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 RUNI LIMARY

1. My name is Runi Limary. I am a Plaintiff in the above-captioned case.

2. I am a 32-year-old Asian-American woman living in Texas.

3. When I was 28 years old, I found a lump in my right breast. I was told by my doctor that I was too young to have cancer. It was only after I insisted that my doctors look further that I was diagnosed with an aggressive breast cancer, in November 2005.

4. After my diagnosis, my doctor advised me that I was an appropriate candidate for BRCA genetic testing, especially because of my age. People with BRCA mutations are more

likely to experience cancer at younger ages. I decided that I wanted to get the testing, because if I had a BRCA mutation, I would be at higher future risk of breast and ovarian cancers and could make treatment decisions accordingly. But my insurance plan did not cover the test, and I could not afford to pay the $3000 cost of the test out-of-pocket. I was forced to make important medical decisions without knowing whether I was positive for a mutation.

5. I was not able to get tested until nearly two years after my diagnosis. I switched jobs, and my new insurance policy covered the Comprehensive BRACAnalysis test offered by Myriad Genetics. In November 2007, I received my test results: "GENETIC VARIANT OF UNCERTAIN SIGNIFICANCE." The results showed "No Mutation Detected" for my BRCA2 sequence and a genetic variant of "Uncertain Significance" for my BRCA1 gene.

6. I was surprised and disturbed by these results. I had not known that this was a possible outcome – that I could have a mutation but not know whether it was connected to a higher risk of cancer. I called Myriad Genetics and was told that this variant had been identified in other women of Asian descent but that they did not know whether it was correlated to cancer.

7. Later, I discovered that I could not get BRCA sequencing done at a lab other than Myriad's, and that there was additional testing offered through Myriad that I had not received that looked for certain large rearrangements along the BRCA genes. This additional test, called BART, is a separate test that costs approximately $650. I also learned that variants of uncertain significance are disproportionately found in women who belong to minority racial groups.

8. I want to make the most informed health and medical decisions for myself, but it is difficult to weigh my options when I do not know the significance of the genetic variant I have. I am deeply concerned that the patents are a barrier for minority women who want to be tested and for scientists who want to uncover the significance of variants such as the one in my

genes. A commercial laboratory may not have much financial incentive to determine the meaning of a mutation that tends to appear in a small percentage of the population in the U.S., like women of Asian descent. If I knew I was positive for a deleterious mutation, I would choose to have an oophorectomy (ovarian surgery), because screening methods for ovarian cancer often do not detect cancer until it has advanced. But I do not have any children and do not want to end my ability to have children by removing my ovaries unless my risk of cancer is high.

9. 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 additional 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 verify my results and have my genes tested using other methods, 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. Dr. Chung also has stated that she would conduct further testing and analysis to determine the meaning of variants of uncertain significance, including the variant I have, and I would immediately agree to participate in this testing and analysis. I would choose to participate with a laboratory that will share its data, including the data about my variant, with other researchers.

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 10, 2009

RUNI LIMARY