



JALBCA

JUDGES AND LAWYERS
BREAST CANCER ALERT

Vol. 17 No. 3

Editor: Martha L. Golar, Esq.

November 2012

THE SEVENTEENTH ANNUAL ELLEN P. HERMANSON MEMORIAL SYMPOSIUM

TOPIC: "Evolution of Medical Care and Research: What is Happening to Medicine and How Will it Affect Us?"

DATE: Monday, December 3, 2012

TIME: 6:00 PM - 8:30 PM

PLACE: New York City Bar Association
42 West 44th Street, 2nd Floor Meeting Hall

Dr. Larry Norton will present the latest developments in the fight against breast cancer to be followed by the program.

Moderator

Hon. Judith S. Kaye, Chief Judge, New York State (Retired)

Legal Panel

Hon. Jennifer G. Schechter and Edward S. Kornreich, Esq.
JALBCA Co-Presidents

Panel of Experts

Kathleen M. Boozang, Professor of Law, Seton Hall University, School of Law

Larry Norton, MD, Head, Division of Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center

Bruce C. Vladeck, Ph.D., Senior Advisor to Nexera, Inc.

Panel in formation

Symposium Co-Chairs

Hon. Shirley Werner Kornreich, Mikki Golar, Esq., Barbara A. Ryan, Esq.

Sponsor

The Ellen P. Hermanson Foundation

Presenting Organizations

Women's Bar Association of the State of New York

The New York Women's Bar Association

Note: non-CLE Program

OVARIAN CANCER EXPO

JALBCA participated at the Ovarian Cancer Expo, sponsored by Color of Teal, on September 29, 2012. Member Sandra Lespinasse and JALBCA Intern Stephanie D'Agostino worked as volunteers to ensure that information was made available about JALBCA and its sponsorship of mammography vans. We participated in order to do outreach to women who may be at a heightened risk for breast cancer. The event took place at the Hotel Pennsylvania in Manhattan. Color of Teal, Inc. is a not-for-profit organization that was formed solely on the basis of raising awareness for ovarian cancer, uterine cancer, and cervical cancer.



Sandra Lespinasse and Stephanie D'Agostino

ANNUAL COURTHOUSE ALERT COCKTAIL RECEPTION

A wonderful turnout of people attended JALBCA's cocktail reception on September 12 to kick off JALBCA's Annual Courthouse Alert. The event took place at the Appellate Division, Second Department Courthouse. As in prior years, Hon. Gail Prudenti served as Honorary Event Chair and Hon. Ellen Spodek and Hon. William C. Thompson served as event co-chairs.

BROOKLYN PROCLAMATION FOR BREAST CANCER AWARENESS MONTH

On October 30, 2012, Brooklyn borough President, Hon. Marty Markowitz was scheduled to present a proclamation declaring October as breast cancer awareness month. The proclamation was to be presented to the Brooklyn Women's Bar Association and JALBCA.

NEWS BRIEFS

Discovery of New Mechanism Behind Resistance To Chemotherapy Treatment

In August 2012, in what was described as a "completely unexpected" breakthrough, scientists at the Fred Hutchinson Cancer Research Center found that chemotherapy actually heavily damages healthy cells and the DNA-damaged, non-cancerous fibroblasts then drive the production of an array of factors that stimulate solid tumor cancer growth. Specifically, the damaged fibroblasts overproduce a healthy protein (WNT 16B) that interacts with nearby tumor cells and causes them to grow and invade.

Under normal circumstances, fibroblasts help maintain the structural integrity of connective tissue and play a critical role

in wound healing and collagen production. Additionally, they found that chemotherapy even makes the tumor resistant to future treatment. Resistance to chemotherapy is crucial to therapy effectiveness and survival time and it is almost a universal, lethal result for cancer patients who have solid tumors (e.g., breast, prostate, lung and colon) that have metastasized. Dr. Peter Nelson of Hutchinson was the senior author of the findings.

The researchers observed up to an unexpected 30-fold increase in WNT production. The WNT family of genes and proteins was known to play an important role both in normal development and in the development of some cancers. Its role in treatment resistance is a new discovery. This discovery

suggests that finding a way to block this treatment response in the tumor micro-environment may improve the effectiveness of therapy.

Researcher Nelson said that, "(c)ancer therapies are increasingly evolving to be very specific, targeting key molecular engines that drive the cancer rather than more generic vulnerabilities, such as damaging DNA. Our findings indicate that the tumor microenvironment also can influence the success or failure of these more precise therapies." He explained that the major clinical reason that chemotherapy ultimately fails to halt advanced cancer is because the dose that would be needed to accomplish this – which can be accomplished in the laboratory – would be toxic to normal cells and

the host/patient. Therefore, doctors use lesser doses and administration in cycles or intervals; but this leaves behind cancer cells that survive and these can become resistant to subsequent administrations of anti-cancer therapy.

The team of researchers also involved investigators at the University of Washington, Oregon Health and Science University, the Buck Institute for Research on Aging, the Lawrence Berkeley National Laboratory. They examined cancer cells from prostate, breast and ovarian cancer patients who had been treated with chemotherapy. The National Institutes of Health, the National Cancer Institute, the Department of Defense and the Prostate Cancer Foundation funded the research.

