Biomedical Diagnostic Patents
Post *Prometheus*

JPO / U.S. Bar Liaison Council Meeting
June 27, 2012, Washington, D.C.
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• Supreme Ct. takes up the case after Fed.Cir. Rules claims are patentable subject matter under machine or transformation test.
• Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable as they are the basic tools of scientific and technological work
• However, a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm
• Question determined by the court:
  – Whether the claimed processes have transformed unpatentable natural laws into patent eligible applications of those laws.
Mayo Collaborative Services v. Prometheus Labs., Inc., v. Prometheus Labs., Inc.,
132 S.Ct.1289 (March 20, 2012).

The claim at issue:
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 Collaborative Services v. Prometheus Labs., Inc.,
v. Prometheus Labs., Inc.,
132 S.Ct.1289 (March 20, 2012).

• Do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible process that apply natural laws?

• Supreme court answered **no** for the following reasons:
  – Claim can be divided into “administering” step, “determining” step, and “wherein” steps
  – “Administering” step simply refers to technological environment and is therefore not sufficient limitation
  – “Wherein” clauses simply tell a doctor about the relevant natural laws
  – “Determining” step simply states methods well known in the art and “conventional or obvious” pre-solution activity is not sufficient to transform claim to a patent elibilble application of a law of nature
Mayo Collaborative Services v. Prometheus Labs., Inc., v. Prometheus Labs., Inc.,
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• Court reviewed its controlling precedent in Diehr, Flook, Bilski, and Benson

• Diehr
  – Claims:
    • A method having the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal “a device” to open the press.
    – Steps of putting rubber into the press, closing the mold and opening the press at the proper time transformed the method into an inventive application of the Arrhenius equation
Mayo Collaborative Services v. Prometheus Labs., Inc.,
v. Prometheus Labs., Inc.,
132 S.Ct.1289 (March 20, 2012).

• *Flook*
  – Claims
    • An improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, *e.g.*, the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm-limit values.
    – The claim did not explain how the variables used in the formula were to be selected, nor did the claim contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit
    – Post solution activity that was merely conventional or obvious did not transform an unpatentable principal into a patentable process
Mayo Collaborative Services v. Prometheus Labs., Inc., v. Prometheus Labs., Inc.,
132 S.Ct.1289 (March 20, 2012).

- *Prometheus* in light of *Diehr* and *Flook*
  - the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law.
  - the effect of the claims is simply to tell doctors to apply the law of nature somehow when treating their patients

- *Bilski*
  - Claims were simply directed to the concept of hedging, an abstract idea
  - The fact that some claims were limited to commodities and energy markets and specified well-known random analysis techniques did not make the concept patentable
  - Limiting an abstract idea to one field of use or adding token post-solution components did not make the concept patentable.

- **Benson**
  - Claims
    - a mathematical process for converting binary-coded decimal numerals into pure binary numbers on a general purpose digital computer.
    - Simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle
  - Conclusion
    - The claims at issue effectively claim the underlying laws of nature themselves and are therefore not patentable subject matter.
    - Court recognized the effect that this holding might have on the diagnostic industry represented in *amicus* briefs, but sighted other parties, such as the AMA that had opposite fears of stifled innovation from the issuance of patents that too broadly claimed the correlation between metabolite concentration and drug effectiveness.
    - Unlike a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.

- How will Prometheus be applied?
  - The case does not make diagnostic methods unpatentable
  - However, the courts will require significant post and/or pre-solution activity as in the S. Ct. precedent
  - The general question is whether the claims are so broad as to preempt all applications of an abstract idea, or represent a specific application of that idea
Association for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2010) (Myriad)

- Federal Circuit decision holding, inter alia, isolated DNA claims valid
- Case is remanded for reconsideration in view of Prometheus
- Patentee position:
  - Prometheus related process claims not composition of matter claims—no effect on this case
  - Controlling precedent is Chakrabarty
  - Isolated BRCA1 and BRCA2 molecules have a distinctive name, character and use from naturally occurring genetic material
  - To rule otherwise would mean that other useful substances isolated from nature, like Aspirin, would not be patentable
Myriad

- Plaintiffs position:
  - Isolated DNA that claims laws and products of nature impermissibly foreclose future scientific work and innovation
  - Isolated DNA claims are directed to products and laws of nature—the correlation between genetic mutation and disease, in this case breast cancer
  - Humans did not invent the DNA
  - Patent protection for these molecules would inhibit innovation

- Oral Argument will be heard July 20, 2012