

JUDGE INVALIDATES HUMAN GENE PATENTS



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US District Judge Robert Sweet on March 29, 2010 ruled as invalid the claims of seven Myriad Genetics Inc. patents covering two human genes (BRCA1 and BRCA2) linked to breast cancer tumour suppression. This 152-page decision is significant and has sent shockwaves through the life sciences and medical fields. There is considerable debate on all sides of the issue, both within and outside the scientific community. An appeal process that could take years is a certainty and will include an appeal to the Federal Circuit and, from there, a likely appeal to the US Supreme Court.

Judge Sweet sided with many who oppose gene patents, including plaintiff American Civil Liberties Union (ACLU), saying that “they are directed to a law of nature” and therefore should never have been granted by the US Patent and Trademark Office (USPTO). The ACLU sued Myriad and the directors of the University of Utah Research Foundation on behalf of groups that include the Association for Molecular Pathology (AMP) and the American College of Medical Genetics (ACMG). Claims by the ACLU against the USPTO, originally named as a defendant in the lawsuit, were dropped.

The ACLU issued a statement that “the precedent-setting ruling marks the first time a court has found patents on genes unlawful and calls into question the validity of patents now held on approximately 2,000 human genes”. There are some 100,000 human genes in all. AMP issued a statement setting forth the belief that this decision could lead to improved patient access to genetic testing. ACMG is of the belief that this decision has “far-reaching positive implications for physicians, researchers and patients”. Others who have applauded the decision include the American Society for Clinical Pathology and the American Medical Association.

At issue in this case is whether a patient is able to obtain a second testing opinion prior to undergoing a mastectomy or ovarian surgery. It is argued by those who oppose gene patenting that, but for the outcome in this case, Myriad holds a monopoly on medical testing for the BRCA1 and BRCA2 genes, with no other company able to legally perform testing for which Myriad charges \$3,000. The emotional climate surrounding this lawsuit intensified when six breast cancer patients joined the suit, along with tens of thousands of scientists, pathologists, geneticists and women’s health groups, as reported by *The Responsibility Project*.

Myriad argues that it has a right to defend its intellectual property rights, noting that the USPTO has for years granted gene patents. If a company spends millions of dollars cracking a genetic code, is it entitled to any exclusive intellectual property rights and, if so, what would such IP rights cover? Multibillion dollar industries have been supported by intellectual property rights in gene patents. Myriad was unable to persuade Judge Sweet to adopt its contention that its patents are valid because its tests

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use “isolated DNA”, which is slightly different from the actual DNA in the human body. This decision should not affect drug companies such as Amgen and Pfizer, which develop biotech drugs that involve genetically engineered organisms not existing in nature.

Should Judge Sweet’s decision survive an appeal, “it should greatly widen access to BRCA testing in the US, where Myriad’s patent has inflated the cost”. In Europe, where patents on the two BRCA genes are either limited or shared with cancer research organisations, there is already wider access to the test, according to London’s *The Times* newspaper.

Kenneth Chahine, a visiting law professor at the University of Utah, who filed an *amicus* brief on the side of Myriad, is quoted by *The New York Times* as saying: “If a decision like this were upheld, it would have a pretty significant impact on the future of medicine.” Chahine believes that medicine is becoming more personalised, with genetic tests being used not only to diagnose diseases but to identify the medicines best suited for each patient.

Patents are not normally granted by the USPTO for rules of nature, natural phenomena or abstract ideas. Unless this case is reversed, the USPTO will continue to grant gene patents directed to specific isolated gene sequencing, their chemical composition, the processes for obtaining or using them, or a combination thereof. Only after the dust from the appeal process settles will we have a better idea of the future of gene patents.

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