

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,

No. 09 Civ. 4515 (RWS)

ECF Case

Declaration of
Melanie K. Bone M.D.,
FACOG

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.

I, Melanie K. Bone, declare:

A. Background

1. I received my undergraduate degree in Russian Language and English Literature from Georgetown University, graduating *Magna Cum Laude* in 1981. I was elected to Phi Beta Kappa at that time and continued with honors in medical school at Albany Medical College where I was elected to *Alpha Omega Alpha*. I did my residency training in Obstetrics and

Gynecology at George Washington University Medical Center where I served as Chief Resident in 1989. I spent one year teaching George Washington residents before moving to Florida to enter private practice.

2. I presently am in private practice in Palm Beach County, Florida, providing gynecologic care and breast cancer risk assessment.
3. I am involved in many community-wide organizations. Since October 2006, I have been writing a weekly column for the Palm Beach Post called Surviving Life. The column deals with issues about cancer and survivorship. I also served as President of both the Palm Beach County Ob/Gyn Society and the Hope Project, a mobile mammogram unit providing free and low-cost mammograms to underserved and uninsured women in Palm Beach County. I have received several local awards including March of Dimes Woman of the Year in 1999, Palm Beach Medical Society Women's Advocacy Award 2000, American Jewish Committee Woman of Valor, and American Committee for the Weitzmann Institute of Science Woman of Vision 2003.
4. At the state level, I served on the Executive Committee of the Florida Ob/Gyn Society and was also on the Board of Directors of the Florida Breast Cancer Coalition.
5. Nationally, I am an emeritus member of the Board of Directors of BreastCancer.Org, a worldwide organization devoted to developing and sustaining a website with information and support about breast cancer. In addition, I am a national speaker for Myriad Genetic Laboratories, Inc. ("Myriad"), and donate many hours teaching doctors, nurses, and the public at large about hereditary cancer syndromes. I do not accept any honoraria from Myriad, but rather have them donated to a not-for profit cancer foundation.

B. Personal Experience

6. In January 2000 I felt a lump in my left armpit. After a negative mammogram and sonogram, I finally underwent a biopsy in August 2000 and was diagnosed with stage III breast cancer. My treatment consisted of bilateral mastectomies, six months of intensive chemotherapy, six weeks of external beam radiation, and then Tamoxifen and Arimidex for a total of five more years. During the first two years after diagnosis I was seen by an oncologist almost every month. I was never offered BRCA testing, even though I qualified both based on my age at diagnosis (barely 40) and my Ashkenazi heritage. In 2002 I asked to be tested. The oncologist felt there was no need because of the fact that nobody in my family had breast or ovarian cancer with exception of my father's first cousin. I was insistent because I felt my oncologist's belief that I developed cancer because I had given birth to four children in less than four years seemed implausible. I felt both vindicated and anxious when I tested positive for a mutation in my BRCA 2 gene.
7. The results provided to me, based on my BRCAAnalysis® test, were very empowering. My test results were timely and accurate, and allowed me to select a medical management plan appropriate for me. Immediately I scheduled removal of my ovaries and tubes to prevent ovarian cancer and fallopian tube cancer, known to be much more common in BRCA positive patients. Had I not had testing for this mutation, I would never have known to undertake this lifesaving procedure. I cannot emphasize enough all the positive changes that have occurred to me because I am aware of my BRCA status. I have told all my first degree relatives and advised them that they have a 50-50 chance of having this same mutation. Oddly enough, I discovered that a first cousin has both the BRCA 1 and the BRCA 2 mutation and my sister-in-law also tested positive for a different BRCA 2 mutation. It turns out that my father and my father-in-law were both mutation carriers but never expressed the

gene. Unfortunately, three of four women in my generation had cancer before age 43. Now I worry about my four children and their children. We must test all of them to know who is going to be at risk for cancer or passing on this genetic mutation. I acknowledge and thank Myriad for their exceptional efforts to help in the important campaign to raise the awareness of the risks for hereditary breast and ovarian cancer.

8. I have never felt the need to obtain a second BRCAAnalysis® test. I trust Myriad's results. They have checks and balances in place to be certain that a mutation identified during testing is confirmed by more than one person. In my professional experience I have never had a patient ask for another opinion or doubt the authenticity of the results.

C. Professional Experience

9. I have been screening patients for hereditary cancers since 2006. For patients with a personal or family history of cancer, or which had other "red flags" indicative of a hereditary syndrome, I routinely screen these patients for their risks for hereditary breast and ovarian cancer. Part of this screen or review, where appropriate, includes a discussion surrounding the possibility of genetic testing, and medical management options. I take a careful family history on every patient and be sure to include second and third degree relatives on the paternal side. This diligence pays off when looking for BRCA gene mutations. If I encounter a positive test, I can advise the patient about careful surveillance, chemoprevention, and prophylactic surgery to decrease their risk of breast cancer. I use oral contraceptives and careful family planning in the young BRCA positive patients, and offer surgery to those finished with reproduction to reduce their risk of ovarian and fallopian tube cancer.

10. I firmly believe that hereditary cancer risk assessment is critical to the medical management of my patients; and again, where appropriate, genetic testing is equally important to determine if there are any mutations in an individual's genes which would increase their inherited risk for cancer. Accordingly, as part of my medical practice, I have ordered, and will continue to order, the BRCAAnalysis® test provided by Myriad which tests for mutations in the BRCA1 and BRCA2 genes. In my experience test results have been accurate and returned in a timely fashion which is important, particularly where surgical options are being pursued.
11. Because of the efforts of Myriad, my ability to provide critical medical care and advice to patients who are at risk for hereditary cancer has been greatly enhanced.
12. When I was tested, I do not believe that I paid anything at all for the BRCAAnalysis. My health insurance covered the cost without question. Most of my patients have had excellent coverage for the cost and those that have opted not to go through with testing have been those who have not met their deductible. Since finding out I was positive, my insurance company has not denied nor changed my coverage and all testing to date related to my BRCA positivity has been fully covered.

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



Melanie K. Bone M.D., FACOG

Executed on December 18, 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