

Biotechnology Chemistry
Pharmaceutical Partnership
Meeting
September 8, 2010

D. Benjamin Borson, M.A., J.D., Ph.D.
Borson Law Group, PC

BCP Partnership

- To promote progress of science and useful arts, by securing for limited times to Authors and Inventors the exclusive right to their respective Writings and ***Discoveries***.
- Constitution, Article I, Section 8, Clause 8.

Discovery Inventions

- Discovery is the **realization** or **understanding** of something useful that already exists
- Biotechnological, Chemical and Pharmaceutical inventions rely upon discoveries
- “Nature speaks clearly, but in a language that is difficult to understand or translate.”

Discoveries

- Making a discovery involves observation, experiment, and evaluation of accuracy
 - Methods of observation
 - Correlating cause and effect
 - Hypothesis testing
 - Repeatability/reproducibility
 - Confirmation

Patentability of Discoveries

- Whoever invents or ***discovers*** a 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.
- 35 U.S.C. §101: two prongs
 - Utility
 - Concrete, tangible, useful
 - Scope of claims
 - Patentable subject matter

Exceptions to Patentable Subject Matter

- Phenomena of Nature
- Laws of Nature
- Abstract Intellectual Concepts
- Mental Processes
- Naturally Occurring Organisms
- Legal Contracts
- Games (?)
- Companies
- Algorithms *per se*
- Transitory Signals *per se*
- Human beings *per se*
- Computer programs *per se*

Rationales

Exclusions are needed:

- Basic tools of scientific and technological work are available to all
- Prevent “preemption” of an entire field
 - Problem: The “entire field” is difficult to determine
 - *i.e.*, a patent by its nature preempts the entire field encompassed by the claim. This would lead to interminable arguments

In re Nuijten

- Signal Claims *per se* are unpatentable
- However, Judge Linn's Dissent points out that Morse's claims to use of Morse code
 - "... the system of signs, consisting of dots and spaces, and of dots, spaces, and horizontal lines, for numerals, letters, words, or sentences substantially as herein set forth and illustrated, for telegraphic purposes."
 - Is this a "signal claim?"

Bilski (briefly)

- Machine or Transformation test affirmed
- There are other tests that could apply
 - “The [M or T] test is not the sole test for deciding whether an invention is a **patent-eligible** ‘process’”
 - Comment: this is not the “unpatentable” language of KSR. Is this a distinction without a difference?
 - “Section 101’s terms suggest that new technologies may call for **new inquiries**”
 - To “freeze process patents to old technologies leaving no room for the revelations of the new, onrushing technology ... is not our purpose” (Benson)

Prometheus vs. Mayo

- Method for optimizing ...
- a) administering ... 6-thioguanine (6-SG) to a subject having an immune-mediate GI disorder;
- b) determining the level of 6-SG in said subject;
- c) wherein the level of 6-SG is < 230 pmol indicates need to increase dose;
- d) wherein the level of 6-SG > 400 pmol indicates need to decrease dose.

Prometheus

- Mayo alleged the claims were to a natural phenomenon:
 - correlations between thiopurine metabolism and efficacy and toxicity are natural phenomena
 - Dist. Court: “inventors merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity”

Prometheus

- Fed. Cir. Upheld the claim under M/T test:
 - The samples are transformed
 - The measurements could not be made on “whole blood”
- “Everything proceeds according to Natural Laws”
- Comments:
 - **Identification** of “thresholds” for 6-SG are not “natural,” they are a human conception of the **meaning** of the data as reflecting a disorder.
 - “Disorder” is defined by people practically, in order to do something (e.g., treat)
 - A “mechanism” of disorder may be a natural phenomenon, but
 - a practical application of a mechanism to identify similar disorders should be patentable subject matter.

In re Grams

- A method for diagnosing an abnormal condition...
- Plurality of correlated parameters, comprising data resulting from a plurality of clinical tests, which measure levels of chemical or biological constituents and a reference range, comprising:
 - a) performing the tests, and measure values of parameters,
 - b) producing a first quantity representative of the condition,

Grams (con't)

- c) comparing the first quantity to a first predetermined value to determine whether the person's condition is abnormal,
- d) if abnormal, successively testing a plurality of different combinations of the constituents to eliminate parameters producing ... a second quantity with a second predetermined value...; and
- e) identifying as a result of said testing a complementary subset of parameters corresponding to a combination of constituents responsible for the abnormal condition...

