

## Review of the Gene Patent Supreme Court Case

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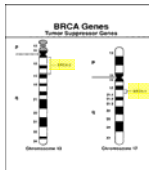
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## Patents on BRCA1 and BRCA2



- 1990 Linkage to chromosome 17 found by Dr. Mary-Claire King
- 1994 Dr. Mark Skolnick with Myriad Genetics sequenced the gene and filed for BRCA1 patents
- 1997 BRCA2 patents
- 1998 Myriad sent cease-and-desist letters



**United States Patent** [19] (11) **Patent Number:** 5,747,282  
Skolnick et al. (45) **Date of Patent:** May 5, 1998

[54] 17q-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE [56] **References Cited PUBLICATIONS**

[75] **Inventors:** Mark H. Skolnick; David E. Goldgar; Yoshio Mikki; Jeff Swenson; Alexander Kamb; Keith D. Harkness; Thomas E. Marshall (1995) Science 269:1050-1055. Viza et al (1995) Targeted Gene Therapy 9:190-199.

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## Challenged BRCA Patent Claims - Compositions

- 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."
- E.g., Claim 5 of patent 5,837,492:  
"An isolated DNA having at least 15 nucleotides of the DNA of claim 1."

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### Challenged BRCA Patent Claims - Compositions (cont.)



- E.g., Claim 6 of patent 5,837,492:  
“An isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide set forth in SEQ ID No. 2, wherein said mutated form of the BRCA2 polypeptide is associated with a susceptibility to cancer.”

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### Method Claims Challenged But Not Before the Supreme Court



- 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.”

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### Effects of Human Gene Patenting



- Diagnostic Testing
- Patient Care
- Data Sharing
- Research
- New technologies

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## Patents and Progress



*The Congress shall have the power... To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.*

- United States Constitution, Article I, Section 8, Clause 8

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“The information contained in our shared instruction book is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”



-- Dr. Francis Collins, Director of the National Institutes of Health, *The Language of Life: DNA and the Revolution in Personalized Medicine* (2010)

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## Lawsuit challenging BRCA1/2 patents



### PLAINTIFFS

#### Organizations

Association For Molecular Pathology  
 American College Of Medical Genetics  
 American Society For Clinical Pathology  
 College Of American Pathologists

#### Researchers/Clinicians

Haig Kazazian, MD  
 Arupa Ganguly, PhD  
 Wendy Chung, MD, PhD  
 Harry Ostrer, MD  
 David Ledbetter, PhD  
 Stephen Warren, PhD

#### Genetic Counselors

Ellen Matloff, MS  
 Elsa Reich, MS

Breast Cancer Action  
 Our Bodies Ourselves

#### Patients

Lisbeth Ceriani  
 Runi Limary  
 Genae Girard  
 Vicky Thomason  
 Kathleen Raker  
 Patrice Fortune

### DEFENDANTS

United States Patent  
 and Trademark Office  
 (PTO)

Myriad Genetics

University of Utah  
 Research Foundation  
 (UURF) directors

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## Legal Issues



Challenged 15 patent claims in 7 patents: DNA claims and method claims

- **Standing**
- **Section 101 of the Patent Act: products and laws of nature, abstract thought**
- **U.S. Constitution, Article I, Clause 8 and First Amendment**

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## Supreme Court Precedent



- Does the patented composition have “markedly different characteristics from any found in nature” – *Chakrabarty* (1980)
- Are the claimed composition's qualities “the work of nature” – *Funk Brothers* (1948)
- Is the patent based on an “inventive concept” – *Mayo* (2012)
- Does the patent “risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries” – *Mayo* (2012)

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## Court Case



- **May 12, 2009:** *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.* filed in the U.S. District Court for the Southern District of New York.
- **November 2, 2009:** Judge Robert Sweet denied defendants' motions to dismiss and found plaintiffs had standing to file case.
- **March 30, 2010:** Judge Robert Sweet found that all of the challenged patent claims are invalid because they cover products of nature and abstract ideas.

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### Judge Sweet's Decision



"DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other found in nature. It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter."



