Association for Molecular Pathology v. Myriad Genetics, Inc.

THE SCOTUS RULING
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THE IMPACT ON PATIENTS AND LAB PRACTICE
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Supreme Court Strikes Down Gene Patents:
Association for Molecular Pathology v. Myriad Genetics

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Patenting Human Genes

1987  Patent Officer: patents on “isolated” DNA
1990  BRCA1 linked to chromosome 17
1994-5  BRCA1 and BRCA2 sequenced
1997-8  BRCA1 and BRCA2 patents
1998  Cease-and-desist letters

### United States Patent

**BRCA1 breast and ovarian cancer susceptibility gene**

**Patent Number:** 5,747,282
**Date of Patent:** May 4, 1998

**Inventors:** Mark L. Ludwig, David H. Martin

**Assignee:** Genentech, Inc.

Challenged BRCA Patent Claims

- **Composition claims** - E.g., Claim 1 of patent 5,747,282:

  “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID No. 2.”

- Also challenged method claims.
  E.g., Claim 1 of patent 6,033,857:

  “A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequence identifies a mutant BRCA2 nucleotide sequence.”

  ⇒ Held invalid by courts below; not before the Supreme Court.

Effects of Human Gene Patenting

- Diagnostic Testing
- Patient Care
- Data Sharing
- Research
- New technologies
Lawsuit challenging BRCA1/2 patents

PLAINTIFFS
Organizations
Association For Molecular Pathology (AMP)
American College Of Medical Genetics (ACMG)
American Society For Clinical Pathology (ASCP)
College Of American Pathologists (CAP)

Researchers/Clinicians
Haig Kazazian, MD
Angela Garapich, PhD
Susan Vargiu, PhD
Harry Ostrer, MD
David Goldstein, PhD
Stephen Warren, PhD

Genetic Counselors
Eileen Matloff, MS
Dana Reck, MS

DEFENDANTS

Brevi Cancer Action
Our Bodies Ourselves

Myriad Genetics
University of Utah Research Foundation (UURF)

Timeline
- May 2009  Suit filed in NY federal court by ACLU and PubPat.  Main legal argument: patents cover products and laws of nature, and thus invalid under Section 101 of Patent Act
- Mar. 2010  Judge Robert Sweet found challenged patent claims invalid.
- July 2011  U.S. Court of Appeals for the Federal Circuit (2-1) reversed Judge Sweet's ruling on the isolated DNA claims.
- Aug. 2012  Second Federal Circuit decision (again 2-1)
- Nov. 2012  Supreme Court granted petition.

Question presented: “Are human genes patentable?”

Supreme Court Decision
- Unanimous, written by Justice Thomas
- Isolated genomic DNA is not patent-eligible under Section 101 of the Patent Act; it is a product of nature.
  “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”
- cDNA is not a product of nature.
- Issued June 13, 2013, Scalia concurrence
Understanding the Decision

- Robust product and law of nature doctrine
- Recognized patents were really claiming genetic sequence
- Effort alone does not satisfy Section 101
- No deference owed to Patent Office or reliance by patent holders
- No explicit limitation to human genes
- Does not deal with method claims (Mayo)
- Does not deal with applications of knowledge
- Does not deal with DNA where order of nucleotides has been altered

Reactions

Patent Office Preliminary Guidance:

"Myriad significantly changes the Office's examination policy regarding nucleic-acid related technology... Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not."


"a victory for all those eagerly awaiting more individualized, gene-based approaches to medical care"

-- NIH director Francis Collins

Resources

- Website for more info: www.aclu.org/genepatents
- Blog posts: www.aclu.org/blog/tag/gene-patenting
**AMP v. Gene Patents**

**Benefit for Patients**

- Test monopolies based on ownership of gene or genotype-phenotype relationship bad for patients
- The Supreme Court’s decision will benefit patients by:
  - lowering test costs
  - increasing patient access
  - enhancing innovation in test services
  - facilitating clinical and basic research
Innovation - Scientific Research

- Gene patents presented challenges to studying genome in an integrated manner
  - etiology of cancer, hypertension, heart disease, diabetes, mental illness
  - identify and prioritize drug targets
  - select individuals for clinical trials
  - translation of discoveries into tests for diagnosis, prognosis, prediction of response to therapy

- Meaning of specific genetic changes for individual patients
  - variants of unknown significance (publication, databases)
  - penetrance and expression

Innovation - Clinical Services

- Innovation in test services
  - includes, but extends beyond technical performance
  - what exactly is tested, e.g. types of mutations or gene regions
  - how the services are delivered
  - differences in the manner in which results are reported and subsequent follow-up with changes in knowledge

DNA Patents and Biotechnology

“Most medically important biotechnology products are protected by cDNA or recombinant DNA molecules”
Molecular genetic testing – Where do we stand?

PRESENTED BY: Roger D. Klein, MD JD, Cleveland Clinic
Mayo v. Prometheus

Patent on “the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects.”

Physicians infringe patent by thinking about relationships...

Thiopurine Patent Claim

“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 8x10⁸ 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 8x10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.”

“To transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’”
"Laws of nature, natural phenomena, and abstract ideas are not patentable...they are the basic tools of scientific and technological work 'that lie beyond the domain of patent protection. Without this exception there would be considerable danger that the grant of patents would 'tie up' the use of such tools and 'thereby inhibit future innovation premised upon them.'"

**Diagnosis of Myeloproliferative Neoplasms**

**JAK2 V617F**

An in vitro method to determine if a human patient is currently suffering from or is likely to develop a myeloproliferative disorder... comprising: (a) obtaining and analyzing a nucleic acid sample from the human patient; (b) detecting a T in the JAK2 gene at position 2343...in the sample; and recording the presence of a T in the JAK2 gene at position 2343...wherein the presence of a T at position 2343...indicates the human patient is suffering from or is likely to develop a myeloproliferative disorder...

**Prognosis in Acute Myeloid Leukemia**

**FLT3 ITD**

A method for detecting diagnostically a nucleic acid encoding FLT3 kinase and having a tandem duplication mutation...comprising: step (a) preparing a human nucleic acid sample; (b) subjecting the nucleic acid sample obtained in step (a) to a gene amplification reaction... (c) detecting the presence of the tandem duplication mutation in the nucleic acid fragment...wherein the presence of a tandem duplication mutation is indicative of a disease...
**EGFR mutations in NSCLC**

A method for determining an increased likelihood of pharmacological effectiveness of treatment by gefitinib or erlotinib in an individual diagnosed with non-small cell lung cancer comprising:

- obtaining DNA from a non-small cell lung cancer tumor sample from the individual;
- determining the presence or absence of at least one nucleotide variance of the epidermal growth factor receptor (EGFR) gene, wherein the presence of at least one nucleotide variance indicates an increased likelihood of pharmacological effectiveness of treatment by gefitinib or erlotinib in the individual.

**QUESTIONS?**

Please use the chat box to submit your questions!

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