

**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)
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

Civil Action No. 09-4515 (RWS)

**DECLARATION OF
ARUPA GANGULY, PhD**

1. My name is Arupa Ganguly. I am an Associate Professor in the Department of Genetics at the Hospital of the University of Pennsylvania, University of

Pennsylvania School of Medicine as well as Director of the University of Pennsylvania Genetic Diagnostic Laboratory.

2. I received my Ph.D. in Biophysics from the University of Calcutta in 1984. I completed a post doctoral fellowship at Thomas Jefferson University in 1990. I have been Associate Professor of Genetics at the University of Pennsylvania School of Medicine since 2003, previous to which I was Assistant Professor of Genetics since 1996. I have been the Director of the R&D Genetic Diagnostic Laboratory at the University of Pennsylvania since 1995. I also speak and write frequently on genetics related topics. Articles I have authored or co-authored have appeared in *American Journal of Medical Genetics*, *Molecular Genetics & Metabolism*, and *Human Genetics*. A copy of my curriculum vitae is attached hereto as Exhibit 1.
3. In the R&D division of the Genetic Diagnostic Laboratory, my work included comprehensive screening of both the BRCA1 and BRCA2 genes. My BRCA screening was for both research and clinical purposes and at some points my lab was the only other provider of BRCA testing services that included the full screening of the BRCA1 gene in the nation other than the defendant, Myriad Genetics.
4. However, in the late 1990s I was compelled to stop all of my BRCA screening after we received an extensive series of communications from Myriad in which Myriad accused my lab of violating its BRCA related patents (the same patents

involved in this case). The details of the communications we had with Myriad about their patents and my lab's activities are as follows.

5. On or about May 29, 1998, my colleague and co-Director of the Genetic Diagnostic Laboratory, Haig Kazazian, who is also a co-plaintiff with me in this case, received a letter from William A. Hockett, Director of Corporate Communications for Myriad. A copy of this letter is attached hereto as Exhibit 2. The letter stated that Myriad knew we were providing diagnostic testing services for BRCA1 and asserted that Myriad is "the patent holder for the BRCA1 gene." The letter specified that Myriad had five patents on BRCA1, that covered, amongst other things, "composition of matter covering the BRCA1 gene [and] any fragments of the BRCA1 gene." The letter then stated that Myriad was offering a collaboration license to the University of Pennsylvania Medical Center, but only for single mutation tests and multiple mutation panels up to four mutations to allow for testing [of] patients of Ashkenazi Jewish descent." Thus, the license offered was of very limited scope, as it would not allow us to provide complete diagnostic testing services for BRCA1, or comprehensive research on the BRCA1 gene which we had been doing at the lab.
6. Then, on or about August 26, 1998, Dr. Kazazian received another letter, this time from George A. Riley of O'Melveny & Myers, LLP, who claimed to be representing Myriad Genetics. A copy of this letter is attached hereto as Exhibit 3. This letter again stated that, "Myriad is the owner of United States Patents

Nos. 5,693,473; 5,709,999; 5,710,001; 5,747,282; and 5,753,441 covering, among other things, the BRCA1 gene sequence, mutations in the BRCA1 gene, ... and methods for detecting alterations in the BRCA1 sequence.” The letter continued to assert that, “It has come to Myriad's attention that you are engaged in commercial testing activities that infringe Myriad's patents.” The letter then demanded that, “you should cease all infringing testing activity.”

7. On or about June 10, 1999, the University of Pennsylvania general counsel, Robert Terrell, received a letter from Myriad Genetics' General Counsel, Christopher Wight. A copy of this letter is attached hereto as Exhibit 4. This letter stated, “It has come to our attention that Dr. Haig H. Kazazian, Jr. of the University of Pennsylvania is continuing to willfully engage in commercial BRCA1 and BRCA2 genetic testing activities, in violation of the University of Pennsylvania's previous assurances that such commercial testing activities would be discontinued.” The letter continued to assert that, “Dr. Kazazian's commercial testing activities infringe one or more of the following U.S. Patents owned by Myriad Genetics: 5,693,473; 5,709,999; 5,710,001; 5,747,282; 5,753,441, and 5,837,492.” The letter then demanded that, “the University of Pennsylvania discontinue offering and conducting all such commercial genetic testing services,” and requested that Myriad be provided with, “written assurances that the University of Pennsylvania has stopped providing the infringing tests.”

