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Re: Genetic Testing Study; Docket No. PTO-P-2012-0003

To Whom It May Concern:

I was diagnosed with breast cancer for the first time at the age of 28. I consider myself an educated woman – an honors graduate of Columbia University, an accomplished attorney – but I had not heard of genetic counseling or genetic testing at the time of my diagnosis despite my family history of cancer and my Ashkenazi Jewish ancestry.

Genetic testing became the linchpin in the decision I made regarding my cancer surgery. Genetic testing became the start of critical conversations I had with my family after diagnosis. And genetic testing is now the key to future research that will affect not only my well-being and that of my two sons, but the well-being of an entire community of Ashkenazi Jews at increased risk of hereditary breast cancer and ovarian cancer.[1]

As a breast cancer survivor and national breast cancer patient advocate,[2] I know first hand the critical implications of research and knowledge that emerge from genetic testing. I feel strongly that additional research and information about genetic testing will enhance a field that has not had enough positive public attention. We are sidetracked in our efforts to move forward as a result of lawsuits and media coverage that shed only the harshest light on a field that could explode with possibility.

[1] 1 in 40 Jews of Ashkenazi descent carries a mutation in the BRCA1 or BRCA2 gene that increases the likelihood that they will develop breast cancer, ovarian cancer, or other related cancers in their lifetime. Scheuer L, Lauff N, Robson M, et al: Outcome of Preventive Surgery and Screening for Breast and Ovarian Cancer in BRCA Mutation Carriers. J Clin Oncol 20:1260-1268, 2002; King MC, Marks J, Mandell J: Breast and Ovarian Cancer Risks Due to Inherited Mutations in BRCA1 and BRCA2. Science 302:643-646, 2003.

[2] Ms. Shoretz is the Founder and Executive Director of Sharsheret, a national organization supporting young Jewish women facing breast cancer. She is also a member of the Federal Advisory Committee on Breast Cancer in Young Women, under the auspices of the Centers for Disease Control and Prevention.

I feel so strongly about the significance of genetic diagnostic testing, that I am taking time out of active treatment for Stage IV breast cancer to provide the following additional comments:

1. **The issue of independent second opinion genetic diagnostic testing**: Without regard to the legal ramifications of trademark and intellectual property law generally, respectfully consider the fact that there is virtually no aspect of cancer diagnosis or treatment during which patients are not encouraged to seek a second opinion. Whether they are confirming a stage of diagnosis, surgery options, treatment protocols, or reconstruction, women with breast cancer are encouraged to meet with more than one member of a given medical discipline to ensure they have received accurate information and understand their options.
2. **Considerations relevant to medical costs and insurance costs**: Patients understand that second opinions increase the overall cost of their medical treatment. They don't seem to mind. The broader questions of the overall cost and availability of cancer screening and treatment are addressed, in part, in the Affordable Care Act.
3. **Practical consequences of second opinion genetic diagnostic testing**: Having been diagnosed with breast cancer a second time at the age of 37, I have considered whether the results of my first genetic test were accurate. I understand, rationally, that the statistical probability of error is small. Nevertheless, the quality of life for those, like me, who are not positioned to request a second opinion is diminished by the uncertainty that lingers long after the test results are in.

I am grateful for the time the USTPO has taken to understand the critical issues surrounding genetic testing.

Respectfully submitted,

Rochelle L. Shoretz