

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
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  
VICKY THOMASON

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.

- X
1. My name is Vicky Thomason. I am a Plaintiff in the above-captioned case.
  2. I am a 52-year-old woman living in Kentucky.
  3. In 2006, when I was 49 years old, I was diagnosed with cancer in my left ovary.
  4. After undergoing surgery and chemotherapy, I consulted with my doctor and a genetic counselor about the best course for further surveillance and treatment. They advised me that I was an appropriate candidate for BRCA genetic testing, based on my personal history and my family history of cancer. My mother was diagnosed with breast cancer at age 48, and my

only maternal uncle died at age 69 after being diagnosed with pancreatic cancer. They informed me that if I was positive for a BRCA mutation, I was at higher future risk for breast cancer. My genetic counselor estimated that I had approximately a 23% chance of carrying a BRCA1 or BRCA2 mutation. I decided to be tested in order to help me make informed medical care decisions about screening and other options, which could include prophylactic mastectomy.

5. In September 2007, my doctor ordered Myriad Genetics' Comprehensive BRCAAnalysis test for me. I received the following result: "NO MUTATION DETECTED." However, my test results also stated:

"This test is also designed to detect five specific BRCA1 genomic rearrangements, including a 3.835-kb deletion involving exon 13, a 510-bp deletion involving exon 22, a 6-kb insertion involving exon 13, a 7.1-kb deletion involving exons 8 and 9, and a 26-kb deletion involving exons 14-20. The proportion of all BRCA1 genomic rearrangements represented by these specific abnormalities has not yet been characterized. There are other, uncommon genetic abnormalities in BRCA1 and BRCA2 that this test will not detect. This result, however, rules out the majority of abnormalities believed to be responsible for hereditary susceptibility to breast and ovarian cancer..." (emphasis added)

6. My genetic counselor informed me that while my genes were negative for mutations based on Comprehensive BRCAAnalysis, 5-10% of mutations are missed by this test. Myriad has an additional test, called BRCAAnalysis Rearrangement Testing ("BART"), that she said has a 1-2% chance of finding a missed mutation. BART is offered separately from the first test and requires additional payment. My genetic counselor told me that it was appropriate for me to get BART testing.

7. I was upset when I found out that the test I had received did not look for all known mutations. I had only gotten a partial answer to the question about my hereditary cancer risk. It was important to me to get the additional testing so that I would have more information when making health decisions.

8. I was told that my insurance would not cover the entire cost of BART. My husband and I already have many financial concerns as he is disabled, I have recently undergone cancer treatment, and our combined income is low. I cannot spend hundreds of dollars on this additional test. I also learned that no other labs offer this test at a lower price, because only Myriad can perform the test.

9. It has been almost two years since I received my negative BRCA mutation test result and since my genetic counselor advised me regarding the supplemental BART test. Because I still cannot afford this test, I continue to face life-altering medical decisions without knowing for sure whether I have a BRCA mutation.

10. 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 testing that would look for large rearrangements. I would be able to get more information about my genes and my hereditary breast cancer risk 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.

11. The reason I have not been able to obtain BRCA large rearrangement testing to date is that the gene patents prevent any other laboratory in the United States from performing BRCA testing for patients. As a result, the company that controls the patents can decide what tests to offer, how to offer them, and how much to charge for each. If the patents were invalidated, I could finally obtain the large rearrangement analysis of my genes that was not performed when I was first tested and could more fully understand my genes and my hereditary risk for 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 8, 2009

  
\_\_\_\_\_  
VICKY THOMASON