



JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

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Editor: Martha L. Golar, Esq.

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JANUARY PROGRAM

- DATE:** Tuesday, January 5, 2010
TIME: 6:30 PM
PLACE: Skadden Arps Slate Meagher & Flom
4 Times Square, NY, NY (between 6th & Broadway)
TOPIC: Breaking News From the San Antonio Breast Cancer Symposium
SPEAKER: Marcia Stein, Chief Executive Officer, Young Survival Coalition

The 32nd Annual San Antonio Breast Cancer Symposium is scheduled for December 9-13, 2009. It is hailed as "(a)n international scientific symposium for interaction and exchange among basic scientists and clinicians in breast cancer." The speaker will report on the new and late-breaking breast cancer research, as well as new findings from clinical trials, presented at this Symposium.



SAVE THE DATE

JALBCA'S ANNUAL DINNER

May 10, 2010

The Water's Edge

Long Island City, NY

JALBCA's 2010 ANNUAL SYMPOSIUM

JALBCA presented its 14th annual Symposium on October 14 on the subject of gene patents and whether or not gene patents stifle medical research, are patentable under U.S. patent law and the U.S. Constitution and impact on patient care. The line-up of panelists, both judges and experts, was excellent. The participating judges this year included Hon. Judith S. Kaye (as moderator) and Judges Helen Freedman, Karla Moskowitz, Ellen Spodek and William C. Thompson. The participating experts included Larry Norton, MD (of Memorial Sloan Kettering Cancer Center), Sandra Park, Esq. (of the ACLU), Martin Pavane, Esq. (of Cohen, Pontani, Lieberman and Pavane LLP) and Mindell Seidlin, MD (of Seidlin Consulting LLC).

Dr. Norton first provided an overview of recent progress in cancer research. He cited to the enormous strides which have been made over the last three years to understand what makes normal cells become cancer cells, emphasizing that the problem is very much tied to how cancer cells relate to the cells around them. Studies focus on what causes supporting cells to do the three things that are characteristic of cancer cells: grow too much, invade surrounding tissue and spread to other parts of the body. One of the primary problems, if not the primary one, with cancer cells is their migration. Most helper cells, he stated, come from the bone marrow. He indicated that, unlike 10 years ago, researchers now know what they need to study, and now it is time to accelerate the research process to find the answers. Dr. Norton stated that there is no reason to be pessimistic and reminded the audience that pessimism leads to failure.

The CLE program was organized around the issues presented in a case brought by the ACLU on behalf of the following plaintiffs: four prominent, national organizations including pathologists, clinical laboratory scientists, other medical professionals, and researchers (Association for Molecular Pathology, American College of Medical Genetics, American Society for Clinical Pathology, and College of American Pathologists), six pre-eminent geneticists, two genetic counselors, two breast cancer and women's health advocacy organizations, and six

individual women.¹ The defendants in the case are the U.S. Patent and Trademark Office (USPTO), Myriad Genetics (Myriad), and individuals in their capacity as directors of the University of Utah Research Foundation. The case was filed in the U.S. District Court for the Southern District of New York. The case challenges seven specific patents issued to Myriad for BRCA1 and BRCA2 genes (ones related to BRCA1 and BRCA2 after these genes are isolated, and both the healthy gene and numerous variations of the gene, some of which Myriad identified, and some of which it did not, and some of which have not yet been identified). The complaint alleges, among other things, that

"2. The gene patents that are challenged in this case are patents covering the BRCA1 and BRCA2 genes, which relate to an increased risk of breast and/or ovarian cancer. Ease of access to genomic discoveries is cruel if basic research is to be expeditiously translated into clinical laboratory tests that benefit patients in the emerging era of personalized and predictive medicine. The patents make ease of access more restricted. Because of the patents, defendant Myriad has the right to prevent clinicians from independently looking at

or interpreting a person's BRCA1 and BRCA2 genes to determine if the person is at a higher risk of breast and/or ovarian cancer. Because of the patents and because Myriad chooses not to license the patents broadly, women who fear they may be at an increased risk of breast and/or ovarian cancer are barred from having anyone look at their BRCA1 and BRCA2 genes or interpret them except for the patent holder. Women are thereby prevented from obtaining information about their health risks from anyone other than the patent holder, whether as an initial matter or to obtain a second opinion. The patents also prevent doctors or laboratories from independently offering testing to their patients, externally validating the test, or working cooperatively to improve testing. Many women at risk cannot even be tested because they are uninsured and/or cannot afford the test offered by Myriad...

