

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
LISBETH CERIANI

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 Lisbeth Ceriani. I am a Plaintiff in the above-captioned case.
2. I am a 43-year-old woman living in Massachusetts.
3. In May 2008, when I was 42 years old, I was diagnosed with multiple tumors in both breasts (bilateral breast cancer). Soon after my diagnosis, I was told about BRCA genetic testing but the hospital staff said the test could not be done with the insurance I had.
4. During the course of my cancer treatment, I switched hospitals. My new doctor and genetic counselor advised me that my family history of breast cancer, along with the early

onset of my bilateral breast cancer, suggests a possible mutation in my BRCA genes. Because people with BRCA mutations are at higher future risk of breast and ovarian cancers, and because ovarian cancer is often difficult to detect, they recommended that I obtain genetic testing to help assess my risk for ovarian cancer.

5. Based on this advice, I was determined to get BRCA genetic testing done as soon as possible. In December 2008, my doctor took a blood sample from me and sent it to Myriad Genetics for BRCA genetic testing. My doctor told me that Myriad, which is based in Utah, is the only laboratory in the United States that can do this testing. Soon after my blood was sent, a Myriad representative called me and said that the company would not process my test because it does not accept my insurance. The only option I was given was to pay out-of-pocket.

6. I am currently insured through MassHealth, a Medicaid insurance program for low-income people in Massachusetts. Although my health insurance covers genetic testing done through contracted laboratories, Myriad refuses to contract with MassHealth. I was told that Myriad refuses to accept the \$1599 reimbursement rate that MassHealth offers for the test. Myriad is the only laboratory in the U.S. that provides full BRCA gene sequencing, so it is impossible for MassHealth to "contract" with another laboratory to cover this test for its insured.

7. Therefore, the only way for me to obtain this test would be to pay Myriad for the full cost, out-of-pocket. I currently work part-time, support my young daughter as a single mother, and cannot afford to pay more than \$3000 for this test. I looked into available scholarship programs to fund my test through Myriad, but did not find anything.

8. I would like to obtain genetic testing through another lab that would accept my insurance, but my genetic counselor informed me that Myriad Genetics is the only provider of this test in the United States because it owns the patents on the BRCA genes.

9. Even if I could get the test through Myriad, I could not get full sequencing done at another lab to confirm my results due to these patents. If I tested positive for a BRCA mutation, I would likely opt for an oophorectomy. But before choosing to remove my ovaries, which can have long-term consequences and side effects, I would want a verification of my results. Second opinions become impossible when patents give exclusive rights to analyze particular genes.

10. Without the BRCA genetic test, my future is uncertain. I have undergone extensive treatment for my breast cancer, including a bilateral mastectomy, chemotherapy, radiation, and physical therapy, but I still have not been able to obtain BRCA genetic testing, the key test in determining my hereditary risk for ovarian cancer. My doctors suspect that I have a BRCA mutation and will strongly recommend a prophylactic oophorectomy to remove my ovaries if I do. However, I would not risk putting myself through such a serious surgery and accompanying side effects without validation of increased risk of ovarian cancer such as a confirmed BRCA genetic mutation.

11. If I learned that the 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.

12. More than a year has passed since I was diagnosed with cancer, and I still do not know whether I have a BRCA genetic mutation. I am in this situation because the patents over the BRCA genes allow one company to control all genetic testing, and that company has chosen not to accept my insurance. It has been and will continue to be difficult to make medical decisions without this piece of information about my genes. Also, without testing, I cannot pass on the information about my genes to my daughter. She is only 8 years old now, but when she is older, she might want to know about my genes so that she can assess her hereditary risk of cancer.

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 13, 2009


LISBETH CERIANI