

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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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,

09 Civ. 4515 (RWS)

Plaintiffs,

ECF Case

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,

DECLARATION OF  
MADHURI HEGDE, PhD

Defendants.

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I, Madhuri Hegde, declare under penalty of perjury:

1. I am currently Senior Laboratory Director at the Emory Genetics Laboratory. I am also an Associate Professor in the Department of Human Genetics at Emory University School of Medicine and Adjunct Assistant Professor at the University of Texas M.D. Anderson Cancer Center.

2. I have a B.S. Degree in Microbiology/Genetics, a M.Sc. in Microbiology/Genetics and a PhD in Applied Science.

3. I am a member of plaintiff organizations American College of Medical Genetics (ACMG) and Association for Molecular Pathology (AMP).

4. I have received hundreds of thousands of dollars in grants for research in genetics including from the Federal government and from private foundations.

5. I have published and spoken widely on the subject of genetics. A complete copy of my curriculum vitae is attached.

6. As part of my current responsibilities, I do research on human genes. I also supervise a clinical laboratory that currently analyzes approximately 200 different genes. The lab I supervise is also supervised by plaintiff Dr. Ledbetter.

7. I would estimate we analyze approximately 60 genes every day. Analysis of genes includes sequencing the genes and then looking at the sequence to determine if there are any variants and if those variants have clinical significance.

8. The lab that I supervise is one of the largest in the country. We have the personnel, equipment, and expertise to sequence genes including the BRCA1 and BRCA2 genes.

9. I personally sequenced the BRCA1 and BRCA2 genes while at the Auckland Hospital in New Zealand.

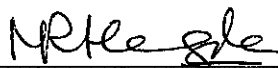
10. Our lab could begin sequencing BRCA1 and BRCA2 genes, and analyzing them to determine if there are variants and if those variants have clinical significance virtually immediately. The only thing that prevents us from doing so is the patents at issue in this case. I am aware that, based on these patents, other labs were sent cease-and-desist letters and that is why we do not do BRCA analysis.

11. If the patents were declared invalid, my lab would begin sequencing BRCA1 and BRCA2 genes as quickly as possible. I estimate we could begin within weeks. Even that delay

is caused only because we would need to purchase certain widely-available, relatively inexpensive, and simple items to use in sequencing. We do not currently stock those items in our lab solely because we are prohibited by the patents from analyzing BRCA1 and BRCA2.

12. Our lab is not only among the largest in the country, it also utilizes the most advanced equipment and techniques. For example, we are developing high-throughput sequencing assays for rare disorders using robotics, automated sequence platforms, oligonucleotide array platforms, robotics and using predictive analysis tools and biological testing. If we were permitted to sequence the BRCA1 and BRCA2 genes, we could do so quickly and efficiently using state-of-the art techniques.

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.

  
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Madhuri Hegde, PdD

Executed on August 13, 2009