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INVALIDATES PATENTS ON
A PAIR OF GENES LINKED TO
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U.S. District Court Invalidates Patents on a Pair of Genes Linked to Breast and Ovarian Cancer

The most significant impact of this decision could well be the funneling of future genetic research and development out of the commercial sector into the academic sector.

In a potentially precedent-setting decision that could have a significant effect on health care and biomedical research, the U.S. District Court for the Southern District of New York on March 29, 2010, invalidated patents on a pair of genes linked to breast and ovarian cancer. The court found that the patents, held by Myriad Genetics Inc., violated long-standing precedents barring the patentability of natural phenomena, stating the genes patented represented "the physical embodiment of laws of nature."

The decision in *Association for Molecular Pathology v. United States Patent and Trademark Office* ("the Myriad decision") invalidated several patents with claims covering genes associated with breast cancer. The result surprised many in the biotechnology industry because the broad holding, if upheld on appeal, would eliminate future gene patenting as well as effectively make existing gene patents invalid. As a result, the ultimate outcome of this case will be critical for those operating in the developing biotechnology industry.

The case was filed last year in relation to patents covering the breast and ovarian cancer genes BRCA1 and BRCA2 and diagnostic methods using these genes to determine a person's risk of developing breast and/or ovarian cancer. Five to ten percent of breast cancers are thought to be due to mutations in these genes. It has not been unusual for the U.S. Patent Office ("Patent Office") to issue patents covering genes such as BRCA1 and BRCA2. The National Institutes of Health has estimated the number of patents in the United States that cover similar genes to be around twenty percent of all human genes, and include those associated with forms of cancer, Alzheimer's, and other diseases.

The American Civil Liberties Union ("ACLU") in 2009, acting on behalf of several individuals, medical professionals, genetic researchers and other scientists, and advocacy [CONTINUED ON PAGE 2](#)





HEALTH LAW BROADCAST
BROUGHT TO YOU BY HALL RENDER

HEALTH CARE REFORM. THE TOPIC HAS DOMINATED THE HEADLINES. The debate on health care reform focused on the need to improve access to health care, expand coverage, and increase quality while decreasing overall health care spending. Now with historic and sweeping health care reform legislation in place, we will see significant changes to our industry.

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U.S. District Court Invalidates Patents (Continued)

organizations, filed a lawsuit to challenge the validity of Myriad Genetics' gene patents, naming the Patent Office and Myriad Genetics as defendants. The lawsuit also had the effect of attacking the legitimacy of all gene patents issued to date in the U.S. The ACLU noted that well-established patent law principles hold that a product of nature is not patentable, absent some change to it that creates a new product, and argued that no process to which Myriad Genetics had subjected the BRCA1 and BRCA2 genes had changed them in any fundamental way such to create a new product.

In addition, ACLU attorneys argued that the patents issued to Myriad Genetics by the Patent Office prevented others from testing for these genes or developing alternative tests, which makes it practically impossible for women to use another company or get an outside second opinion about test results. Because Myriad Genetics had exclusive rights to the use of the BRCA1 and BRCA2 genes and related diagnostic testing, Myriad was the only laboratory in the United States where commercial diagnostic testing could be performed, meaning some women were unable to confirm their cancer test results elsewhere. Moreover, the tests were expensive—Myriad Genetics charged over \$3,000.00 for the tests, which made them prohibitively expensive for many patients. In addition, several researchers already engaged in similar testing were forced to stop their work once Myriad Genetics began enforcing its patent.

Myriad Genetics argued in court documents that it did break new ground, and the genes it isolated were different from those occurring naturally in the human body. Myriad Genetics also stated that the decision conflicted with prior case law requiring broad application of federal patent statutes. The court was not persuaded, however, and stated that the isolated genes contained the identical nucleotide found in native DNA and so were the same whether inside or outside the body. The court also failed to find anything novel in Myriad Genetics' comparative testing methods, stating that the claimed process specified no further action beyond that of "analyzing" and "comparing."

The matter is far from settled, however. It is likely this decision will be appealed to the Federal Circuit Court of Appeals, and perhaps to the U.S. Supreme Court. If ultimately upheld, of course, this decision will prevent the Patent Office from issuing similar gene patents in the future, and will potentially invalidate similar **CONTINUED ON PAGE 3**

claims in many existing patents. Applicants in the future will only be able to get patents for genetic material that has "markedly different characteristics" from native DNA.

