

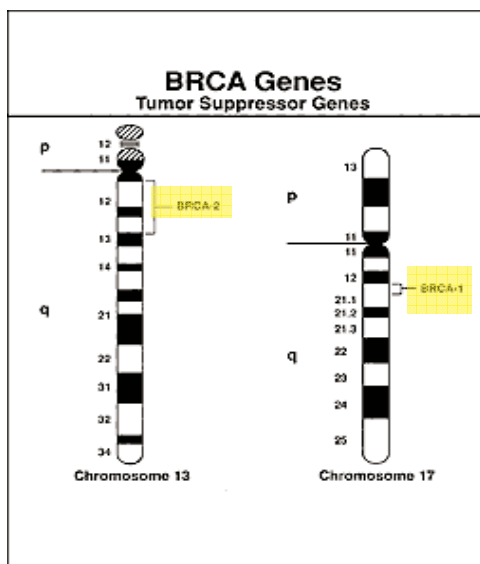
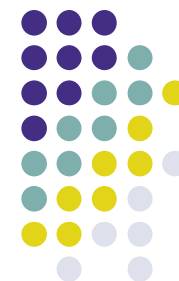


Making the Case Against Gene Patents

*Sandra Park, Staff Attorney,
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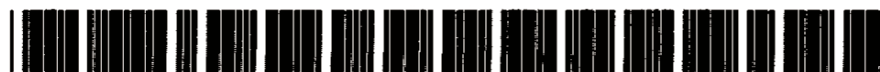
Tarrytown Meeting, July 26, 2011

Patents on BRCA1 and BRCA2



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

Claim 1: "An isolated DNA coding for a BRCA1 polypeptide..."



US005747282A

United States Patent [19]
Skolnick et al.

[11] **Patent Number:** **5,747,282**
 [45] **Date of Patent:** **May 5, 1998**

[54] **17Q-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE**

[75] **Inventors: Mark H. Skolnick; David E. Goldgar; Yoshio Miki; Jeff Swenson; Alexander Kamb; Keith D. Harshman; Donna**

[56] **References Cited PUBLICATIONS**

E. Marshall (1995) *Science* 269:1050–1055.
 Vila et al (1995) *Targeted Gene Therapy* 9:190–199.
 Molecular Biology of the Gene, 4th Edition, vol. 1, Ed. J. D.



What Is Patented?

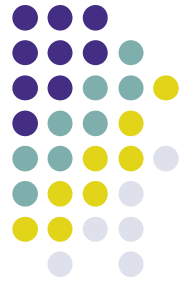
- Composition of Matter Claims to “Isolated DNA”
 - Whole genes
 - Fragments of genes
 - Mutations
- Methods Claims
 - Claims to a method of detecting a mutation (*e.g.*, comparing two DNA sequences to see if they are the same or different)
 - Claims to processes involving associating a genotype with a phenotype (*e.g.*, any method of testing that involves detecting a mutation and correlating it with disease)

Legal 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, Southern District of NY.
- Legal claims:
 - **Section 101 of the Patent Act – patentable subject matter**
 - **U.S. Constitution – Patent Clause & 1st Am.**
- Case challenged 15 patent claims in 7 patents: 9 on “isolated DNA,” 6 on methods or processes.

District Court Ruling



“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”

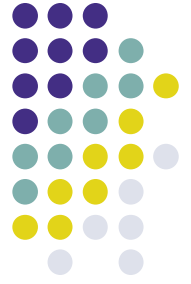
March 30, 2010



Current Legal Status

- Appeal filed by Myriad to the U.S. Court of Appeals for the Federal Circuit
- Legal issues raised: 1) Standing of plaintiffs
2) Section 101
- U.S. amicus brief (Solicitor General)
- Argument on April 4, 2011
- Prometheus v. Mayo

Parties



PLAINTIFFS

Organizations

Association for Molecular Pathology **Breast Cancer Action**
American College of Medical Genetics **Our Bodies Ourselves**
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

Patients

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

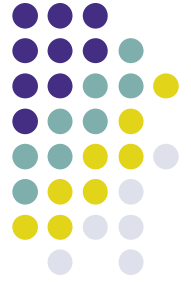
DEFENDANTS

**United States Patent
and Trademark
Office (PTO)**

Myriad Genetics

**University of Utah
Research
Foundation (UURF)
directors**

Experts for Plaintiffs



- John Sulston (Manchester)
- Chris Mason (Cornell)
- Robert Nussbaum (UCSF)
- Debra Leonard (Cornell)
- Wayne Grody (UCLA)
- Mildred Cho (Stanford)
- Elizabeth Swisher (U Wash)
- Susan Love (UCLA)
- Myles Jackson (NYU Poly)
- Shobita Parthasarathy (U Mich)
- Joseph Stiglitz (Columbia)
- Fiona Murray (MIT)
- Thomas Kepler and Bob Cook-Deegan (Duke)
- Roger Klein (Med. Coll. WI)

Amici supporting Plaintiffs



- American Medical Association, American Society for Human Genetics, and other medical/genetics groups
- Canavan Foundation, Claire Altman Heine Foundation, March of Dimes, and other patient groups
- AARP
- National Women's Health Network and women's health groups
- Southern Baptist Convention
- Cancer Council Australia
- International Center for Technology Assessment, Indigenous Peoples Council, Greenpeace, Friends of the Earth, and Council for Responsible Genetics
- Richard Gold, James Evans, and Tania Bubela
- IP scholars