3) **comparing** the growth rate of the host cells.
Essentially, the real question being asked of the S. Ct. is whether *Prometheus* extends to composition of matter claims, *i.e.*: What level of “additional features” must one claim to provide the necessary assurances that a claim reciting human genes “is more than a drafting effort designed to monopolize the [natural phenomenon] itself?”
What will the S. Ct. do?

• Based on the lessons of *Prometheus* (and *Bilski*)
  – will not likely hold that all composition claims reciting human genes are patent-ineligible

• Hopefully
  – will give further clarity to the analysis of determining patent eligibility for fundamental principles
CLS Bank at the Federal Circuit (Again!)
February 8, 2013
Are computer-implemented business methods patentable?
History

– DC District Court (summary judgment)
  • Found claims ineligible - the mere use of a computer “without any further exposition or meaningful limitation” does not make it patentable

– CAFC panel
  • Reversed - it is not “manifestly evident” that each of the claims is directed to an abstract idea
  • The full court vacated the panel decision and granted rehearing *en banc* to reconsider two questions (really four)
Claim 1 of US 7,725,375 recites:

A data processing system to enable the exchange of an obligation between parties, the system comprising:

1. a first party device,
2. a data storage unit having stored therein (a) information about a first account ..., and (b) information about a third account ...; and
3. a computer, coupled to said data storage unit, that is configured to (a) receive a transaction from said first party device; (b) electronically adjust said first account and said third account ...; and (c) generate an instruction to said first exchange institution ....
Questions to be decided:

1. What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible "abstract idea"?

When, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?
Test should be: A computer-implemented method must include an inventive concept beyond the abstract idea on which it is based. Citing Prometheus and Bilski

A “computer must be integral to the claimed invention” and specialized to the invention. Citing Bancorp
Alice Corp.

- Inventiveness is not the test
  - S. Ct. precedent does not impose a separate “inventiveness” requirement

- Test should be: “whether the role of the computer in the claim is sufficient to make the claimed invention an application of the abstract idea, not the abstract idea itself.”
Test should be the inquiry required by *Bilski* and *Prometheus*: “whether the claim, properly construed, incorporates enough **meaningful** limitations to ensure that it amounts to more than a claim for the abstract idea itself.”

- The inquiry should be conducted in light of the presumption of validity
- The CAFC should provide a “non-exhaustive list of factors”
Amici:

- Google, HP, Red Hat, Twitter
  - Based on *Prometheus*:
    - claims must include an inventive concept
    - identified “four guideposts” for determining whether a patent claims significantly more than an abstract idea

- Computer & Communications Indus. Ass’n.
  - *Prometheus* requires an inventive concept
Questions to be decided (cont.):

2. Should it matter whether the invention is claimed as a method, system, or storage medium?

Should such claims at times be considered equivalent for § 101 purposes?
CLS Bank

- CLS Bank and USPTO
  - Patent eligibility does not turn on the statutory form of the claim.

- Alice Corp.:
  - Patent eligibility turns on the limitations of the particular claim.
Summary

- The area of patent eligible subject matter in the US continues to evolve.

- The S. Ct. is demonstrating a new willingness to give guidance to the interpretation of § 101 especially as relates to fundamental principles (laws of nature, natural phenomena, and abstract ideas).

- Stay tuned!
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Questions?

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