

**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 BRITAIN, 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
WILLIAM E. RUSCONI**

I, William Rusconi, declare:

1. In 1983 I received a B.S. in molecular biology, with minors in German, chemistry and psychology, from Vanderbilt University, Nashville, Tennessee. In 1994 I received an M.B.A. (MM) with majors in marketing, finance, and international business, while making the Dean's List in 1993-1994, from the Kellogg Graduate School of Management at Northwestern University, Evanston,

Illinois. In 1982 I was a genetic engineering intern with the U.S. Environmental Protection Agency-IERL, Toxics Staff, in Cincinnati, Ohio.

2. I am Senior Vice President of Marketing at Myriad Genetic Laboratories, Inc. ("Myriad"). I also oversee Myriad's Managed Care department. These departments are responsible for Myriad's patient and physician awareness and education efforts and for Myriad's ongoing relationships with insurance payors.

3. Myriad has undertaken extensive efforts and incurred significant expense for over 13 years to secure insurance reimbursement for Myriad's *BRACAnalysis*[®] test for as many appropriate patients as possible. Myriad has nearly a dozen full-time staff members whose sole responsibility is securing criteria, medical policy, and coverage with the numerous insurance payors in the United States. This process includes educating payors on hereditary cancer syndromes and professional society guidelines for genetic testing.

4. After considerable time and expense, this effort has borne substantial fruit, much to the benefit of patients. Myriad has received reimbursement for its *BRACAnalysis*[®] test for patients from over 2,600 different health insurance payors from every state. Myriad is a "participating provider" under 25 state Medicaid programs. These payors encompass over 80,000 distinct health insurance plan groups covering more than 130 million lives. Additionally, Myriad's *BRACAnalysis*[®] test is reimbursed under Medicare.

5. Until Myriad is approved by each state as a "participating provider," we cannot offer testing to that state's Medicaid patients. Myriad has been pursuing Medicaid coverage for years and has secured "participating provider" status in 25

states. Unfortunately, while Myriad continues its efforts to secure Medicaid coverage in all states, Myriad has not yet been granted “participating provider” status in some states, which may create gaps in coverage for some patients.

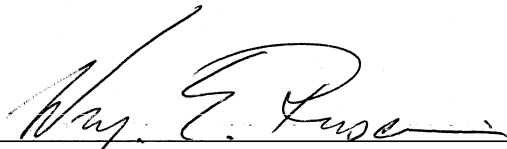
6. However, Myriad provides free testing to indigent patients . For example, Myriad has a financial assistance program that allows for free testing for patients meeting specific criteria. Further, in 2009 Myriad began granting free *BRACAnalysis*[®] testing to The Cancer Resource Foundation (CRF) to be distributed to needy Massachusetts patients at CRF’s discretion (i.e., based upon medical and financial criteria of CRF’s choice). This is the type of program under which MassHealth patients such as Plaintiff Ceriani have an opportunity to receive *BRACAnalysis*[®] testing at no cost.

7. Since identifying and characterizing the BRCA genes, Myriad has spent over \$200 million raising patient and physician awareness about hereditary breast and ovarian cancer and promoting BRCA testing.

8. For physicians, Myriad: provides web-based, print and in-person education (including professional society meetings, regional education events, etc.); contributes to numerous journal publications that help in hereditary breast and ovarian cancer (“HBOC”) education and awareness; has produced thousands of hours of CME material on HBOC; has produced office-based tools to help doctors to identify and counsel patients; employs regional medical specialists who assist physicians in understanding HBOC testing and their test results; and maintains a detailed website with extensive resources for doctors and other health care professionals.

9. For patients, Myriad: has spent over \$20 million in the last three years alone on a mass-media awareness campaign; produces and distributes patient education videos and written materials explaining HBOC and genetic testing; supports advocacy organizations such as Susan G. Komen for the Cure, Be Bright Pink, National Ovarian Cancer Coalition, Young Survival, Y-ME, etc.; provides clinical support to providers and patients, including a hotline, to help patients understand HBOC testing; and maintains a detailed website with extensive resources for patients and their families.

Pursuant to 28 USC § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



William E. Rusconi

Executed on 22 December, 2009

CERTIFICATE OF SERVICE

This is to certify that on December 23, 2009, a true and correct copy of the foregoing document has been served on all counsel of record via the court's ECF system.

/s/ Brian M. Poissant

Brian M. Poissant