

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
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.

Civil Action No. 09-4515 (RWS)

DECLARATION OF
HAIG H. KAZAZIAN, JR., M.D.

- 1. My name is Haig H. Kazazian, Jr.. I am the Seymour Gray Professor of
Molecular Medicine in the Department of Genetics at the University of
Pennsylvania School of Medicine as well as co-Director of the University of

Pennsylvania Genetic Diagnostic Laboratory. I am one of the plaintiffs in this case.

2. I received my medical degree from Johns Hopkins University in 1962. I have been the Seymour Gray Professor of Medicine in the Department of Genetics at the University of Pennsylvania School of Medicine since 1994, and I was chair of the Department from 1994 to 2006. From 1989 to 1994 I was a Professor of Medicine, Pediatrics, Obstetrics and Gynecology, and Biology at The Johns Hopkins University School of Medicine, where I directed the Center for Medical Genetics from 1989 to 1993. I received my board certification in Molecular Genetics from the American Board of Medical Genetics in 1993. I am a member of the American Board of Medical Genetics and was president of the Board from 1999-2000. I am on the editorial boards of *Human Mutation*, *Human Genetics*, *Somatic Cell and Molecular Biology*, and *Mobile DNA*. A copy of my curriculum vitae is attached hereto as Exhibit 1.
3. I have directed the Genetic Diagnostic Laboratory since 1995 along with my colleague Dr. Arupa Ganguly. Through the Genetic Diagnostic Laboratory, Dr. Ganguly and I provide state-of-the-art DNA-based diagnostic testing for a variety of genetic conditions and diseases, as well as prenatal and predictive testing and genetic counseling services. Prior to 1995, I started the first clinical gene diagnostic lab at Johns Hopkins in 1978.

4. Sometime around 1996, after the BRCA1 gene was identified, Dr. Ganguly and I designed tests to screen the BRCA1 gene in our lab. Dr. Ganguly made considerable effort over roughly a six-month period to set up these tests. By roughly the middle of 1996, we were providing BRCA1 genetic testing services to approximately 500 women per year. We designed and provided a similar test for the BRCA2 gene by late 1996, after that genetic sequence was identified.
5. Dr. Ganguly and I were forced to stop providing our BRCA1 and BRCA2 testing services in 1999 after we were accused by Myriad Genetics of infringing their BRCA related patents. The details of the communications comprising that accusation, as I recall them, are as follows.
6. Sometime in the late 1990s, I had a dinner meeting with Dr. Mark Skolnick, who is one of the named inventors of Myriad's BRCA patents as well as Chief Science officer at Myriad. The purpose of our dinner meeting, which took place in New York City, did not relate to BRCA research. However, during dinner, Mark told me that Myriad planned to stop the BRCA testing activity that Dr. Ganguly and I were performing. I understood from the context of our conversation that the Myriad BRCA patents were his basis for objecting to our testing.
7. About a month or two after my dinner meeting with Dr. Skolnick, either I or the University's General Counsel, Mr. Robert Terrell, received a letter from a Myriad representative claiming that the BRCA testing activity we were conducting at our Genetic Diagnostic Laboratory infringed Myriad's BRCA patents and asking us to

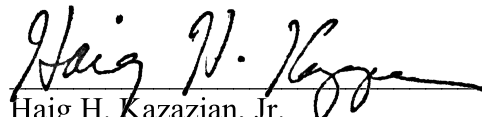
cease the activity. When I spoke to Mr. Terrell about the letter, he communicated that the University would not be contesting the accusation and advised us to stop our BRCA testing. Dr. Ganguly and I stopped performing BRCA screening at that time and have not resumed since.

8. At the time we were forced to stop offering BRCA genetic services, we were charging patients less than Myriad was charging. If we, or another laboratory, were to begin offering such genetic testing again, I believe that it would be offered at a price significantly lower than Myriad's current pricing for the same or similar testing.
9. Further, the test we had developed to screen for BRCA mutations was not the same kind of test that Myriad was using. While they were similar, ours started with a screening of all the exons by a method Dr. Ganguly had developed and that was followed by sequencing of any abnormal exon found by the first procedure. Their method went directly to sequencing all the exons. Regardless, Myriad accused us of patent infringement because we were analyzing the genes, not because we were using a particular test that had been developed by Myriad.
10. Before we were forced to stop offering BRCA genetic testing, we were the only laboratory in the nation providing BRCA genetic testing to patients other than Myriad Genetics. Since the time we ceased offering our BRCA genetic testing services, no other laboratory in the nation has offered BRCA genetic testing to patients other than Myriad. There may be a couple of isolated university affiliated

labs that are permitted to perform a specific test for particular mutations for their own patients, but they are not allowed to perform a full sequencing test or a test for large rearrangements, or to offer their services to the public at large.

11. Our laboratory currently has all of the technological capability necessary to begin performing BRCA testing again. If Dr. Ganguly and I were to learn that Myriad's BRCA patents no longer had legal effect and we decided to resume BRCA testing, we would be able to do so within a matter of a few weeks.

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.

  
Haig H. Kazazian, Jr.

Executed on August 17, 2009