Many health care providers and researchers believe this decision will pave the way for broader research and more accessible treatments for patients, as it will remove restrictions on sharing information regarding genetic material with more parties than just a patent holder, which it is hoped will further

more efficient ways of doing genetic testing. However, patent lawyers and biotechnology firms argue that this decision could hinder such developments if the patent system isn't available to help attract the investment needed for new research. The most significant impact of this decision could well be the funneling of future genetic research and development out of the commercial sector into the academic sector. There may as a result be fewer dollars available for genetic research. The American

Medical Association, in support of the plaintiffs in the case, agreed that patents can be useful in spurring medical inventions, such as new drugs, but argued that overly broad patents, like those held by Myriad Genetics, created a monopoly that hampered scientific discovery and medical care. Whatever the ultimate outcome of this case, it is certain that the effects will be felt far beyond current U.S. holders or would-be holders of gene patents. ■

Obama's Bioethics Commission Set to Begin Meeting in July

President Obama established the Presidential Commission for the Study of Bioethical Issues by Executive Order 13521. The Commission's mission is "to advise the President on bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology." In particular, the Commission is charged with "identifying and promoting policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in an ethically responsible manner."

The Commission's Chair, Amy Gutmann, Ph.D., and Vice Chair, James W. Wagner, Ph.D., were appointed in November, 2009. The remaining ten members of the Commission were appointed on April 7, 2010. The Commission will begin meeting in July. Meeting notices, transcripts and background materials will be available on the Commission's website, www.Bioethics.gov.

The Office of Presidential Personnel disbanded the President's Council on Bioethics appointed by President George W. Bush months before

it was scheduled to expire. A White House press officer described Bush's Council as a "philosophically leaning advisory group," and promised that the new Commission would be "practical" and "policy-related." The Executive Order identifies several issues that the Commission may consider related to specific technologies. These include:

- the creation of stem cells by novel means
- intellectual property issues involving genetic sequencing, biomarkers, and other screening tests used for risk assessment
- the application of neuro- and robotic sciences.

In addition, the Commission may consider broad issues related to research integrity and the intersection of science and human rights.

The Commission will not create policy regarding stem cells, research ethics or other emerging issues; that is a task performed by federal agencies like the National Institutes of Health and the Department of Health and Human Services. Even without policy-making

authority, however, bioethics commissions have been successful in the past at influencing policy. The first bioethics commission was established by Congress in 1974 and produced the Belmont Report, one of the most influential documents for U.S. research policy. Other commissions, like President Clinton's National Bioethics Advisory Committee, were influential in federal and state laws addressing stem cell research and cloning, among other issues. ■

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ABOUT HALL RENDER

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Health Reform Weighs in on Comparative Effectiveness Research

Complex health care decisions are often made by patients and their health care providers without access to reliable evidence that could help them decide which medications or treatments offer the greatest medical benefit with the fewest risks or side effects. Comparative Effectiveness Research ("CER") assists patients and providers by comparing two or more available medical treatments, services, or items such as drugs and devices. It is hoped that the results of CER will lead to better decision-making by patients, providers and other decision-makers, and that health outcomes will improve.

CER received a boost of \$1.1 billion in the American Recovery and Reinvestment Act of 2009 ("ARRA"). Section 6301 of the Patient Protection and Affordable Care Act ("PPACA")

defines the limits of the uses of CER results and establishes a private, nonprofit organization, called the Patient-Centered Outcomes Research Institute ("Institute") that will help identify priorities for CER and disseminate research results. The Comptroller General will name a 19-member board of governors within six months. Members of the Board will include three representatives of drug, device and diagnostic-testing companies; patient advocates; physicians; and the National Institutes of Health.

PPACA answers some of the lingering questions about how CER will be used to guide decisions about payment by third-party payors, particularly Medicare. PPACA should put to rest stakeholders' fears that the results of CER could lead to the rationing of expensive but effective care, or government mandates that

the most effective treatment, drug or device be used. The new law prohibits the Secretary from denying coverage for items or services solely on the basis of CER, and requires any such coverage decisions to be made through "an iterative and transparent process which includes public comment and considers the effect on subpopulations." However, the question remains whether research results will yield better clinical decisions without aligning financial incentives. ■

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