

Re: the gene patent inquiry.

I would like to bring this challenge to your attention.

Regards,  
Dr Rimmer

#### ACLU AND PUBPAT CHALLENGE PATENTS ON BREAST CANCER GENES: Gene Patents Stifle Patient Access To Medical Care And Critical Research

NEW YORK -- May 12, 2009 -- The American Civil Liberties Union (ACLU) and the Public Patent Foundation at Benjamin N. Cardozo School of Law (PUBPAT) filed a lawsuit today charging that patents on two human genes associated with breast and ovarian cancer stifle research that could lead to cures and limit women's options regarding their medical care. Mutations along the genes, known as BRCA1 and BRCA2, are responsible for most cases of hereditary breast and ovarian cancers. The lawsuit argues that the patents on these genes are unconstitutional and invalid.

"Knowledge about our own bodies and the ability to make decisions about our health care are some of our most personal and fundamental rights," said Anthony D. Romero, Executive Director of the ACLU. "The government should not be granting private entities control over something as personal and basic to who we are as our genes. Moreover, granting patents that limit scientific research, learning and the free flow of information violates the First Amendment."

Today's lawsuit was filed in U.S. District Court for the Southern District of New York on behalf of breast cancer and women's health groups, individual women and scientific associations representing approximately 150,000 researchers, pathologists and laboratory professionals against the U.S. Patent and Trademark Office (PTO), as well as Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the BRCA genes. It is the first to apply the First Amendment to a gene patent challenge.

The patents granted to Myriad give the company the exclusive right to perform diagnostic tests on the BRCA1 and BRCA2 genes and to prevent any researcher from even looking at the genes without first getting permission from Myriad. According to the lawsuit, such monopolistic control over these genes hampers clinical diagnosis and serves as a disincentive for research because Myriad not only has the right to enforce its patents against other entities but also has the rights to future mutations discovered on the BRCA2 gene. The gene patents are also illegal under patent law because genes are "products of nature."

"Patents are meant to protect inventions, not things that exist in nature like genes in the human body," said Chris Hansen, a staff attorney with the ACLU. "Genes isolated from the human body are no more patentable than gold extracted from a mountain."

Many women with a history of breast and ovarian cancer in their families opt to undergo genetic testing to determine if they have the mutations on their BRCA genes that put them at increased risk for these diseases. This information is critical in helping these women decide on a plan of treatment or prevention, including increased surveillance or preventive mastectomies or ovary removal. However, the fact that Myriad can exclude others from providing this testing has several negative consequences for patients: many women cannot afford the more than \$3,000 Myriad charges for the test; patients cannot get second opinions on their test results; and patients whose tests come back with inconclusive results do not have the option to seek additional testing elsewhere.

"Women whose doctors recommend genetic testing should be able to find out whether they have the gene mutations linked to breast and ovarian cancer so that they are able to make choices that could save their lives, and these patents interfere with their ability to do so," said Lenora Lapidus, Director of the ACLU Women's Rights Project.

"The patents on the BRCA genes block women's access to medical information necessary for making vital health care decisions, impeding their control over their own bodies," said Sandra Park, staff attorney with the ACLU Women's Rights Project.

Because the ACLU's lawsuit challenges the whole notion of gene patenting, it could have far reaching effects beyond the patents on the BRCA genes. Approximately 20 percent of all human genes are

patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma and many other illnesses.

"Scientific research and testing have been delayed, limited or even shut down as a result of gene patents, stifling the development of new diagnostics and treatments," said Tania Simoncelli, ACLU science advisor. "The government should be encouraging scientific innovation, not hindering it."

"Patenting human genes is counter to common sense, patent law and the Constitution," said Daniel B. Ravicher, Executive Director of PUBPAT and co-counsel in the lawsuit. "Genes are identified, not invented, and patenting genetic sequences is like patenting blood, air or  $e=mc^2$ ."

If Myriad's BRCA genes patents were invalidated, the clinicians, pathologists and researchers represented by the ACLU and PUBPAT would be able to engage freely in research, testing and clinical practice involving the BRCA1 and BRCA2 genes, and the patients would be able to obtain second opinions on test results and have access to genetic testing services from multiple, and perhaps more affordable, sources.

In addition to several individual women patients, plaintiffs in the case include:

- Association for Molecular Pathology
- American College of Medical Genetics
- American Society for Clinical Pathology
- College of American Pathologists
- Haig Kazazian, MD, Professor in the Department of Genetics at the University of Pennsylvania School of Medicine
- Arupa Ganguly, PhD, Associate Professor in the Department of Genetics at the Hospital of the University of Pennsylvania
- Wendy Chung, MD, PhD, Director of Clinical Genetics at Columbia University
- Harry Ostrer, MD, Professor of Pediatrics, Pathology and Medicine and Director of the Human Genetics Program at New York University School of Medicine
- David Ledbetter, PhD, Professor of Human Genetics and Director of the Division of Medical Genetics at the Emory University School of Medicine
- Stephen Warren, PhD, William Patterson Timmie Professor of Human Genetics and Chair of the Department of Human Genetics at Emory University
- Ellen Matloff, M.S., genetic counselor
- Elsa Reich, M.S., Professor in the Department of Pediatrics (Human Genetics Program) at New York University
- Breast Cancer Action
- Boston Women's Health Book Collective (Our Bodies Ourselves)

Attorneys on the case, Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al., include Hansen and Aden Fine of the ACLU First Amendment Working Group; Lapidus and Park of the ACLU Women's Rights Project; and Ravicher of PUBPAT. Simoncelli, the ACLU's science advisor, provides expert guidance on the case.

More information, including plaintiff and supporter statements and a copy of the complaint, can be found online at: [www.aclu.org/brca](http://www.aclu.org/brca) and [www.pubpat.org/brca](http://www.pubpat.org/brca).