UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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	Civil Action No. 09-4515 (RWS) **DECLARATION OF ELLEN T. MATLOFF, M.S.**

1. My name is Ellen T. Matloff. I am the Director of the Cancer Genetic Counseling Shared Resource at the Yale Cancer Center in New Haven, Connecticut. I am also a Research Scientist in the Department of Genetics at the Yale University School of Medicine.

2. I am a plaintiff in this matter. The statements herein represent my views as an individual and not those of Yale University.

3. I received my B.S. in Biology from Union College in 1991 and my M.S. in Genetic Counseling from Northwestern University in 1993. In 1996, I was certified by the American Board of Genetic Counseling. I have served as Director of the Cancer Genetic Counseling Shared Resource at the Yale Cancer Center since 1997. I have authored and co-authored published articles in the field of genetic counseling in various scientific journals including *Journal of Genetic Counseling*, *The Cancer Journal from Scientific American*, and *Journal of Clinical Oncology*. A copy of my curriculum vitae is attached hereto as Exhibit 1.

4. I advise women on the risks and benefits of obtaining an analysis of their genes to determine if they have genetic mutations that correlate with an increased risk of developing breast and ovarian cancer. Specifically, the genes we most commonly analyze are known as the BRCA1 and BRCA2 genes. If I determine that such an analysis is warranted for a woman and she concurs, I arrange for the analysis and advise the woman of the significance of the results. The only provider available to me to perform full sequencing of BRCA1 and BRCA2 is Myriad Genetics. This is not because of the high level of difficulty of the analysis, but instead it is because Myriad Genetics holds certain patents relating to BRCA1 and BRCA2 and has asserted those patents in a continuous and systematic way that has foreclosed any other provider from offering such analysis to me and my patients.

5. I am in regular contact with geneticists and lab employees. We have regularly discussed the fact that I can only use Myriad for full BRCA1 and BRCA2 testing and the harm that this situation has created. Despite the fact that many of these geneticists and their labs could perform this same testing, they have not offered such testing because it is widely known in the field that doing so would, according to Myriad, violate its patents

6. I am aware of multiple instances in which Myriad Genetics used its patents to stop genetic testing by others of the BRCA genes.

7. First, sometime in or around December 2000, I learned that the director of the Yale DNA Diagnostics Lab received a letter from Myriad Genetics directing the lab to cease BRCA1 and BRCA2 genetic testing that was being conducted in the laboratory because that testing allegedly infringed Myriad's patents. Prior to receipt of the letter, the Yale DNA Diagnostics Lab had offered BRCA1 and BRCA2 genetic analysis to me and my patients at a much lower cost of $1600. After receipt of the letter, the lab ceased to offer such genetic analysis.

8. In a separate instance in about 2005, I telephoned Myriad to inquire whether it was permissible for the Yale DNA Diagnostics Lab to perform an additional genetic screening of the BRCA genes that looked for large rearrangements. Several scientific studies had demonstrated that Myriad's full sequencing test missed large rearrangements that are also correlated with cancer risk. The Myriad Genetics representative with whom I spoke told me that he would research my

question and return my call. Approximately a week later, another Myriad representative called me and said that large rearrangement testing could not be done at the DNA Diagnostics Lab because it would infringe Myriad's BRCA patents. It took Myriad approximately a year to begin offering large rearrangement testing which they called "BRCA Analysis Rearrangement Testing," or BART, even though the DNA Diagnostics Lab could have performed such additional analysis immediately. This period caused me grave concern for my patients, because large rearrangement testing is capable of identifying cancer related mutations that the basic BRCA1 and BRCA2 testing offered by Myriad does not identify.

9. It is my belief that Myriad's continuous and systematic assertion of its BRCA patents has resulted in the elimination of other genetic testing options available to me and my patients that could be cheaper, better and more appropriate. Through the BRCA patents, Myriad has exclusive access to extensive data about the women whose BRCA genes it has screened. If other researchers had access to this type of data, they could analyze it to potentially provide better information about important topics such as how the BRCA gene works, what drugs most effectively treat women with particular BRCA mutations, and the meaning of the ambiguous test result received by some women that states "variants of unknown significance," to name a few. Because of the BRCA patents, studies that would shed light on issues like these have not been performed, and the quality of care that genetic counselors are able to provide patients has suffered.

10. If I learned that the BRCA patents owned by Myriad were invalidated, I would immediately begin to do several things that I have the capability and desire to do today, but am unable to do because of the BRCA patents.

11. First, I would send genetic samples from women who are appropriate candidates for BRCA gene analysis to laboratories other than Myriad Genetics, which would then be free to test for BRCA mutations without legal repercussion. This is not merely a hypothetical possibility, as I understand that several labs have the capability and desire to provide such service as soon as possible, including the labs of my co-plaintiffs Chung, Ledbetter and Ostrer.

12. Second, because competition would cause the cost of BRCA gene analysis to decrease if Myriad no longer monopolized the BRCA gene testing market, I would order gene analysis for a larger percentage of the population of women who come to me for genetic counseling. The lower cost would be a significant factor for a large population of women, because while Myriad has a program to help cover the cost of testing for some indigent women, the program does not apply to women who either have an income that exceeds twelve thousand dollars per year or have not been diagnosed with cancer (even though Myriad advertises their testing to women who have never had cancer). I understand from discussions I have had with personnel in the Yale Department of Genetics that the cost to provide such genetic analysis is much less than what Myriad currently charges.

13. Third, also due to the reduced cost of BRCA gene testing, I would expand the population of women whom I counsel and for whom I arrange genetic testing. Specifically, I would arrange for BRCA1 and BRCA2 testing for all women with certain types of cancer including triple negative breast cancer, medullary breast cancer, and epithelial invasive ovarian cancer, because women with these types of cancers are overrepresented in the population of women having BRCA1 and BRCA2 mutations.

14. Fourth, I would arrange for large rearrangement testing on genetic samples from all women who warrant BRCA1 and BRCA2 testing, as full sequencing does not reveal all genetic mutations along the BRCA genes. Myriad currently charges an additional $650 on top of the cost of BRCA1 and BRCA2 testing for its large rearrangement test, or BART, and most insurance companies are unwilling to pay this additional cost. I understand that several other labs have the capability and desire to provide large rearrangement testing as soon as possible, including the labs of my co-plaintiffs Chung, Ostrer and Ledbetter. Without Myriad's patent-based monopoly on BRCA testing, a decrease in the cost of such genetic testing would ensue, significantly expanding the population of women with access to testing for large rearrangements.

15. I have the desire and capability to immediately do each of these things. The only reason I am not doing so today is because of the monopolization of the market for

BRCA-related genetic testing by Myriad that has resulted from its assertion of its gene patents.

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..

Ellen T. Matloff, M.S.

Executed on August 12, 2009