

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
PATRICE FORTUNE

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 Patrice Fortune. I am a Plaintiff in the above-captioned case.
 2. I am a 48-year-old woman living in California.
 3. After a regular screening mammogram, I was diagnosed with breast cancer in February 2009. As I was considering my treatment options, I consulted a genetic counselor. She reviewed my personal medical history and my family medical history. My maternal great-aunt and maternal great-grandmother died of breast cancer in their 40's, as well my paternal

grandmother and two paternal great-aunts also had breast cancer. In addition, I have relatives who were diagnosed with other forms of cancer.

4. My genetic counselor and my physician advised me that BRCA genetic testing was appropriate for me. People with BRCA mutations are at high future risk of cancer – both breast and ovarian. Many choose to get prophylactic breast and ovarian surgery to reduce their risk of future cancers, particularly because it is difficult to screen for ovarian cancer. Also, doctors tailor screening and treatment for people who have a BRCA mutation.

5. Based on this information, I wanted to get BRCA genetic testing done as soon as possible. However, my genetic counselor told me Myriad Genetics is the only testing provider in the United States because of its patents and that it does not accept my insurance for BRCA testing. I have insurance through Medi-Cal, California's Medicaid program. I was told that even though Medi-Cal has agreed to cover some of the cost of my testing, Myriad would refuse to process my blood sample unless I could pay out-of-pocket for the cost of the test. I am currently working in unpaid positions as I receive cancer treatment and cannot afford to pay out of pocket for a test. I looked into scholarship programs that could cover the over \$3000 cost of the test, but did not identify anything that could help me.

6. Because I do not have access to BRCA full sequencing through Myriad, and because no other laboratory can offer it to me, I am not able to make the most informed decisions about the course of my current cancer treatment and about oophorectomy (surgery to remove the ovaries). I also want to let my children know about my genes. I have three children: 25-year-old male/female twins and a 20-year-old son. If I get tested, they will have the information about my genes to assess their hereditary risk of cancer.

7. Another problem with the patents is that even if you can get the test through Myriad, you cannot confirm your results by getting full sequencing at another lab. I would want a verification of my results - whether they were negative or positive - because I know that labs sometimes make mistakes. After I was diagnosed with breast cancer, I made sure to seek second opinions before making major choices about treatment. I would not want to opt for or against major surgery based on one test result.

8. If I learned that Myriad's patents on the BRCA1 and BRCA2 genes were invalidated, I would take action right away. I would pursue and order BRCA genetic testing through another laboratory. Without the patents, geneticists and laboratory professionals other than Myriad would be able to offer BRCA full sequencing. I would be able to find out whether my genes have any mutations that are connected to cancer and make life decisions accordingly. This is not just speculation on my part. I understand that some of the other plaintiffs in this case, including Dr. Chung and Dr. Ostrer, would offer BRCA genetic testing to me if the patents were no longer a barrier. I would immediately seek testing through their laboratories if the patents were no longer in effect. I would also seek verification of my BRCA genetic test results at a second lab. I do not want to base important, life-changing medical decisions on one test.

9. The reason I do not know whether I have a BRCA genetic mutation is that the gene patents give all rights over genetic testing to the patent holder, and Myriad has refused to contract with my insurance company. Patients should not be forced to get information about their genes from only one source, at whatever cost and conditions that one source sets.

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 12, 2009


PATRICE FORTUNE