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; GBNAE 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. JOHN FRANKLIN SANDBACH

I, John Franklin Sandbach, declare under penalty of perjury:

1. I am board certified in hematology and medical oncology. I have treated patients as a partner at Texas Oncology, P.A. since 1994. I have served on the Board of Texas Oncology since 2002.

2. In 1967 I received a B.S. and in 1971 I received an MD, both from the University of Kentucky. From 1971-1972 I was an intern in the internal medicine department at the University of North Carolina, from 1972-1973 I was a internal

medicine resident, and from 1973-1974 I was a fellow in hematology at North Carolina Memorial Hospital. A full copy of my *curriculum vitae*, including a list of publications, is attached as Exhibit 1.

3. I recently headed two clinical research studies into hereditary breast and ovarian cancer (HBOC) syndrome and the BRCA genes. I was aware that Myriad's patent rights covered certain aspects of the BRCA genes.

4. In one study I looked at *BRCA1/BRCA2* testing in a traditionally understudied setting: community oncology clinics. We found that mutation rates and demographics in these clinics mirror those found nationally. We also found a significantly higher than expected proportion of patients whose family history warranted *BRCA1/BRCA2* testing. We concluded that community oncology practices can effectively identify and test women who are at risk for *BRCA1/2* mutations, but to do so these practices must implement an effective screening method to identify patients, address patient reasons for declining testing, provide comprehensive pre- and post-test consultation, and provide appropriate patient management options.

5. In another study, which is ongoing, I am looking at the rate of *BRCA1/BRCA2* mutations in patients with "triple-negative" breast cancer (*i.e.*, tumors show an absence of estrogen, progesterone, and HER2/neu receptors). In this study we are evaluating the hypotheses that patients who present with triple-negative breast cancer have a significantly elevated likelihood of carrying a mutation in *BRCA1/2* and that this elevated likelihood is also prevalent among the sub-set of triple-negative patients that do not have a family history of breast or ovarian cancer. If triple-negative breast cancers are enriched for *BRCA1*

mutations, they may be more likely to respond to specific therapy such as cisplatin and PARP inhibitors, thus potentially increasing the chance for meaningful responses to therapy or improved cure rates in the adjuvant setting. Because patients with *BRCA1* mutations are also at risk for second breast cancers and ovarian cancers, preventative measures and screening are crucial to early detection and improved overall survival. Therefore identifying patients with elevated likelihood for carrying a *BRCA1/2* mutation is a high priority. If the hypotheses listed above are true, this would comprise compelling evidence that genetic testing for *BRCA1/2* mutations in patients with triple-negative breast tumors would be indicated, providing an opportunity for live-saving interventions particularly in individuals whose family history would not have identified them as being at sufficiently high risk for testing. Patients meeting the criteria for inclusion in this study are receiving *BRCA1/BRCA2* testing at Myriad at no cost.

7. Neither the patents at issue in this suit nor Myriad Genetics, Inc. have in any way hampered my research. To the contrary, in both of these research endeavors I collaborated with and enjoyed the contribution of Myriad researchers.

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

John Franklin Sandbach, MD

Executed on December 22, 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