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 ELSA W. REICH, M.S.**

1. My name is Elsa W. Reich. I am a professor in the Human Genetics Program in the Department of Pediatrics at New York University School of Medicine. I am also a board certified genetic counselor. I am one of the plaintiffs in this action.

2. I received my B.S. in biology from the University of Chicago in 1956 and my M.S. in Human Genetics and Genetic Counseling from Sarah Lawrence College in 1974. I was certified by the American Board of Medical Genetics in Genetic Counseling in 1982 and by the American Board of Genetic Counseling in 1993 and recertified in 2006. I was appointed Professor (clinical) of Pediatrics in the Human Genetics Program in the New York University School of Medicine Department of Pediatrics in 2003. I have been a genetic counselor at New York University School of Medicine since 1974. I have co-authored published articles in the field of genetic counseling in various scientific journals including *Human Genetics* and *American Journal of Human Genetics*. I am a member of the American College of Medical Genetics, an organization that is also a plaintiff in this action. A copy of my curriculum vitae is attached hereto as Exhibit 1.

3. As a genetic counselor, I provide risk assessment and information to women and men about the probability of their having a heritable form of cancer in themselves or their families and advise them on the potential utility of obtaining an analysis of their genes to determine if they have genetic mutations that correlate with an increased risk of developing breast or ovarian cancer or potentially other malignancies as well. Specifically, the genes of most interest to be analyzed are known as the BRCA1 and BRCA2 genes. If a woman/man requests this testing, I arrange for the analysis and provide an extensive explanation about the significance of the results. The only provider currently available to me to perform such analysis is Myriad Genetics. This is not because of the high level of

difficulty of the test, but instead it is because Myriad Genetics holds certain patents relating to BRCA1 and BRCA2 and has asserted those patents in a continuous and systemic way that has foreclosed any other provider from offering such analysis to me and my patients.

4. From July 1, 2008 until June 30, 2009, Myriad has tested the genetic samples of approximately 350-400 patients whom I have counseled and who have elected genetic testing. The vast majority of these patients reside in New York.

5. As part of my daily responsibilities, I am in regular contact with geneticists, genetic counselors and lab employees. We have regularly discussed the fact that I can only use Myriad for BRCA1 and BRCA2 testing and the harm that this monopolization causes. 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. It is my belief that Myriad's continuous and systematic assertion of its BRCA patents has resulted in the elimination and prevention of other genetic testing options available to me and my patients that could be cheaper, more appropriate, or useful as a source of a second opinion on Myriad's results for any given patient.

7. If I learned that the BRCA patents owned by Myriad were invalidated, I would potentially alter my testing choices in numerous ways.

8. First, I would send genetic samples from patients who are appropriate candidates for BRCA gene analysis and whose genes have not previously been screened to laboratories other than or in addition to Myriad Genetics. This is not merely a hypothetical possibility, as I understand that several laboratories, including those of my co-plaintiffs Drs. Chung, Ostrer and Ledbetter, have the capability and desire to provide such service as soon as the risk of patent infringement allegations is eliminated. To be precise, Dr. Ostrer is my colleague at NYU and I know personally that his lab has the capability and desire to provide such testing services to our patients. I would use these and other alternate labs for several reasons, including cost efficiency because it is my belief that once the patents are removed as a barrier to other labs providing BRCA testing, other labs would compete with Myriad, resulting in a lower price for the test. For other genetic testing, where there is more than one lab providing the test, I select the laboratory offering a lower cost providing that the testing is at least comparable in quality. This reduced cost could potentially give patients whose insurance companies do not pay for testing and who cannot otherwise afford to pay out of pocket for BRCA testing access to the service that they currently do not have.

9. Second, for some of my patients whose genetic samples have already been screened by Myriad, I might have genetic samples tested again by one of the alternate laboratories. In certain cases it may be important for a patient to obtain a second analysis, *e.g.*, if Myriad states that there is a mutation that creates an increased susceptibility to breast and ovarian cancer. For example, a woman

contemplating surgical removal of her breasts or ovaries as a risk-reducing measure may wish to verify that she does indeed have a harmful mutation. I counseled such a patient recently and although she was prepared to undergo surgery once it was determined conclusively that she had a mutation, the single positive test result that Myriad provided did not provide her with the confidence level she needed; yet she was unable to obtain a confirming opinion from an independent laboratory.

10. Third, I might exercise more discretion over the methodology used in each patient's BRCA testing. There are several ways to screen for BRCA mutations. Myriad offers four alternatives:

    A. The test most commonly utilized is "Comprehensive BRCAnalysis" which includes full sequencing of both genes as well as detection of five common rearrangements of BRCA1.

    B. The second test may target a single mutation that has previously been identified in the family and the care provider may elect to test only for that single mutation.

    C. A third test, also a targeted mutation analysis, identifies the founder mutations that can be identified in certain populations that account for a large fraction of all of the mutations within that population. For example, among Ashkenazi Jews, there are three such "founder" mutations. When one of these founder mutations has been identified in a family, the testing of family members by

convention includes testing for all three founder mutations. These three mutations account for 90-95% of all mutations identified in BRCA1 and 2 in this population and as the result the majority of Ashkenazi Jews do not require full sequencing which is many fold more expensive. Among individuals from Iceland, there is a single founder mutation which would also be targeted initially before any other testing.

D. BRACAnalysis Rearrangement Test or BART, detects large duplications and deletions which are not identified by full sequencing or by any other testing described above. This test is automatically added to the sequencing if a patient's family history, according to Myriad, fulfills specific criteria. I, along with many other counselors, would like to have this testing included in the standard "sequencing" testing. It is not always possible to provide all of the information that would assure that this test was included. That should be the providers' judgment. In addition, many insurers do not cover this test when it is and "add-on" and not included by the laboratory and even when the provider believes that it could potentially be informative, the patient may have to pay several hundred dollars out of pocket.

11. There are other methodologies that a lab might employ to screen for mutations; the extent of the testing described above is what Myriad has decided to offer. By allowing independent labs to perform BRCA related testing, alternative methods could be developed and utilized.

12. The methodology that is appropriate for a given patient depends upon her/his individual circumstances. For example, due to its high cost, with some exceptions, I do not recommend full sequencing for a patient with a known family history of a mutation in one of the BRCA genes for which a targeted and less expensive analysis exists. I am committed, together with my primary concern for the patient and my ability to provide him/her with the most extensive and sensitive testing available that is applicable to the patient, to decreasing the cost to patients as well as to insurers. I do not believe in providing a more expensive test solely because the insurer will reimburse the costs.

13. I believe that once multiple laboratories are performing BRCA testing, additional tests may be developed that will allow patients who must currently pay for full sequencing to instead take advantage of new targeted analyses that screen specific areas on the BRCA1 and BRCA2 genes other than those currently tested by targeted analyses and that the costs will become more competitive.

14. I have the immediate capability and desire to undertake the activities described above. The only reason why I cannot do so today is a result of Myriad's assertion of its BRCA related patents in a way that has foreclosed any other lab from providing BRCA genetic testing.

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.

Elsa W. Reich, M.S.

Executed on August 21, 2009