

Patentable Subject Matter

- **John H. Barton**, *George E. Osborne Professor of Law, Emeritus, Stanford Law School*
- **Oskar Liivak**, *Assistant Professor of Law, Cornell Law School*
- **Mark A. Lemley**, *William H. Neukom Professor of Law, Stanford Law School; Director, Stanford Program in Law, Science and Technology; Partner, Durie Tangri Lemley Roberts & Kent, LLP*
- **Joshua M. Masur**, *Of Counsel, Fish & Richardson PC*
- **Michelle S. Rhyu, Ph.D.**, *Partner, Cooley Godward Kronish LLP*

U.S. Supreme Court's Exceptions

- Laws of Nature
- Natural Phenomena
- Abstract Ideas
- Mental Processes

The Source

Article I, Section 8:

- *The Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries . . .*
- *. . . And To make all laws which shall be necessary and proper for carrying into execution the foregoing powers, and all other powers vested by this Constitution in the government of the United States, or in any department or officer thereof.*

35 U.S.C. § 101:

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Recent Patentability Opinions

- *LabCorp v. Metabolite* (Breyer's dissent from Court's refusal to consider patentability)
- *In re Bilski* (Fed. Cir. October 2008)
- *In re Comiskey* (Fed. Cir. January 2009)
- *In re Classen* (Fed. Cir. December 2008)
- *In re Nuijten* (Fed. Cir. September 2007)
- *Prometheus v. Mayo* (SD Cal. 2008, pending before Fed. Cir.)

Biomedical Inventions: Where is the court headed?

Example 1:

I claim:

- A method for detecting a deficiency of *Molecule A* comprising the steps of:
 - assaying a body fluid for an elevated level of total *Molecule B*; and
 - correlating an elevated level of total *Molecule B* in said body fluid with a deficiency of *Molecule A*.

Example 2:

I claim:

- A method for **treating** a deficiency of *Molecule A* **in a patient** comprising the steps of:
 - assaying a body fluid for an elevated level of total *Molecule B*;
 - correlating an elevated level of total *Molecule B* in said body fluid with a deficiency of *Molecule A*; **and**
 - ***administering Molecule A to the patient at a daily dose of between 10 and 500mg.***

Example 3:

I claim:

- A method for detecting a deficiency of *Molecule A* comprising the steps of:
 - assaying a body fluid for an elevated level of total *Molecule B* *according to a [specifically recited] method*; and
 - correlating an elevated level of total *Molecule B* in said body fluid with a deficiency of *Molecule A*.

Example 4:

I claim:

- A method for *diagnosing a [specific medical] condition, comprising:*
 - assaying a body fluid for an elevated level of total *Molecule A*; and
 - correlating an elevated level of total *Molecule A* in said body fluid with *having the specific medical condition*.

Example 5:

- A method for *diagnosing a [specific medical] condition, comprising:*
 - administering [synthetic] Molecule A to a patient;
 - assaying a body fluid for an elevated level of **a metabolite of Molecule A**; and
 - correlating an elevated level of **the metabolite** in said body fluid with **having the specific medical condition**.

Example 6:

- A method for personalizing medical treatment, comprising
- *predicting a patient's responsiveness to a particular medical treatment, comprising:*
 - assaying a body fluid **of the patient** for an elevated level of total *Molecule A*;
 - correlating an elevated level of total *Molecule A* in said body fluid with *an increased likelihood of efficacy for the medical treatment in that patient; and*
- *administering said medical treatment where the Molecule A level is greater than X amount.*

The Fallout

- Effect on biomedical innovation?
- Effect on biomedical industry funding?
- What will U.S. Supreme Court say?
- Will Congress amend § 101 to render these inventions patentable?

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