Association For Molecular Pathology et al v. United States Patent and Trademark Office et al Doc. 228

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

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.

----------x

09 Civ. 4515 (RWS)

ECF Case

SUPPLEMENTAL DECLARATION OF ELLEN T. MATLOFF, MS

Dockets.Justia.com

1. My name is Ellen T. Matloff. I am the Director of the Cancer Genetic Counseling Shared Resource at the Yale Cancer Center in New Haven, Connecticut. I am also a Research Scientist in the Department of Genetics at the Yale University School of Medicine.

2. I am a plaintiff in this case. The statements herein represent my views as an individual and not those of Yale University.

3. I previously submitted a declaration in support of Plantiffs' Motion for Summary Judgment. Matloff decl., Aug. 12, 2009.

4. I am informed that the declaration of Gregory C. Critchfield, defendant Myriad's President, submitted in connection with Myriad's opposition to plaintiffs' Motion for Summary Judgment discusses the number of scholarly articles that have been written concerning BRCA1/2. I am informed that, as one example, he refers to 17 papers I have written on BRCA1/2. Critchfield ¶4, Exh. 4.

5. My *curriculum vitae* was attached to my prior declaration. An examination of the papers listed in that *vitae* reveals that the vast majority of the papers I have written on BRCA1/2 are observational based on our experience in counseling patients who have tested positive for mutations on the BRCA1/2 genes. For example, I wrote a paper on sexuality of women who had their ovaries removed at an early age, in part as a result of receiving a positive BRCA1/2 result. Matloff ET, Bober S, Barnett RE. Unraveling the Next Chapter: Sexual Development, Body Image and Sexual Functioning in Female BRCA Carriers. *The Cancer Journal 2009*; 15(1):15-18. Research and writing of papers of this kind does not require me to take any action to infringe Myriad's patent.

6. I would like to research, write, and publish other papers but I have not done so because I cannot do so without infringing Myriad's patents. For example, I

would like to research protein truncation testing and other alternative screening methods to identify mutations in BRCA Carriers. I would like to research the percentage of patients with (triple-negative breast cancers, medullary breast cancers, breast cancers with medullary features, isolated breast cancers between ages 40-50, male breast cancer, epithelial ovarian cancer, pancreatic cancer) who carry a BRCA mutation on full sequencing. I would like to research the percentage of patients with (same options as above) who carry a BRCA mutation found on large rearrangement and deletion testing. I would like to research the percentage of patients who tested BRCA negative before Myriad Genetics began offering BART testing who actually carry a BRCA mutation using large rearrangement and deletion testing. I would like to research chemopreventive medications (in the SERM category, such as tamoxifen) specifically geared toward female BRCA carriers which reduce the risk of both breast and ovarian cancers.

7. In order to do these types of research, I would have to do actions that I believe would legally infringe on Myriad's patents. I understand Myriad now asserts that it would never enforce its legal right to sue me for those actions if I were doing them for purely research purposes. Myriad has never told me that and I am unaware of any written statement by Myriad (at least until their submissions in this case) giving me such permission. I am extremely reluctant to engage in behavior that could subject me to a successful suit for infringement based on the hope that Myriad will exercise its discretion not to sue me particularly because I was told by Myriad that we could not even offer our highest risk patients testing for large rearrangements and deletions, which they needed clinically, before their BART testing was available.

8. Thus, whatever the level of research that has occurred with respect to BRCA1/2, I am confident that more would have occurred if the patents did not present a legal impediment.

9. I am informed that Dr. Crichfield also refers to the role played by the Yale DNA Diagnostic Laboratories in affording women "testing for specific BRCA mutations." Critchfield at ¶62. He is correct that the Yale DNA Diagnostic Laboratories offer "testing for specific mutations." http://info.med.yale.edu/genetics/DNA/BRCA-ASH.html; http://info.med.yale.edu/genetics/DNA/BRCA-Familial.html.

11. However, his observation is misleading. The testing offered by Yale is very limited. Yale and other labs can confirm positive test results if the familial mutation is identified by Myriad. However, if a person has full sequencing via Myriad and tests negative (this encompasses the vast majority of all test kits ordered through Myriad), that person cannot have a second opinion by ordering full sequencing elsewhere. That would be an infringement of the patent and Yale's licensing agreement with Myriad does not permit it.

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.

Ellen T. Matloff, MS

Executed this 5 day of Jan., 1020