UNITED STATES DISTRICT COURT
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.

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09 Civ. 4515 (RWS)

ECF Case

DECLARATION OF DR. SUSAN M. LOVE

I, Susan M. Love, MD, MBA, declare under penalty of perjury:

1. I am currently a Clinical Professor of Surgery at the David Geffen School of Medicine at the University of California at Los Angeles ("UCLA"). I am also the President of the Dr. Susan Love Research Foundation, a nonprofit organization dedicated to the eradication of breast cancer. The Foundation conducts breast cancer research and also funds research through grant-making.

2. I submit this declaration in support of the plaintiffs in this case. Patents on the BRCA1 and BRCA2 human genes are obstacles to the clinical care of breast cancer patients and do not further the progress of medicine.

Background

3. I earned my Medical Degree from SUNY Downstate Medical Center in New York in 1974 and my Master's in Business Administration from UCLA in 1998. For more than thirty years, I have specialized in the treatment of breast cancer.

4. I am a member of numerous professional organizations, as noted fully in my curriculum vitae, which is attached. I am currently a Fellow at the American College of Surgeons and a member of the American Society of Breast Surgeons, the American Association for Cancer Research, the American Society of Preventive Oncology, and the Society for the Study of Breast Disease.

5. I was appointed by President Clinton to serve from 1998 to 2004 as a member of the National Cancer Advisory Board, which advises the Department of Health and Human Services and the National Cancer Institute about the Institute's activities and research. I also have served on the boards of many organizations that advocate on behalf of breast cancer patients, including the National Breast Cancer Coalition and the Young Survival Coalition.

6. I am the author of "Dr. Susan Love's Breast Book," which is widely considered the standard reference on all aspects of breast care and breast cancer. The first edition was published in 1990, and the fifth edition will be published next year.

7. My current research focuses on treatments for breast cancer and new methods for detection of risk. I am also investigating new approaches to connecting women and researchers to identify breast cancer causes and methods of prevention. In partnership with the Avon

Foundation for Women, the Dr. Susan Love Research Foundation recently launched the Love/Avon Army of Women, which has two key goals: to recruit one million healthy women of every age and ethnicity, including breast cancer survivors and women at high-risk for the disease, to directly participate in breast cancer research; and to challenge the scientific community to expand its current focus to include breast cancer prevention research conducted on healthy women.

Effects of BRCA Gene Patents on Clinical Care of Breast Cancer Patients

8. I have treated thousands of women with breast cancer during my career. It is based on this experience that I have concluded that the patents granted over the BRCA1/2 genes impede clinical care.

9. As I understand it, the U.S. Patent and Trademark Office has granted patents over the BRCA1 and BRCA2 gene sequences, mutations along the genes, and the correlation between mutations and cancer. Because the patents are on the genes, and not on a particular test or device, the patent holder has the exclusive right to perform genetic testing and research on these genes in the United States.

10. All of us have BRCA1/2 genes. A small percentage of people have mutations that have been so far associated with cancer. Women who have BRCA1 or BRCA2 mutations have an elevated risk of breast cancer – anywhere between 50 to 80 percent – as well as a lifetime risk of ovarian cancer between 20 and 50 percent. Male carriers of mutations are also at increased risk of breast and prostate cancers. We are born with these genes and their mutations. The correlation between particular mutations with disease is a biological fact. None of this was invented by a human, and no patent on genetic sequences should prevent a doctor, scientist, or geneticist from analyzing or examining a person's genes.

11. BRCA1/2 genetic testing can provide vital information to a patient. She will not only learn her risk for hereditary breast and ovarian cancer, but also can gain information that may be useful in determining prevention and treatment options. Some research has shown that people who test positive for a BRCA mutation can reduce their risk of cancer by participating in physical activity and avoiding obesity. Many women will opt for prophylactic mastectomy or oophorectomy, major surgeries that can cut risk. These are extremely difficult decisions for women, and those who are appropriate candidates for testing need timely information about their genetic status. Some women might opt for a lumpectomy before they receive their genetic test results, only to later decide to undergo a mastectomy when they find out they are positive for a mutation. Women might decide to take hormonal therapy prior to finding out that they were carriers of a mutation suggesting that prophylactic oophorectomy might be a better choice. For women who have been diagnosed with cancer, recent studies have shown certain forms of chemotherapy may be more effective in targeting BRCA-mutated cells.[1] Because BRCA genetic status can dramatically affect a patient's decisions, it is important to ensure that patients have appropriate access to high quality timely BRCA genetic testing, as well as confirmatory testing.

