# Patents on Human Genes: A Patient's Perspective

ACLU
AMERICAN CIVIL LIBERTIES UNION

## You've been advised to get tested for your risk of hereditary breast and ovarian cancer. How do patents affect you?

**Two genes associated with hereditary breast and ovarian cancer, BRCA1 and BRCA2, are patented.**

Number of human genes:

**23,688** [a.]

Number of human genes that are patented:

**4,382** [b.]

Percentage of genes that are patented in the U.S.:

**18.5 %**

## What is the price of the test?

**Current Price** of Myriad's Comprehensive BRAC Analysis and BART testing: **$4,040** [c.]

**Number of states** where patients with Medicaid insurance are not covered for BRCA testing through Myriad:

[d.]

**Federal tax money** that funded the pursuit of the BRCA1 gene: **$5 million** [e.]

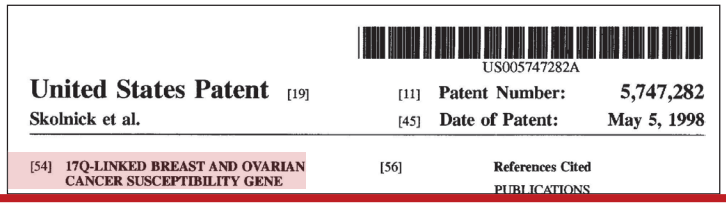
## Where can you get tested?

**Myriad Genetics has patents on the actual BRCA genes, not just on a test.**


Number of labs **in the U.S.** that provide clinical full sequencing of the BRCA1/2 genes:

**BRCA testing in other countries:**
Number of labs in **Germany**: **5** [f.]
Number of labs in **Europe**: **10** [g.]
Number of labs in **Australia**: **10** [h.]

Gene patents mean that a company has exclusive rights to the gene. The patentholder can control the test price, lab location, and how the gene is used for scientific research. **Patents on the BRCA genes mean that in the U.S., you can't get a second opinion.**


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

[56] References Cited
PUBLICATIONS

## Why is there only one lab?

**After Myriad obtained its patents, it sent letters ordering other labs to stop testing. A survey of U.S. laboratory directors showed:**

--> **25% stopped performing a genetic test** that they had been offering as a result of gene patent or license-holders exercising their intellectual property rights.

--> **More than 50%** had decided not to develop or perform a genetic test for clinical or research purposes because of a patent.

--> **More than 90%** thought patents had negative effects on the development of genetic tests and increased the cost of testing. [i.]

## What the ACLU is doing to fight human gene patents:


In May 2009, twenty plaintiffs represented by the ACLU and the Public Patent Foundation filed a lawsuit against the United States Patent Office and Myriad Genetics charging that Myriad's patents on the BRCA genes are invalid.

**We believe that these patents violate individuals' rights to know about their own genetic makeup, doctors' rights to provide their patients with crucial medical information, and scientists' rights to study the human genome and develop new treatments and genetic tests.**

The district court agreed with us on March 29, 2010, finding that the patents cover products and laws of nature. Myriad has appealed the decision.

For more infomation, visit our website: **www.aclu.org/brca**

**a.** Kyle Jensen & Fiona Murray, "Intellectual Property Landscape of the Human Genome," *Science* 310(5746):239-240 (October 14, 2005). **b.** *Id.* **c.** Yale Cancer Genetic Counseling, "Myriad Raises Price of BRCA Testing, Again," (Apr. 19, 2010), http://yalecancergeneticcounseling.blogspot.com/2010/04/myriad-raises-price-of-brca-testing.html (accessed June 16, 2010). **d.** Decl. of William E. Rusconi ¶¶ 4-5 in support of Defs.' Mot. For Summary Judgment, *Assoc. for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y. Dec. 23, 2009). **e.** Bryn Williams-Jones, "History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing," 10 *Health Law Journal* 131 (2002). **f.** NCBI: Gene Tests, "BRCA1 Hereditary Breast/Ovarian Cancer," http://www.ncbi.nlm.nih.gov/sites/GeneTests/lab/clinical_disease_id/2422?db=genetests%20 (accessed June 8, 2010). **g.** *Id.* **h.** Australian Life Scientist, "BRCA Time's up – GTG," Oct. 23, 2008, http://www.lifescientist.com.au/article/264818/brca_time_up_-_gtg (accessed June 16, 2010). **i.** Mildred K. Cho, et al., "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services," *Journal of Molecular Diagnostics* 5(1):3-8 (February 2003).

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