

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS;
HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD;
WENDY CHUNG, MD, PhD; HARRY OSTRER, MD;
DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD;
ELLEN MATLOFF, M.S.; ELSA REICH, M.S.;
BREAST CANCER ACTION; BOSTON WOMEN'S
HEALTH BOOK COLLECTIVE; LISBETH CERIANI;
RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE;
VICKY THOMASON; KATHLEEN RAKER,

09 Civ. 4515 (RWS)

ECF Case

Plaintiffs,

v.

DECLARATION OF
JUDY NORSIGIAN

UNITED STATES PATENT AND TRADEMARK
OFFICE; MYRIAD GENETICS; LORRIS BETZ,
ROGER BOYER, JACK BRITTAIN, ARNOLD B.
COMBE, RAYMOND GESTELAND, JAMES U.
JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS,
DAVID W. PERSHING, and MICHAEL K. YOUNG,
in their official capacity as Directors of the University
of Utah Research Foundation,

Defendants.
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1. My name is Judy Norsigian. I am Executive Director of the Boston Women's Health Book Collective ("BWHBC"). BWHBC is a Plaintiff in the above-captioned case.

2. The Boston Women's Health Book Collective, more commonly known as Our Bodies Ourselves, is a nonprofit, public interest women's health education, advocacy, and consulting organization.

3. Our mission is to provide truthful, accessible, research-based information about women's health and sexuality. We vigorously advocate for women's health by challenging the

institutions and systems that block women from full control over our bodies and inspiring and empowering women to become engaged in health policy.

4. Since 1970, we have authored eight editions of *Our Bodies Ourselves* (published by Simon and Schuster since 1973). This book has become a classic resource educating women about health, sexuality, and reproduction. The eighth edition was published in 2005. We have written additional books, have distributed more than 10,000 books and materials free of charge worldwide, and currently facilitate translation and adaptation projects in such countries as India/Bangladesh, Israel, Turkey, Nepal, Nigeria, and Tanzania. Similar projects completed in other countries (for example, Russia, Albania, South Korea, Serbia, and Thailand) are described at our website, www.ourbodiesourselves.org. In recent years, we launched a blog, which currently is read by several thousand people on a daily basis.

5. This case seeks to invalidate patents that have been granted on the BRCA1 and BRCA2 genes. That goal is completely in line with the mission of BWHBC. Two of our core principles are: women can become their own health experts, particularly through discussing issues of health and sexuality with each other; and health consumers have a right to know about controversies surrounding medical practice and about where consensus among medical experts may be forming.

6. The BRCA gene patents contradict these principles. The gene patents give the patentholder the right to control all testing and research done on the genes – in effect, the right to control the information that is learned about the BRCA1/2 genes. This is harmful to women's health. Women and their doctors should have access to information about a particular patient's genes, as well as aggregated data for research purposes. Instead, women have been unable to afford BRCA genetic testing because of the high cost of the test and they also have access only

to the testing the patentholder allows. In the U.S., that means that patients can get BRCA1/2 full sequencing done only through Myriad Genetics. As we reported on our website in March 2006, Myriad's standard full sequencing test was shown to yield a 12% false negative rate in high-risk women in one major scientific study.¹ BWHBC cannot advocate for researchers and clinicians to perform BRCA1 and BRCA2 related activities, even when the activities might be aimed at creating new testing methods that Myriad Genetics does not offer or performing testing at a lower price. We cannot refer readers to or publicize full gene sequencing services at laboratories other than or in addition to Myriad Genetics.

7. These broad patents – which cover the actual BRCA1/2 genetic sequences, mutations, and their correlations with hereditary breast and ovarian cancers – are a barrier to a woman's ability to know about her body and make informed health decisions. A hypothetical, but not unrealistic, example illustrates the extent to which the patents restrict a woman's access to information about the genes in her own body: Imagine a woman who has an extensive family history of breast cancer and has been diagnosed with cancer wants to learn about her hereditary risk; she is a trained laboratory professional with the resources and ability to conduct a test to examine a blood sample for mutations along the BRCA1/2 genes; and yet, she cannot draw her own blood and run the test without technically violating the patents. That is because the patents are on the genes and the information they hold, including her own genetic information.

8. BWHBC's work has been frustrated by the BRCA1/2 gene patents and Myriad Genetics' exclusive control over genetic testing. We have had to use our scarce resources to identify and address the problems that result, including staff time for investigating, writing and publishing articles about these problems and engaging in advocacy on these issues. For example, I wrote a letter in May 2007 on behalf of Our Bodies Ourselves in support of a federal bill that

¹ Available at www.ourbodiesourselves.org/book/news.asp?newsID=32.

would limit patenting of human genes.² We also have voiced our concerns about Myriad's direct to consumer marketing practices.³ And because the patents extend over the correlation between mutations and hereditary risk of cancer, any publication of that correlation by BWHBC could be alleged to induce patent infringement, even though one of BWHBC's main purposes is to educate the public about women's health, including breast and ovarian health. Invalidation of the patents would advance our mission of ensuring that women have full access to truthful information about their bodies and health.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.

Executed on August 17, 2009


JUDY NORSIGIAN

² Available at <http://becerra.house.gov/HoR/CA31/Issues/OurBodiesOurselvesLetter.htm>.

³ See, for example, www.ourbodiesourselves.org/book/companion.asp?id=28&compID=27, and www.ourbodiesourblog.org/blog/2007/09/selling-women-fear-through-genetic-testing-ad.