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, -against- 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.	No. 09 Civ. 4515 (RWS) ECF Case DECLARATION OF DR. GREGORY C. CRITCHFIELD

I, Gregory C. Critchfield, declare:

1. I am President of Myriad Genetic Laboratories, Inc., a wholly owned subsidiary of Myriad Genetics, Inc. (referred together as "Myriad"). I have held this position since July 1998. I received my M.D. from the University of Utah, and my M.S. in Biophysical Sciences from the University of Minnesota. I am Board Certified in Clinical Pathology. Before joining Myriad, I served as Senior Vice President, Chief

Medical and Science Officer of Quest Diagnostics Inc. A copy of my curriculum vitae and a list of publications by me are provided in the **Exhibits 1 and 2**, respectively.

I. MYRIAD'S PATENT RIGHTS HAVE PROMOTED RESEARCH

2. Myriad was founded to conduct innovative research to discover and isolate disease genes, and to commercialize genetic testing based on the disease genes. Today Myriad is still active in research and discovery to develop prognostic, personalized, and predictive medicine testing products. It is in Myriad's own interest that neither basic nor clinical research be stifled by patents. In fact, Myriad has consistently promoted and encouraged both basic and clinical research on the *BRCA1* and *BRCA2* genes by others, by (1) allowing academic scientists to conduct research studies on the *BRCA1* and *BRCA2* genes freely; (2) providing direct assistance to researchers in their studies on the *BRCA1* and *BRCA2* genes; and (3) conducting its own research on the *BRCA1* and *BRCA2* genes, publishing the research results and actively disseminating information on the *BRCA1* and *BRCA2* genes.

Myriad Allows Research on the *BRCA1* and *BRCA2* Genes Freely

3. It has been, and still is, Myriad's policy and practice to allow scientists to conduct research studies on the *BRCA1* and *BRCA2* genes freely. This has been commonly understood by academic scientists in the field. For example, Plaintiff Wendy Chung acknowledges that researchers "could sequence the *BRCA1* and *BRCA2* genes for purely research purposes." D. Chung ¶ 15. In fact, Dr. Chung has been doing so. *See e.g.,* D. Chung ¶ 11 ("As part of my molecular genetics research, we sequence human genes, including the *BRCA1* and *BRCA2* genes of research subjects in my research lab. We look at the sequences to determine if there are any alterations and investigate whether

those alterations have clinical significance."). Indeed, tens of thousands of researchers have been conducting research on the *BRCA1* and *BRCA2* genes and published thousands of research papers on the *BRCA1* and *BRCA2* genes. *See* ¶ 13 below; *see also*, D. Parvin; D. Li; D. Baer; D. Sandbach.

Myriad Provides Direct Assistance to Researchers in Their Studies

4. Myriad and its collaborators published their landmark research on the *BRCA1* and *BRCA2* genes in 1994 and 1996, respectively. Since then, Myriad has provided assistance to researchers around the world in their independent studies on the genes.

5. Since 1994, Myriad has provided genetic materials such as cDNA clones of the *BRCA1* and *BRCA2* genes free to researchers at over 30 research institutions all over the world, including, among others, the University of Pennsylvania, Emory University, the University of Chicago, and the University of Rochester. These researchers have since published a total of 336 peer-reviewed scientific papers related to *BRCA1* and *BRCA2*.

6. Myriad also has a policy to collaborate with researchers on studies relating to the *BRCA1* and *BRCA2* genes. In fact, since the *BRCA1* and *BRCA2* genes were discovered, Myriad has collaborated with over 440 outside researchers and participated in more than 110 research programs/studies by outside researchers in further studies of *BRCA 1* and *BRCA2*.

7. For example, in 1999, to further encourage research on the *BRCA1* and *BRCA2* genes, I proposed to Dr. Richard Klausner, the then National Cancer Institute ("NCI") Director, for Myriad to provide *BRCA* testing services to researchers conducting

studies funded by NCI and other NIH Institutes. In December 1999, a Memorandum of Understanding (MOU) between Myriad and NCI was signed. Under the MOU, Myriad agreed to provide research testing services at a fraction of the commercial testing price to researchers conducting research funded by NCI or another Institute under the National Institute of Health. The MOU was renewed twice for a total of six years. During those six years, 178 scientists received the discounted research testing services and 5,932 individuals were tested for *BRCA* mutations under the MOU. This program provided support for a number of key research groups that led to important publications on *BRCA* mutation prevalence and the value of clinical intervention in *BRCA* mutation carriers.

8. In another important area, Myriad worked with noted researchers on efforts to classify genetic variants of uncertain clinical significance ("VUS"), making data available from our large sequence database.[1] In these studies, Myriad provided the researchers with information from its database of gene sequence information built upon the largest scale of clinical genetic testing on *BRCA1* and *BRCA2* in the world. This was critical to the researchers' studies. The published research results have the potential of improving the diagnostic testing for a number of other genes.

9. Myriad's contribution to research is also evidenced by the tens of millions of dollars in patent royalty payments made to research institutions such as the University of Utah, National Institute of Health, the University of Pennsylvania, the University of Toronto, and Laval University, all of which collaborated with Myriad in research to identify and isolate the *BRCA1* and *BRCA2* genes.

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[1] *See e.g.,* Abkevich *et al.*, *Analysis of Missense Variation in Human* BRCA1 *in the Context of Interspecific Sequence Variation*, J. MED. GENET., 40:492-507 (2004); Goldgar *et al.* & Breast Cancer Information Core (BIC) Steering Committee, *Integrated Evaluation of DNA Sequence Variants of Unknown Clinical Significance: Application to* BRCA1 *and* BRCA2, AM. J. MED. GENET., 75:535-544 (2004).

Myriad Actively Publishes Its Own Research and Disseminates Scientific Information on the *BRCA1* and *BRCA2* Genes

10. Besides assisting outside researchers in their research, Myriad also has been actively conducting its own research for a better understanding of the *BRCA1* and *BRCA2* genes. More importantly, Myriad has been actively publishing its research findings in peer-reviewed journals, and abstracts and posters in scientific meetings. To date, Myriad has made 128 publications on the *BRCA1* and *BRCA2* genes in peer-reviewed journals and scientific meetings.

11. Shortly after the discoveries of the *BRCA* genes by Myriad and its collaborators, Myriad, under no obligation to do so, worked with other researchers to build the Breast Cancer Information Core ("BIC") database (http://www.research.nhgri.nih.gov/bic/), a central repository for information regarding *BRCA* mutations. The BIC database is an open access on-line database that provides valuable information to scientists in their early research on the *BRCA1* and *BRCA2* genes. Myriad is the largest contributor to this database, and made more than 20,000 submissions to the database.

12. In addition, Myriad has published the most clinical data on mutation risk in the *BRCA1* and *BRCA2* genes based on its extensive experience from the largest scale of genetic testing ever conducted in the world.[2] The mutation risk data have been tabulated and posted on Myriad's website (http://www.myriadtests.com/provider/mutprevo.htm), and are frequently updated by Myriad and freely available to researchers and clinicians throughout the world. Using these mutation prevalence tables, researchers and physicians can readily determine an

[2] *See* Frank *et al.*, *Clinical Characteristics of Individuals with Germline Mutations in* BRCA1 *and* BRCA2: *Analysis of 10,000 Individuals*, J. CLIN. ONCOL., 20:1480-90 (2002).

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