



JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 14 No. 4

Editor: Martha L. Golar, Esq.

June 2010

JALBCA ANNUAL DINNER

JALBCA's Annual Dinner was both a great success and great fun. Judge Kaye supervised the installation of JALBCA's directors and officers for the 2010/2011 year, including the incoming Co-Presidents, Hon. Ellen Spodek and Cynthia B. Rubin, Esq.

Former Co-President Roy Reardon presented the Leadership Achievement Award to Clifford A. Hudis, MD, chief of the breast cancer medicine service and attending physician at Memorial Sloan-Kettering Cancer Center. Among other positions he holds, Dr. Hudis is also chair of the Scientific Advisory Board of the Breast Cancer Research Foundation as well as an Associate Editor of the Journal of Clinical Oncology.



Honoree Clifford Hudis, MD & Roy L. Reardon, Esq.



Hon. William C. Thompson & Hsiu Chen Yeh



Hon. Helen Freedman & Hon. Jacqueline Silbermann



Hon. Judith S. Kaye & JALBCA Co-Presidents Cynthia Rubin, Esq. & Hon. Ellen Spodek



Dinner Chairperson Sandra C. Katz, Esq. & JALBCA Co-Presidents Cynthia Rubin, Esq. & Hon. Ellen Spodek



Hon. Judith S. Kaye & Honoree Julie Ratner,
Ellen's Run

Next, Judge Kaye presented the Hon. William C. Thompson Family Award to The Ellen P. Hermanson Foundation/ Ellen's Run. The award was accepted by Julie Ratner who is one of Ellen Hermanson's sisters. The Foundation was established in 1997 to honor the memory of Ellen Hermanson – the first Executive Director of JALBCA – and carry on the important work to which she devoted so much of her time and energy. Trained as a journalist, Ellen became an activist and an advocate in the breast cancer community. The Foundation sponsors an annual 5k

race. The 2010 summer race is scheduled for Sunday, August 22, starting from Southampton Hospital, Southampton, New York.

Finally, former JALBCA Co-President Judith Livingston provided an update on the mammography vans, the cost of which is subsidized by JALBCA as part of its Courthouse Alert project. Ms. Livingston obtained a lengthy and impressive group of sponsors for the 2010 project. Each donor offered subsidization of either a van or a mammogram(s).

APRIL PROGRAM – BREAST CANCER AND GENETICS

On April 6, 2010, Dr. Petra Rietschel MD, PhD, a medical oncologist at Montefiore Einstein Cancer Center, discussed inherited or hereditary predispositions to cancer. In Dr. Rietschel's presentation, she emphasized that all cancer is genetic, however not all cancer can be considered hereditary. An individual can either be born with an inherited predisposition to cancer or, through various environmental factors, a gene can break down and improperly replicate to create a cancerous cell. Only where there is history of multiple family members that have been affected by the same type of cancer or cancers, at an extent greater than would be expected by chance, can one state that there is a hereditary predisposition.

One form of hereditary cancer highlighted in the presentation was breast cancer, specifically the BRCA gene and the development of breast cancer. Studies have indicated that there is a positive correlation between the presence of the inherited BRCA gene and/or a family history of breast cancer that predisposes both men and women to develop breast cancer at some point in their lives. Although maternal history of breast cancer is strongly indicative of potentially inheriting this BRCA genetic mutation, paternal history is just as important. Fifty percent of hereditary breast and ovarian cancer is inherited from fathers.

Women who inherit either the BRCA1 or BRCA2 genetic mutation have been found to have an increased lifetime risk of developing breast and/or ovarian cancer. The potential for developing breast

and/or ovarian cancer at an early age (before menopause) is compounded when there are multiple, close family members (i.e., mother, grandmother, sister) who have been diagnosed with these diseases. The BRCA1 mutation also has been linked to a higher risk of developing cervical, uterine, pancreatic, and colon cancer. Similarly, the presence of BRCA2 mutations apparently increase the risk of pancreatic, stomach, gallbladder and bile duct cancer, and melanoma.

Although men do not have as high an incidence of breast cancer as women (only 1% of the male population will develop breast cancer), studies indicate that those who have the BRCA2 mutation carry an 80 times greater risk than other men of developing several types of cancer; approximately 15% of men who have a mutation of their BRCA gene have a higher-than-normal chance of developing several types of cancer, according to researchers from Cedars-Sinai Medical Center in Los Angeles and Sunnybrook & Women's College Health Sciences Center in Toronto. Studies have indicated that men with the BRCA1 mutations also have an increased risk of breast and, possibly, pancreatic, testicular, and early-onset prostate cancer, while those that have tested positive for the BRCA2 mutation correlate with a higher risk of developing breast, pancreatic and prostate cancer.

Due to the high correlation of the BRCA mutation and cancer development, it is recommended that those individuals that have a family history should

be genetically tested. The BRCA gene test is a blood test that uses DNA analysis to identify changes in either one of two breast cancer susceptibility genes. Genetic counseling is part of the BRCA gene test process. In many cases, the results of genetic testing may be used to guide clinical management of patients and, in some cases, prophylactic surgery may be beneficial to prevent cancer development. Further, decisions about courses of treatment and chemo dosing may be guided by genetic testing. Although full genetic counseling can be expensive, for those individuals that have a family history, most insurance will cover the cost. In the future, there is the possibility that genetic testing can be performed for a relatively nominal cost.