8. On September 10, 1999, Robert Terrell responded to Christopher Wight by letter. Both Dr. Kazazian and I were copied on this letter, a copy of which is attached hereto as Exhibit 5. In the letter, Mr. Terrell admits that our lab's activities after receipt of the August 26, 1998, letter from George Riley had been modified to comply with Myriad's demands set forth in that letter. The letter also states that, "the University agrees that it will not accept samples for BRCA1 research testing from third parties."
9. On or about September 22, 1999, Robert Terrell received a response from Christopher Wight. A copy of this letter is attached hereto as Exhibit 6. In this letter, Wight reiterated Myriad's belief that the genetic testing activities being performed at the University of Pennsylvania infringed Myriad's patents and again demanding written assurance that such activities had stopped.
10. As a result of the series of communications described above, I was compelled to cease all BRCA1 and BRCA2 testing, whether for research or clinical purposes. While I still have the capability to do such services and the desire to consider offering them again, I feel unable to do so because of the past patent assertion by Myriad against my work. Thus, I have moved on to other areas of investigation.
11. I am aware of at least two other instances in which Myriad asserted that BRCA genetic testing activity infringed its patents.
12. In 1998, my colleague Barbara Weber was the principal investigator on a project sponsored by the National Cancer Institute ("NCI") called the Cancer Genetics

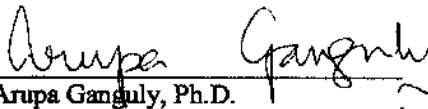
Network Project. The project involved eight cancer centers across the United States. As a Co-Principal Investigator of that project, I provided BRCA1 and BRCA2 screening to Dr. Weber's research participants at relatively low cost. On or about September 15, 1998, the President of Myriad, Gregory Critchfield, sent a letter to Susan Nayfield of the NCI. A copy of that letter is attached hereto as Exhibit 7. In the letter, Myriad's President addressed "concerns that have arisen about how Myriad Genetics' BRCA1 patent position might impact on research efforts sponsored by the National Cancer Institute." The letter continued to say that Myriad would offer licenses to third-party laboratories performing BRCA testing, inferring that such licenses were required to avoid such patent based "concerns." At the time, mine was the only such third-party laboratory offering such services, so the letter was a direct attack on my activities. In essence, Myriad was telling Dr. Weber that my BRCA related activities in support of her project infringed their patents. As a result of that letter, I stopped performing BRCA testing for the Cancer Genetics Network Project.

13. Further, Georgetown University was one of the cancer centers that participated in the Cancer Genetics Network Project. As such, Georgetown had also been sending genetic samples of research participants to my laboratory for BRCA1 and BRCA2 screening. On or about September 2, 1999, a Myriad representative sent a letter to the Georgetown laboratory demanding that Georgetown no longer send genetic samples to my laboratory for testing, because such activity, in their

opinion, infringed Myriad's BRCA patents. As a result of that letter, Georgetown stopped sending samples to my lab for BRCA screening.

14. If Myriad's BRCA patents were invalidated, I would immediately consider resuming BRCA testing in my laboratory. I currently possess all of the resources and technological capability necessary to do so. I would resume BRCA testing to advance research and/or to offer what I believe is an important service to the public, including at minimum the individual women who are co-plaintiffs with me in this case. If I decided to resume offering such services, I could do so within a matter of weeks. The only thing preventing me from resuming BRCA testing in my lab is the assertion of the BRCA related patents by Myriad and I have the earnest desire to immediately consider doing so.

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.


Arupa Ganguly, Ph.D.

Executed on August 18, 2009