"lawyer's trick"

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### Appeal – Federal Circuit



- Amicus brief filed by Department of Justice, agreeing that isolated DNA is not patentable subject matter, but arguing cDNA is patentable.
- U.S. Court of Appeals for the Federal Circuit (2-1) reversed Judge Sweet's ruling on the isolated DNA claims and claim 20 in July 2011.
  - Standing – Harry Ostrer
  - Upheld cDNA claims
  - Invalidated all method claims except cl. 20

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### Judge Lourie's Decision



Focus on breaking of covalent bonds when isolating DNA:

"We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature..."



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### Judge Moore's Decision



Deference to industry reliance and PTO practice:



"If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter."

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### Judge Bryson's Dissent



Myriad's contribution is not "remotely consonant" with the patents' effects.

"Myriad is claiming the genes themselves, which appear in nature on the chromosomes of living human beings. The only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are found in nature."



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### Appeal - Supreme Court



- Supreme Court granted Plaintiffs' petition, vacated the Circuit's decision, and ordered reconsideration in light of *Mayo v. Prometheus* in March 2012.
- Implications of *Mayo*:
  - Preemption
  - Section 101 and patentees' interests

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### Remand – Federal Circuit



Decision issued in August 2012.

- Rejected law of nature arguments
- Did not address preemption

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### Supreme Court II



- Petition granted Nov. 30, 2012
- Question presented: “Are human genes patentable?”
- Brief filed Jan. 24; Myriad’s brief filed Mar. 7; Reply brief filed Apr. 2.

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### Amici Supporting Invalidation of Patents



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| <ul style="list-style-type: none"> <li>• American Medical Association, American Society for Human Genetics, and other medical/genetics groups</li> <li>• Canavan Foundation, Claire Altman Heine Foundation, March of Dimes, FORCE, Ovarian Cancer Nat’l Alliance, Mass. Breast Cancer Coalition, Nat’l Assoc. for Pseudoxanthoma Elasticum, and other patient groups</li> </ul> | <ul style="list-style-type: none"> <li>• Southern Baptist Convention</li> <li>• AARP</li> <li>• National Women’s Health Network and women’s health groups</li> <li>• Eric Lander</li> <li>• James Watson</li> <li>• Genetic testing laboratories including GeneDx and InVitae</li> </ul> |
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### Myriad's Amici (partial list - 30)



- BIO (Biotechnology Industry Organization)
- Genentech, Roche
- Patent attorneys, bar associations
- Ananda Chakrabarty

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Oral Argument - April 15, 2013



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### Key Issues



- What did Myriad invent?
  - "Nothing"; added to scientific knowledge - or
  - "A new molecule that had never before been known to the world"
  - Dispute about Lander's brief

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### Key Issues (cont.)



- At what point is patenting appropriate?
  - Recombinant DNA, tests, methods, uses
  - "isolated" chromosome, piece of liver
  - Chocolate chip cookie ingredients
  - Baseball bat from tree
  - Drug from plant

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### Key Issues (cont.)



- Applicable legal doctrine?
  - Section 101 – patentable subject matter – or
  - Rely on other sections of the Patent Act
- What is the Section 101 standard?
  - Products / laws of nature – or
  - Human ingenuity, human intervention

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### Key Issues (cont.)



- Role of Supreme Court?
  - Decide based on 150 years of Supreme Court doctrine, taking into consideration the position of US government – or
  - Defer to Patent Office
- Patent eligibility of cDNA?

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### Key Issues (cont.)



- Role of the patent incentive in innovation?
  - Need to evaluate depending on what is being patented – or
  - Assume that patenting always spurs innovation
- Impact on industry?
  - Invalidating gene patents will help industry – or
  - ?? “I can’t tell you for a certainty whether it will hurt the industry as a general matter to not have isolated gene but only have cDNA patents.”

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### Conclusion



- Decision expected in June
- Transcript and recording available on [www.supremecourt.gov](http://www.supremecourt.gov)
- Website for more info:  
[www.aclu.org/genepatents](http://www.aclu.org/genepatents)  
[www.aclu.org/blog/tag/voices-human-gene-patents](http://www.aclu.org/blog/tag/voices-human-gene-patents)

Questions??

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