4. The patenting of human genes, the concept of looking at or comparing human genes, and correlations found in nature between certain genes and an increased risk of breast and/or ovarian cancer violates long estab-



JALBCA Symposium Panelists



Dr. Larry Norton



Attendees

lished legal principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas. These patents also violate the First Amendment and Article I, section 8, clause 8 of the United States Constitution.”

To commence the discussion, Mr. Pavane provided a short overview of the U.S. patent system. He noted that the system derives from the Constitution, specifically Article I, Section I, Clause 8, which authorizes Congress to grant exclusive rights to inventors for limited times. Congress implemented this authority through patent laws codified at 35 U.S.C. sec. 101 et seq., which empower the USPTO to grant patents for a period of 20 years from the filing date of an application for a patent. In the case of drugs, this period can be extended to compensate for delays in obtaining marketing approval from the Food & Drug Administration. A guiding concept is that by applying for a patent, the applicant must disclose to the public the utility and method of the invention. The *quid pro quo*, therefore, for an inventor to obtain exclusive rights to an invention is disclosure. Failing such disclosure, society risks having the innovation retained as a trade secret. Mr. Pavane stressed that, contrary to what many people think, a patent does not confer on the patentee a right to practice the invention but, instead, a right to exclude others from

doing so. Of course, unless legislatively mandated, a patentee is not required to license others to practice the invention and unless the patentee or its/his/her licensee commercializes the invention, society is denied the benefit of the discovery. Mr. Pavane explained that the U.S. Supreme Court has never taken up the question of whether genes *per se* can be patented. To ultimately resolve this question, either the Supreme Court must decide the issue or, alternatively, Congress would need to except genes from the patent statute. In the meantime, all appeals on patent cases from the Federal District Courts are heard by one Federal Circuit Court.

The U.S. Supreme Court *Metabolite* case was mentioned, particularly Justice Breyer’s dissent (joined by Justices Souter and Stephens).² That case involved a patent that claimed a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin, but the Court dismissed as improvidently granted the writ of certiorari and therefore did not determine whether the patent claim was invalid on the ground that it improperly sought to “claim a monopoly over a basic scientific relationship”. In his dissent, Justice Breyer wrote as follows:

“I concede that the category of non patentable “[p]henomena of nature,” like the categories of “mental processes” and “abstract intellectual concepts,” is not easy to define...After all, many a patentable

invention rests upon its inventor’s knowledge of natural phenomena; many “process” patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process...Nor can one easily use such abstract categories directly to distinguish instances of likely beneficial, from likely harmful, forms of protection...

If I am correct in my conclusion in Part III that the patent is invalid, then special public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching...patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery...

In either event, a decision from this generalist Court could contribute to the important ongoing debate, among both specialists and generalists, as to whether the patent system,



Hon. Judith S. Kaye and Julie Ratner

as currently administered and enforced, adequately reflects the “careful balance” that “the federal patent laws...embod[y].”

Dr. Seidlin, who has been involved in the past in drug development for pharmaceutical companies and presently advises biotech companies, attempted to answer the question of whether a gene is an invention. She indicated that genes exist in the cell but some human involvement is needed to identify their functionality, for both normal and pathological situations. Further, genes do not exist in a form which makes them amenable or usable for drug development. Hence, genes are isolated or purified into a usable form.

Ms. Park, one of the ACLU attorneys pursuing the lawsuit, brought to the audience’s attention multiple aspects of the lawsuit. She explained that the USPTO has permitted patents on isolated and purified genes and commented that the process of isolating a gene is not a complicated one. When asked about how the U.S. varies from other countries with regard to Myriad’s patents on the BRCA1/BRCA2 genes, she explained that there have been proceedings in Europe to challenge some of their patents and these have been somewhat successful in narrowing the patents. However, there is a benefit to being granted a patent in the U.S. since, she said, this does transfer to other countries, reinforcing the importance of deciding in the U.S. the patentability of human genes.