Grams (Con't)

- Claim is an unpatentable algorithm
 - “It is of no moment that the algorithm is not expressed in mathematical form.”
 - “Words used in a claim operating on data to solve a problem can serve the same purpose as a formula.”

Labcorp v. Metabolite

- 13. A method for detecting a deficiency of cobalamin or folate ... comprising the steps of:
 - Assaying a body fluid for an elevated level of total homocysteine, and
 - Correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Labcorp

- The specification described the diagnosis as “a two step process:”
 - 1. measure serum total homocysteine, and if elevated, then
 - 2. measure one or more of:
 - a Elevated level of methylmalonic acid; and
 - b detecting a clinical or hematological symptom, such as:
 - i megablasic anemia
 - ii abnormal white blood count
 - iii abnormal platelet count or
 - iv abnormal lactate dehydrogenase levels

Labcorp

- The Federal Circuit defined “correlating” to mean:
 - 1. To relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both, and also
 - 2. To relate the absence of an elevated total homocysteine level to a deficiency in neither.
 - “[T]he accepted definition of ‘correlating’ is to establish a ‘mutual or reciprocal’ relationship.”
 - “The claim in other words, provides that if the assay discloses “an elevated level of total homocysteine” the physician determines whether there is a cobalamin or folate deficiency by “correlating”
 - [i.e., comparing the elevated level with the normal homocysteine level.]

Labcorp

- 18. A method for detecting a deficiency of cobalamin or folate..., comprising:
 - Assaying body fluids for the presence of elevated levels of total homocysteine and methylmalonic acid, wherein
 - normal levels of total homocysteine indicate no cobalamin or folic acid deficiency,
 - elevated levels of total homocysteine and methylmalonic acid indicate cobalamin deficiency, and
 - elevated levels of total homocysteine combined with normal levels of methylmalonic acid indicate folic acid deficiency.

Labcorp

- The Fed. Circuit upheld Dist. Court's holding of validity and infringement
- Labcorp filed for cert. to the Supreme Court
 - Granted cert. on issue 3:
 - Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlate” test results can claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result”

Labcorp

- Comment:
 - The essential nature of the claims is not to claim a basic scientific fact, but rather:
 - To claim tests having ***previously unknown thresholds*** of metabolites, to provide a doctor and patient with ***information*** about the patient's status.
 - A newly discovered threshold is not a basic scientific fact.
 - A newly discovered threshold is a “discovery invention.”

Scope of Unpatentability

- *Prometheus*:
 - “However, although [mental steps] alone are not patent eligible, the claims are not simply to the mental steps. A subsequent mental step does not, by itself, negate the transformative nature of the prior steps.”
 - “[T]he final step of providing a warning based on the results of the prior steps does not detract from the patentability [of the claim].”
 - “The addition of the mental steps to the claimed methods thus does not remove the prior two steps from that realm.”

USPTO Interim Instructions (August 2009)

- “The claimed invention
- (1) must be directed to one of the four statutory categories, and
- (2) must not be *wholly* directed to [an exception].”

Open Questions

- How much pre-emption is (or will in the future be) permitted?
- How does one identify the patent-eligible elements of a claim for 101 purposes?
- What is a “machine”?
- What is meant by “made of parts”?
 - Electrons, photons, quarks, quantum mechanical principles (probabilities)
 - “Fly Quantum Airlines, because you may already be there.” What is a “manufacture”?
- What is a “manufacture”?

Further Questions

- What tests for 101 are contemplated in addition to M/T?
 - *Prometheus* (Grant, Vacate, Remand)
 - If *Prometheus*'s claims met the M or T test, why the GVR? (late in the season?)
- How do older Supreme Court decisions apply to current analysis?
 - *American Fruit Growers* (a chemically treated orange not patentable)
 - Telegraph cases (code transmitted telegraphically [i.e., a “signal”] was patentable)
 - Advisory opinions? Dicta?

Still Further Questions

- How does 101 apply to future industries?
- Alternatives to limit scope of patents under 101
 - 103
 - 112, first paragraph (scope)
 - 112, second paragraph
- Alternatives to limiting scope of the Patent Law
 - March in rights (Fed. Agencies)
 - Compulsory Licensing

Thank You

- Ben Borson
- bborson@borsonlaw.com
 - Tel: (925) 310-2060
- Fax: (925) 310-2061
- Web: www.borsonlaw.com