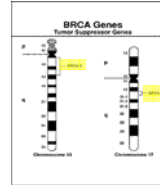


“The information contained in our shared instruction book is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”

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



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...”



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**
 [75] **Inventors:** Mark H. Skolnick; David E. Goldgar; Yoshio Miki; Jeff Swenson; Alexander Kaul; Keith D. Henderson; Thomas

[56] **References Cited PUBLICATIONS**
 E. Marshall (1995) *Science* 269:1050-1055.
 Vlia et al (1995) *Targeted Gene Therapy* 9:190-199.

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

Breast Cancer Action
 Our Bodies Ourselves

Researchers/Clinicians

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

Patients

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

Genetic Counselors

Ellen Matloff, MS
 Elsa Reich, MS

DEFENDANTS

United States Patent and Trademark Office (PTO)

Myriad Genetics

University of Utah Research Foundation (UURF) directors



Supporters of Plaintiffs

- American Medical Association
- March of Dimes
- American Society of Human Genetics
- Sir John Sulston, *Chair of the Institute for Science, Ethics and Innovation at the University of Manchester, Nobel Prize Winner in Physiology or Medicine*
- Joseph Stiglitz, *Chair of Columbia University's Committee on Global Thought, Nobel Prize Winner in Economics*
- Dr. Susan Love
- FORCE
- World Council of Churches - Justice, Diakonia and Responsibility for Creation Program
- Ethics & Religious Liberty Commission, Southern Baptist Convention



Claims in Lawsuit



The PTO's granting of patents on the human BRCA1 and BRCA2 genes and Myriad's and UURF's enforcement of these patents violate:

- **patent law:** genes are "products of nature" and therefore unpatentable
- **U.S. Constitution:** practice amounts to patenting basic scientific knowledge

The effect of the patents is to:

- **prevent doctors and clinicians** from providing their patients with crucial medical information
- **restrict researchers'** scientific freedom to study the human genome and develop new treatments and genetic tests
- **prevent individuals** from having access to information about their own genetic makeup

Court Case



- **May 12, 2009:** *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.* filed in the United States District Court for the Southern District of New York.
- **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.**

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"

* has been appealed

How can you get involved?



- Public awareness
 - Host discussion or other event
 - Write op-ed, letter to the editor, blog
 - Facebook page: Don't Patent My Genes! Liberate the Breast Cancer Genes!
- Advocacy
- www.aclu.org/brca for more information
 - Links to 60 Minutes feature story and a video about the plaintiffs
 - Take the survey about BRCA genetic testing