Source:

<http://www.fhcr.org/en/news/center-news/2012/08/peter-nelson-lab-chemotherapy-resistance-mechanism.html>

Federal Circuit Finds Isolated Human Genes to be Patent-Eligible

A split U.S. Court of Appeals for the Federal Circuit issued its opinion in *Assoc. for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.* (“*Myriad*”) in which it re-affirmed its prior ruling that isolated human genes are patent-eligible (i.e., under 35 U.S.C. § 101). In March 2012, the U.S. Supreme Court had vacated the Federal Circuit’s first decision, remanded the case, and directed the Federal Circuit to reconsider its June 20, 2011 ruling in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, ___ U.S. ___ (March 20, 2012) (“*Prometheus*”). The case concerns Myriad Genetics Inc.’s composition and methods claims involving isolated human BRCA genes. The composition claims are directed to isolated DNA sequences of the BRCA-1 and BRCA-2 genes. The method claims are directed to screening for the presence of mutations in those genes. [See prior JALBCA Newsletters on this subject.]

The Federal Circuit’s First Ruling

In 2011, a split (2-1) Federal Circuit concluded that the isolated DNA molecules coding for certain BRCA sequences were patent-eligible subject matter. They ruled that, because the isolated DNA mol-

ecules are chemically cleaved from native DNA, they have “markedly different” characteristics and, consequently, do not fall within the “products of nature” exception. They further ruled that all but one of Myriad’s method claims were not patent-eligible. The rejected claims were those that cover simply “analyzing” or “comparing” a patient’s BRCA sequence with a normal one to determine if a cancer-pre-disposing mutation is present.

The U.S. S. C. Decision

On March 26, 2012, the U.S. Supreme Court vacated and remanded in light of its opinion in *Prometheus*, a case where it found certain method claims were not patent-eligible. These, the Court found, just involve natural law and, in order to transform a patent-ineligible law of nature into a patent-eligible application of such a law, it is not adequate for an applicant to merely cite the law of nature and state that it is applying it.

The Federal Circuit’s Second Ruling

On remand, the Federal Circuit found, as to the composition claims, that “*Mayo* does not control the question of patent-eligibility of such claims. They are claims to compositions of matter, expressly authorized as suitable patent-eligible subject matter...[W]hen cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity that is obtained by human intervention.” The majority also rejected the Plaintiffs’ argument that allowing patents on isolated DNA would “preempt a law of nature” and, instead, stated that isolated DNA sequences “are the products of man, albeit following, as all materials do, laws of nature.”

As to the method claims, all three judges again affirmed the lower court’s ruling that Myriad’s method claims for “comparing” or analyzing DNA sequences are patent ineligible since these claims “include no transformative steps and cover only patent-ineligible abstract, mental steps.” However, as to the method claims that were directed to methods of screening potential cancer therapeutics, the panel again decided that, even though the claims involved the mental steps of “determining”

and “comparing” the cells’ growth rate, the step of growing transformed cells in the presence or absence of a potential cancer therapeutic was sufficiently transformative to render the claims patent-eligible.

Appeal to the Supreme Court

The plaintiffs have filed a certiorari petition seeking review from the U.S. Supreme Court in the lawsuit. To read the cert petition, you can visit the following website:

www.aclu.org/womens-rights/brca-petition-writ-certiorari

FDA Released Proposals to Strengthen Medical Device Post-market Surveillance System

On September 6, 2012, the FDA made available for comment its report entitled “Strengthening Our National System for Medical Device Postmarket Surveillance.” Medical device postmarket surveillance presents unique challenges compared to drugs and biologics. In its report, the FDA proposed four specific actions in order to strengthen the medical device post-market system, as follows:

- Establish a Unique Device Identification (UDI) system and promote its incorporation into electronic health information;
- Promote the development of national and international device registries for selected products;
- Modernize adverse event reporting and analysis; and
- Develop and use new methods for evidence generation and synthesis and appraisal.

These would augment its existing system for post-market surveillance. Presently, the FDA system relies on these mechanisms: reports of possible injuries, deaths and malfunctions associated with medical devices, surveillance of approximately 280 hospitals nationally, post-approval and post-market surveillance studies for certain devices, certain discretionary studies and tools to track, restrict, ban and/or recall medical devices from the market when needed.

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.cancercare.org
1.800.813.HOPE (4673)

ELLEN'S RUN

200 West End Avenue, Suite 12G
New York, NY 10023
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
212.717.3527

Bendheim Integrative Medicine Center

1429 First Avenue (at 74th Street)
New York, NY

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

TO LIFE!

410 Kenwood Avenue
Delmar, NY 12054
518.439.5975

110 Spring Street
Saratoga Springs, NY 12866
518.587.3820
www.tolife.org

YOUNG SURVIVAL COALITION

61 Broadway
New York, NY
www.youngsurvival.org
646.257.3025

Save the Date:

NYU Cancer Institute Lecture

Topic: When a Friend or Loved One Gets a
Cancer Diagnosis...How to Respond?

Date: Tuesday, December 4, 2012

Time: 6-7:30 pm

Place: NYU Kimmel Center
60 Washington Square South
Room 914

RSVP REQUIRED 212.263.2266 or e-mail
NYUCIcommunityprograms@nyumc.org or
reserve online at www.nyuci.org/rsvp.

JALBCA

c/o Jennifer Fiorentino
Executive Director
1324 Lexington Avenue, PMB 324
New York, New York 10128
www.jalbca.org

Address Service Requested

