

Gene Patent Ruling Could Shake Up Biotech

By Ryan Davis

Law360, New York (March 30, 2010) -- A federal judge's ruling invalidating patents on two genes linked to breast and ovarian cancer could have wide-ranging implications for gene patent law and the biotechnology industry if it is upheld on appeal, experts said.

"It's not a game-changer yet, and there's a long way to go, but if it's affirmed as it currently stands, it certainly would be a game-changer," said Patrick R.H. Waller, a shareholder at Wolf Greenfield & Sacks PC.

In a suit filed by the American Civil Liberties Union on behalf of the Association for Molecular Pathology, Judge Robert W. Sweet of the U.S. District Court for the Southern District of New York ruled Monday that seven patents held by Myriad Genetics related to the genes BRCA1 and BRCA2 are invalid because they involve DNA as it is found in nature.

Myriad uses its gene patents to produce a \$3,000 test that looks for mutations in the genes that raise the risk of breast and ovarian cancer.

The U.S. Patent and Trademark Office has held that "isolated DNA" that is purified from the body is patentable because it is transformed into something distinctly different. However, the judge concluded that isolated DNA cannot be patented because it alters neither the fundamental quality of DNA as it exists in the body nor the information it encodes.

He came down on the side of the critics he cited in the opinion who consider gene patents to be "a 'lawyer's trick' that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result."

Myriad CEO Peter Meldrum said in a statement that the company was disappointed by the verdict, which he said did not follow judicial precedent or the intent of the Patent Act. Meldrum said he was confident that the decision would be reversed by the U.S. Court of Appeals for the Federal Circuit.

Chris Hansen, a staff attorney with the ACLU First Amendment Working Group, said in a statement that the ruling was a victory for the free flow of scientific ideas because gene patents put up unacceptable barriers to research.

"The human genome, like the structure of blood, air or water, was discovered, not created," Hansen said.

Jim Foster, a shareholder at Wolf Greenfield who was not involved in the case, said that while the ruling will certainly be appealed to the Federal Circuit and possibly to the U.S. Supreme Court, it will play an important role in raising the stature of gene patent critics.

“The ruling gives enormous credibility to the arguments raised by the ACLU,” which many lawyers had thought were weak or frivolous, he said. “Now it's a live issue and a very credible issue.”

Bill Warren, chair of the biotechnology and life sciences team at Sutherland Asbill & Brennan LLP, called the ruling a “poor decision” that ignored the fact that isolating DNA is what changes it into a useful product, even though it carries some of the same information as the native gene.

“Certainly, the sequencing of genes and disease-associated mutations for use in developing diagnostic probes and assays provides useful non-naturally occurring subject matter which should qualify for patentability under the statute,” Warren said in an e-mail message. He said he was confident the Federal Circuit will reverse the ruling.

Other attorneys said it was an open question as to how the Federal Circuit will rule, since Judge Sweet's ruling depends on the novel argument that DNA is unpatentable because it appears in nature.

Barbara Caulfield, co-chair of the global life sciences industry sector at Dewey & LeBoeuf LLP, said that since that type of frontal assault on the patentability of genes had not been attempted in any previous case, there was no record to suggest how the Federal Circuit might view the theory.

“It's a matter of first impression for the Federal Circuit. I don't think you can predict how they'll rule based on other cases,” said Caulfield, who filed an amicus brief in the case on behalf of the March of Dimes in support of the ACLU's position.

Lisa Haile, co-chair of the global life sciences sector at DLA Piper, said that if the ruling were affirmed, the impact on the biotechnology industry could be “devastating.” Not only does it throw the validity of thousands of issued patents related to human genes and diagnostic tests into doubt, it could potentially disrupt the industry's business model, she said.

Many biotech companies use their patent portfolio to attract investors, and the risk of those patents being declared invalid could have a chilling effect on funding, according to Haile. There would be no incentive to invest in a given company if the same technology were available to everyone, she said.

“It goes a lot further than 'Is a gene patentable?'" she said. “I have to admit I was surprised by the ruling. It's so significant to say a certain area is not patentable.”

Bill Gaede, a partner at McDermott Will & Emery LLP who represented a coalition of diagnostic companies that filed an amicus brief in the case, also expressed concern about the ruling's impact on investors.

“The incentives to invest in diagnostic and biologic companies rests on certainty in patent law,” he said. “This decision will create uncertainty in investors' minds as to whether the business models of certain companies are sustainable under the patent laws.”

The ruling addressed two types of claims involved in the seven patents. One type involved isolated DNA, and the other deals with methods for comparing and analyzing gene sequences to identify an increased risk of breast or ovarian cancer.

Lawyers said there was a general consensus that the method claims might be vulnerable, given recent court rulings on method patents. The isolated DNA claims, however, were seen as likely to survive because the USPTO has generally accepted such claims as patentable.

That both types of claims were invalidated came as a “bit of a jolt to the industry,” Waller said.

The judge found that the method claims consist of unpatentable abstract mental processes, relying on the Federal Circuit's ruling in *Bilski v. Kappos*, on which the Supreme Court is expected to rule soon. Haile said she found it strange that the ruling relied so heavily on *Bilski*, which could soon be overturned.

Waller noted that, as Myriad pointed out in its news release on the ruling, even if all the claims at issue in the case were declared invalid on appeal, there were dozens of other claims in the patents that were not challenged and could still afford protection to Myriad's technology.

The patents-at-issue are U.S. Patent Numbers 5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,710,001; 5,753,441; and 6,033,857.

Attorneys from the ACLU and the Public Patent Foundation are representing the Association for Molecular Pathology in this matter.

Jones Day is representing Myriad Genetics.

The case is *Association for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al.*, case number 1:09-cv-04515, in the U.S. District Court for the Southern District of New York.