12. BRCA genetic testing is one of the very few tests performed as part of breast cancer care and prevention for which a doctor or patient cannot get a second confirmatory test done through another laboratory. Access to second opinions and verification of results are integral to the standard of care that doctors must provide to their patients.

13. Increasingly, much of cancer research and treatment has focused on identifying the significance of a variety of biological characteristics of a tumor. These biomarkers can help determine the prognosis of a particular cancer, predict how a cancer will respond to a certain

[1] Peter C. Fong et al., *Inhibition of Poly(ADP-Ribose) Polymerase in Tumors from BRCA Mutation Carriers*, N. Engl. J. Med. 2009;361 (July 9, 2009).

treatment, or both. Because so much of how we treat patients turns on an accurate identification of these biomarkers, it is crucial for patients and their doctors to be able to obtain second opinions and confirmatory testing.

14. When a patient is diagnosed with breast cancer, she can have a second pathologist examine the excised tumor to determine the type of cancer she has. The pathologist will analyze the tumor for characteristics such as size, type, rate of cell division, and whether the cancer has invaded blood vessels. Not infrequently, a second pathologist will change a diagnosis rendered elsewhere. This second opinion can be invaluable in determining the course of future treatment.

15. A patient can use more than one method of testing to find out whether her tumor is positive for estrogen receptors. This is the most common type of analysis we perform on tumors and helps resolve whether a patient should receive hormone blocking therapy.

16. Similarly, a patient can receive more than one test for the Her-2/neu receptor in a tumor. Her-2/neu is an oncogene that contributes to cancer by telling cells to grow. Knowing whether a tumor is Her-2/neu positive is important, as positive tumors tend to be more aggressive and may respond differently than negative tumors to particular forms of drug therapy. Currently, there are at least two types of tests: one which measures the effect of overexpression of the Her-2/neu oncogene, whereas the second measures the cause of overexpression.

17. Imaging is done with MRI, bone scans, and xrays to determine whether the cancer may have spread. If a women were to have spread of her cancer to another organ, she is no longer curable and her whole treatment plan is changed. These images can and often are repeated when there is a question or undergo a secondary review to make sure the diagnosis is correct.

18. Just as a pathology report, an MRI, an estrogen receptor test, and a Her-2/neu receptor test structure a course of treatment, testing positive for a BRCA1/2 mutation can also be

a significant factor in choosing the type of chemotherapy. Recent studies have shown that certain enzymes play a key role in repairing DNA.[2] Chemotherapy appears to be more effective in BRCA mutation carriers who are treated with a drug (known as a PARP inhibitor) that inhibits the DNA repair activity of these enzymes, because the drug prevents cancer cells from repairing DNA breaks and growing. Therefore, determining and confirming BRCA genetic status can be crucial to deciding whether to administer a PARP inhibitor to a patient.

19. While access to testing and confirmatory testing are fundamental to breast cancer care, patents on the BRCA genes mean that these services are controlled by the patent holder. If the issue was simply that patents had been granted on a particular test, I believe that other laboratories would offer alternative tests. However, because the patents are on the genes, this is not a possibility. A patient in the U.S. cannot get full BRCA genetic sequencing done at a laboratory other than Myriad Genetics, which controls the patent rights over the genes. As a physician, this is of great concern to me. When patents are granted over genes, the patent holder can dictate how those genes are used in medicine and research – whether a test is offered, what test is performed (which mutations are looked for and which are not), the interpretation of test results, the cost of the test, and the research that is done. It is my professional opinion that genes are so fundamental to science, medicine and clinical care that patents should not be granted so as to exclude doctors and geneticists from examining them. Allowing a company to control the BRCA1/2 genes is harmful to the quality of care we can provide our patients.

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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[2] *Id.*

Executed on August 21, 2009

SUSAN M. LOVE