Several speakers addressed the importance of the researchers’ profit motive to encourage their investment in research on, for example, gene abnormalities and the likelihood of correlation between such abnormalities and the likelihood of developing certain cancers. Ms. Seidlin commented that public funding for research is limited but that the biotech industry spends \$600 billion per year on research, obviously because it has a profit motive to do so. She reminded the audience that the usual number thrown around as the cost to develop a drug is \$800 million, and that this is more than an academic institution can afford. While the cost to develop a diagnostic test made be smaller, that too would still be a large cost. Accordingly, the incentive provided by the patent system is necessary for medical research progress.

Judge Freedman inquired as to the significance of Myriad having control of all testing for the BRCA1 and BRCA2 genes, *i.e.*, whether this stymies research, and whether this cuts out genetic counselors. Ms. Park responded that the monopoly rights granted to a gene patentee does have a potentially chilling effect on research. She stated that while Myriad has never issued a policy actually stating that it will not pursue infringement actions against others who conduct research on the BRCA1 and BRCA2 genes, the company has, in fact, sent out cease-and-desist orders. The patent holder can thus decide, she emphasized, what constitutes permissible research. Dr. Norton remarked, however, that while Ms. Park described a chilling effect on research, there is currently a lot of BRCA1 and BRCA2 research being conducted in labs. This prompted the judges to question why the ACLU is pursuing its claims if other research is indeed being pursued on these mutations. Ms. Park responded that some plaintiffs allege their work is being impeded and that exclusivity has resulted in a lack of their scientific freedom – they are concerned that if, for example, they relay test results to third parties, the patent holder will initiate a claim that these scientists are engaging in impermissible commercial activities.

As for genetic counseling, Ms. Park described this as being an undisputed, vital part of genetic testing. A criticism that has been launched in the BRCA1 context, she said, is that the patent holder has done a lot of direct marketing to the public concern-

ing genetic testing for the gene mutation, which cuts out the genetic counselors. An indirect consequence of granting exclusivity rights to the patent holder, then, is to incentivize the patent holder to be the sole purveyor of information to the public.

The panel tried to grapple with how to work within the present system, short of a definite decision as to whether gene patents are legal. For example, Dr. Seidlin raised an issue about multiple patents and the fact that we probably need a structure, which we do not currently have, to facilitate the exploitation of multiple patents if this is needed for certain research. Judge Moskowitz inquired as to whether there should be compulsory licensing by patent holders. Dr. Seidlin noted that the U.S. government, through the exercise of “march-in” rights, has the right to mandate licensing.³ Dr. Norton noted that since one is not really patenting a gene but rather knowledge, this resembles a copyright; however, since ideas are not copyrightable, perhaps we need new legislation for something that falls between copyrights and patents.

Other countries have had different experiences with gene patents. Ms. Park explained that patents are enforced differently elsewhere – in Canada, for example, she indicated that the government has decided not to respect the Myriad patents and, probably for political reasons, the licensee has not sued the Canadian government. In Australia, as a second example, Ms. Park explained that there was public outcry when Myriad decided to enforce its patents.

There exist studies that address the question of whether gene patents impede medical research. For example, the HHS recently issued a final draft of its recommendations on the subject. (See Secretary’s Advisory Committee on Genetics, Health, and Society-Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests). It was mentioned that, among the findings, they concluded that there are sufficient incentives to investigate without patents, but Ms. Park said that this is partly because a lot of universities are sharing the information. The study also found that patents diminished public knowledge and kinds of research. Dr. Norton noted that Myriad has good quality control in its labs and some

would be concerned about the quality control at other labs. Dr. Seidlin agreed that quality control, and confidence in labs, are important. Ms. Park responded, however, that this should not be the basis for deciding, as a matter of policy or law, that we should permit patents on genes. The official position of the USPTO is that the incentive to make discoveries and inventions is generally spurred, not inhibited, by patents on genes.⁴

In approaching the issue as a policy one, Mr. Pavane articulated the clear balancing act that would need to take place - between the potential disadvantages (*e.g.*, lack of competition; limitations on patient choices; etc.) of gene patents on the one hand and the unwillingness of an inventor to maximize the discovery if there was no profit motive. He hypothesized that perhaps patent holders would be liable to their shareholders if they failed to maximize their investment by taking advantage of their exclusive rights.

Judge Kaye asked whether there were pending bills in Congress on the subject of gene patents. The panel did not know of any, though bills had been introduced in

the past both to exempt from infringement liability doctors and others who work with patented genes and to prohibit the patenting of human genes. The HHS report was said to recommend exemption from infringement liability and Ms. Park remarked that this would in some way mirror the European experience, where there is a research exemption.

