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,

Plaintiffs,

v.

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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09 Civ. 4515 (RWS)

ECF Case

DECLARATION OF KATHLEEN RAKER

1. My name is Kathleen Raker. I am a Plaintiff in the above-captioned case.

2. I am a 42-year-old woman living in Pennsylvania.

3. Since I was a child, I have been concerned about my risk for breast cancer. My mother was diagnosed with advanced breast cancer at age 26 and died less than two years later, when I was three years old. About ten years prior to my mother's death, her mother – my grandmother – also died of breast cancer.

4. I have never been diagnosed with cancer. In November 2004, I had a biopsy because my doctor was concerned about a suspicious rash on my breast that had been there for several months. The biopsy fortunately turned out negative.

5. Afterwards, I enrolled in a special breast surveillance clinic. Upon learning about my family history, my doctor at that clinic recommended that I obtain genetic counseling. I met with a genetic counselor. After reviewing my family history in detail, my genetic counselor presented the option of testing for BRCA1 and BRCA2 genetic mutations, which indicate a higher future risk of breast and ovarian cancers. My genetic counselor facilitated genetic testing with my doctors. I knew that the test results could be crucial information to help me make the most informed medical decisions, including decisions about screening and prevention options.

6. In April 2007, my doctor ordered Myriad Genetics' Comprehensive BRACAnalysis 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 <u>this test will not detect</u>. This result, however, rules out the majority of abnormalities believed to be responsible for hereditary susceptibility to breast and ovarian cancer..." (emphasis added)

7. I was informed that my BRCA test results were negative, finding no deleterious mutation on my BRCA1 or BRCA2 genes. However, my counselor explained to me that I could still be at hereditary risk due to a mutation in my BRCA genes that could not be detected in the initial test. She told me about a second test that can identify additional mutations that are not detected in Myriad's "Comprehensive BRACAnalysis." This second test, also offered by Myriad Genetics, is entirely separate from the first test and would cost an additional $650 to perform. She presented this second test as a follow-up option for me.

8. I was frustrated to learn that the test I had received did not look for all the mutations on my BRCA1 and BRCA2 genes that are known to the scientific community. I couldn't feel sure about my results – I was not really negative for all BRCA mutations, just the ones that they looked for in that first test. I learned that the second test looks for large rearrangements in my BRCA genes that cannot be detected by the first test. Given my family history, it is very important to me to know whether BRCA genetic mutations are something I need to factor into my medical care. Long-term, it is also important for my two children and their future children to have this information about my genes so that they can consider testing, screening and prevention at the appropriate time. Without this information, my family may be lulled into a false sense of security only to once again be taken by surprise by a family member's cancer diagnosis at an early age and incurable stage. I wanted to order this additional test.

9. However, I could not then, and still cannot, afford to pay $650 out-of-pocket for the second test. My family has struggled financially in recent years. Our economic situation has jeopardized our health insurance. My two sons are covered through the government's Children's Health Insurance Program ("CHIP"). My husband and I have insurance but have often fallen behind in making payments, and as a result, our coverage is unstable and insecure.

10. I also learned that there is no lab other than Myriad where I could get large rearrangement or confirmatory testing done, because Myriad controls patents over the BRCA genes. That means that I cannot order large rearrangement testing from another lab at a lower price, or as part of a complete test. I also cannot get verification of the negative result that I received. It is my understanding that even for research purposes, other labs could not tell me whether they see new mutations in my BRCA genes using new testing methods.

11. To date, I still have not obtained Myriad's BRACAnalysis Rearrangement Testing ("BART"), or any other large rearrangement testing, to determine if I have a BRCA mutation that would have been missed by the first "comprehensive" test. I face stressful questions about how to best protect my health without this significant piece of information about my genes. I am particularly worried about the difference this information would make for me with respect to ovarian cancer, because doctors often cannot identify ovarian cancer at an early stage. If I were positive for a BRCA mutation, I would probably have an oophorectomy in order to reduce the likelihood that I will ever experience breast or ovarian cancer. If I learned that I am in fact positive for a BRCA mutation, I would also be more apt to consider chemo-prevention and further steps to ensure adequate screening for breast cancer.

12. 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.

13. The reason I have not yet gotten BRCA large rearrangement testing 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

Kathleen Raker
KATHLEEN RAKER