149 Gene Patents-The Future of Gene Research in an Era of Patents-
Scientific and Legal Considerations

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The following program was a joint presentation by the American Society for Clinical Pathology and Association for Molecular Pathology on February 27, 2011 at USCAP. This symposium will provide an overview of gene patent history and describe the current lawsuit challenging the legality of patents on human genes—specifically, patents covering the BRCA1 and BRCA2 genes, which are associated with breast and ovarian cancer. The lawsuits multiple stages and outcomes are closely being followed by the entire pathology field to determine the implications it will have on the field of pathology and laboratory medicine.

- Outline how patents stifle the innovative and research processes, negating further refinement in test methodology and improvements in quality.
- Inform the audience how gene patents potentially impact patients' rights.

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Entire Pathology Team
Public Health Policy, Health Care Reform
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2.0 CME/CMLE Credits

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The Legal History of Gene Patents

Roger D. Klein, MD, JD
ASCP/AMP Companion Meeting
February 27, 2011

Outline

• Patent basics
• History of gene patents
• Key legal cases

Patents grant property rights in creations of the mind
Right to exclude others from making, using, or selling an invention

“Claims” set the boundaries of the property right

Why Have Patents?

Incentive to invent
Incentive to disclose
Incentive to commercialize
Legal Basis

**Article I, section 8.**

“The Congress shall have the 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;”

Library of Congress Website
http://www.loc.gov/rr/program/bib/ourdocs/Constitution.html


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**NEW!**

Novel

Useful

Nonobvious

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Processes

Machines

Manufactures

Compositions of matter
The 1970s were plagued by high unemployment, high inflation, and shaken U.S. confidence.

U.S. Response

- Increased federal $$ for biomedical research.
- Bayh-Dole Act.
**Diamond v. Chakrabarty**

“Anything under the sun that is made by man.”

**Diamond v. Diehr**

\[ k = A e^{E_a/RT} \]

**Patenting by Universities**

- University assigned patents increased from 264 in 1979 to 3,259 in 2003.

Post-Chakrabarty Patents

- “Harvard Mouse.”
- Leukemia derived cell lines.
- Stem cells.
- Human genes and phenotypic associations

Human Gene Patents

- ~20% of genes associated with at least 1 patent.
- ~1/2 genes known to be involved in cancer patented.
- One Company claims 10% of all human genes.

Biotechnology Growth


Aspirin
Kuehnted v. Farbentafarken, 179 F.701 (1911)

Adrenalin

Vitamin B12
Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156 (1958)

The Genetic Code

10/8/2011
LabCorp v. Metabolite Labs

“At most, respondents have simply described the natural law at issue in the abstract language of a ‘process.’”

Bilski v. Kappos

‘machine or transformation test’

Prometheus v. Mayo

Patent on reference range for thiopurine drugs.
**Classen v. Biogen**

Patent on process of establishing vaccine administration schedule by comparing frequency of adverse events associated with different schedules. Invalid under Bilski interpretation of section 101.

MOORE, Circuit Judge.

In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court’s grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen’s claims are neither “tied to a particular machine or apparatus” nor do they “transform[] a particular article into a different state or thing.” Bilski, 545 F.3d at 954. Therefore we affirm.

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**Association for Molecular Pathology v. USPTO**

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**Obviousness**

Some patented genes may have been ‘obvious to try’
References