Finally, the panel discussed the relevance of insurance coverage and the role of insurance companies with regard to the BRCA1 and BRCA2 tests. Dr. Seidlin acknowledged that comes under the broad subject of health care reform, but that the patent holder indeed must negotiate with insurers for reimbursement (although, she noted, the government made a policy decision when dialysis was first introduced, requiring insurers to cover the procedure). She said that testing for BRCA1 and BRCA2 is covered and there is some assistance for those who do not have health insurance. Ms. Park, however, added that problems exist because Myriad has the power to decide which insurance companies with which to reach agreement, with no opportunity for competition. Therefore,

patients have no alternatives. Further, she reported that Myriad's financial assistance does not cover anyone who is insured.

¹ Assoc. of Molecular Pathology, et al. v. U.S. Patent and Trademark Office (USPTO); Myriad Genetics, Univ. of Utah Research Foundation, et al.

² Lab Corp. v. Metabolite Laboratories, Inc., 54 U.S. 124 (2006).

³ Bayh-Dole Act, 35 USC §203, provides "march-in rights" for government funded inventions owned by small businesses or nonprofit organizations. Rather than grant the government full access to the patented technology, march-in rights allow it to effectively sidestep the exclusivity of a patent and request the patent owner or exclusive licensee to grant an appropriate license to another. If the request is refused, the funding agency may even issue its own license. The agency can even grant a license under the patent to a direct competitor. This right is strictly limited.

⁴ 66 FR 1092, United States Patent and Trademark Office Utility Examination Guidelines.

NEWS BRIEF

Israeli Researcher Unexpectedly Discovers Drug that Kills Cancer Cells Without Harming Normal Cells

Israeli news sources reported that Prof. Malka Cohen-Armon, a biochemist at Tel-Aviv University (The Neufeld Cardiac Research Institute and Dept. of Physiology and Pharmacology, Sackler School of Medicine, Tel-Aviv University), and her international research team have discovered a compound that efficiently eradicated MCF-7 and MDA231 breast cancer cells without impairing normal proliferating cells, such as human epithelial cells, nor normal non-proliferating cells, such as neurons and cardiomyocytes. That compound is phenanthridine derived polyADP-ribose polymerase inhibitors. The research findings are published in the current issue of the journal of Breast Cancer Research. The stated conclusion is that "(t)hese results outline a new therapeutic approach

for a selective eradication of abundant non-hereditary human breast cancers."¹

The compound is a component of a family of drugs developed 10 years ago to preserve nerve cells stressed by a stroke or inflammation but, because further studies showed the drugs were not appropriate for their intended use, they were released for research purposes. Prof. Cohen-Armon and her team worked with the drugs to study how the compound affected signal transmission within the nucleus of cells, intending to find an application for DNA repair. They found, unexpectedly however, that the compounds had an effect on cancer cells. They reported that those drugs turn on a mechanism in breast cancer MCF-7 and MDA231 cells that causes them to die within 48 to 72 hours without harming normal tissue and, additionally, that the normal cells continue to proliferate even in the presence of the drug.

A U.S. pharmaceutical company currently holds the patent on the compound

until 2017 and has licensed a usage patent to Ramot, the technology transfer company of Tel Aviv University. However, the patent enables the research consortium to develop the drug for the treatment of breast cancer and precludes their research into its effectiveness against other forms of cancer or diseases, thereby presenting an obstacle to the scientific community. It is hoped that this public disclosure will be the catalyst into further research and the development of cancer fighting drugs instead of the restriction that many in the scientific community view it to be.

¹ Malka Cohen-Armon et. al, *A Selective Eradication of Human Nonhereditary Breast Cancer Cells By Phenanthridine-derived PolyADP-ribose Polymerase Inhibitors*, BREAST CANCER RESEARCH, November 9, 2009 available at <http://breast-cancer-research.com/content/11/6/R78>

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)

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

GILDA's CLUB WORLDWIDE

48 Wall Street, 11th Floor
New York, NY 10005

WOMEN AT RISK

(Breast cancer program of New York-
Presbyterian Hospital/Columbia
University Medical Center)
601 W 168th St. #7 & #8
New York, NY 10032
212.305.9525
www.womenatrisknyc.org

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