Dr. Rietschel closed with a look at the commonly held belief that breast cancer is the number one cause of death in women. In a recent poll conducted by Gallup, individuals were asked what they perceived to be the number one cause of death among women in the United States. Forty-six percent of those polled believed that it was breast cancer. Actually, it is heart disease. Although lung cancer remains the highest cause of cancer-related death of women in the U.S., breast cancer is the second leading cause of cancer death for such women. There remains a continued need, therefore, for genetic testing and breast screenings.

NOTE: This article was prepared by Gamelin-Arnold Telesfort, JALBCA's 2009/10 Susan Solomon Intern.

NEWS BRIEFS

Update on Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.

On March 30, U.S. District Court Judge Robert Sweet issued a landmark decision in *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y.), holding that human genes are not patentable. Approximately twenty per cent of the genes in our bodies, presently, are under patent (including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma and many other illnesses), giving private corporations, individuals, and universities exclusive authority to test, research and study those genes. The October 2010 JALBCA Symposium addressed this ground-breaking issue and its implications (See JALBCA Newsletter, December 2009)

The case before Judge Sweet was brought by the ACLU and the Public Patent Foundation (PUBPAT) in 2009 on behalf of scientific associations representing approximately 150,000 researchers, geneticists, pathologists, and laboratory professionals, breast cancer and women's health groups and individual women patients. The lawsuit challenged seven patents granted by the U.S. Patent and Trademark Office (PTO) to Myriad Genetics on BRCA1 and BRCA2, two human genes associated with hereditary breast and ovarian cancer. The issue before Judge Sweet was whether isolated human genes, and the comparison of their sequence to identify the presence of mutations indicating a predisposition to breast and ovarian cancers, are patentable.

The PTO had long granted patents on purified and isolated DNA – DNA sequences which have been removed from the cell and separated from non-DNA materials – and on the process of comparing a gene with a mutation to one without mutation. Plaintiffs argued that human genes are unpatentable natural phenomena and their patenting hinders research and violates medical and scientific ethics. Defendants, on the other hand, contended that isolated DNA is patent-eligible subject matter different from naturally-occurring DNA and that patents promote innovation and provide incentive for and protect investment in research.

Recognizing that laws of nature, physical phenomena and ideas are not patentable, Judge Sweet held the challenged patents invalid because they cover products of nature and abstract ideas. He referenced a clear line of Supreme Court precedent and accompanying lower court authorities that established that purification of a product of nature, without more, cannot transform it into patentable subject matter. With respect to the patent claims directed to isolated DNA containing all or a portion of the BRCA1 and BRCA2 gene sequence, he ruled:

The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed

to "isolated DNA" containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.

With respect to the patent claims that were directed to methods for "comparing" or "analyzing" BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast to ovarian cancer, Judge Sweet ruled that:

Similarly, because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter under § 101.

If appealed, the case will next be heard by the U.S. Court of Appeals for the Federal Circuit.

FDA Reviews Ingredient Triclosan for Hormone Effects

In April 2010, the FDA updated its website with information about triclosan, a common ingredient added to many consumer products – antibacterial soaps and body washes, toothpastes and some cosmetics – to reduce or prevent bacterial contamination. Earlier in the year, in January 2010, Rep. Edward Markey, chairman of the House Energy and Commerce Subcommittee on Energy and the Environment, wrote to the FDA and the EPA about triclosan. Triclosan is regulated as an antimicrobial active ingredient by the EPA; the FDA oversees its use in consumer products. Rep. Markey cited concern about the potential effects of triclosan and triclocarbon as "endocrine disruptors" that can adversely affect the function of hormones.

SAVE THE DATE – FIFTEENTH ANNUAL ELLEN'S RUN – 2010 SUMMER RACE

Sunday, August 22, 2010

Southampton Hospital

Meeting House Lane, Southampton, NY

Event will be preceded by a party on Saturday evening, August 21.

SAVE THE DATE – KOMEN NYC RACE FOR THE CURE – SEPTEMBER 12, 2010

JALBCA Team Co-Captains: Hon. Shirley W. Kornreich and Sandra Lespinasse

9 a.m. • Central Park • N.Y., N.Y.

CALENDAR/CONTACTS

ADELPHI NY STATEWIDE BREAST CANCER

Hotline & Support Program

Adelphi University School of Social Work
Garden City, NY 11530
www.breastcancerhotline@adelphi.edu

CancerCare

275 Seventh Avenue
New York, NY 10001
www.cancercares.org
1.800.813.HOPE (4673)

ELLEN's RUN

130 W. 42nd St., 22nd Fl.
New York, NY 10036
www.ellensrun.org
212.840.0916

MEMORIAL SLOAN KETTERING CANCER CENTER

*Post-Treatment Resource Program
Educational Forums*

215 E. 68th St., Ground Fl.
New York, NY 10021
www.mskcc.org/mskcc/html/59513.cfm
212.717.3527

Bendheim Integrative Medicine Center
1429 First Avenue (at 74th Street)

SHARE (*Self-Help for Women with Breast or Ovarian Cancer*)

1501 Broadway, Ste. 704A
New York, NY
www.sharecancersupport.org
212.719.0364
Speak to a survivor toll-free:
1.866.891.2392

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