

Judge Invalidates BRCA Gene Patents

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A Federal district court judge ruled yesterday that certain claims to isolated DNA sequences and methods of using the sequences were not patentable under Section 101 of the Patent Statute. The sequences and tests relate to mutations in the human BRCA1 and BRCA2 genes, which have been shown to increase a woman's risk of developing breast and ovarian cancer. The suit had been brought in the Southern District of New York by the ACLU on behalf the Association for Molecular Pathology and other plaintiffs who claimed to have been prohibited from using the tests or to have been adversely impacted by the patents in other ways. The defendants were the U.S. Patent and Trademark Office, which issued the patents, and Myriad Genetics and the University of Utah Research Foundation, which owned the patents. Myriad offers the tests to doctors and their patients and has built a significant business around this technology.

Section 101 states that a patent can be granted on (among other things) a new and useful composition of matter. Other sections of the statute require the invention to be novel and unobvious. The courts have held that a patent cannot be granted on a "product of nature."

One would have thought that it was pretty obvious that isolated DNA is not a product of nature. It exists only because of human intervention. Nevertheless, relying on several outdated court decisions and misinterpreting more recent ones, the judge ruled that the claimed sequences, even though isolated, were products of nature because they were not "markedly different" from "native DNA" – they were still a physical carrier of biological information, like the genes found in the body. He even quoted the asinine statement by one commentator that claiming isolated DNA is a "cheap lawyers' trick."

The judge also ruled that methods of using the sequences to predict cancer risk were also unpatentable because they pre-empted a natural phenomenon – the correlation between mutated BRCA genes and cancer risk. The judge relied heavily on the much criticized ruling of the Court of Appeals for the Federal Circuit in the *In re Bilski* case – a ruling involving business method patent claims and which common sense mandates should be limited to those situations. I'll spare you the details of the tortured logic and sloppy thinking.

Needless to say, the ruling, if upheld, could have a serious adverse impact on the biotech industry, particularly on companies offering diagnostic tests. Myriad stated in a press release today that it would appeal the decision and vigorously defend the patents:

<http://investor.myriad.com/releasedetail.cfm?ReleaseID=455348>.

Without venturing any predictions on the ultimate outcome, I will say that the opinion contradicts what the patent bar considers to be well-settled law and further that I consider the opinion to be poorly reasoned. All chemicals, in fact all matter, embodies information. A novel laboratory-synthesized drug is the sum of its atomic, molecular, and chemical properties, which properties are ultimately governed by universal scientific laws; i.e., information. Under the judge's rationale, the drug would be a product of nature. Even if one were to accept the judge's

markedly different" requirement for patentability, the claimed isolated DNA is markedly different from the genes in the human body. The ones in the body are useless for predicting a risk for breast or ovarian cancer. It was only when the inventors found and isolated the mutant genes could there be a test for this risk. The judge overlooked the very simple fact that, but for the actions of the inventors, the test would not exist. If this isn't a "markedly different" situation, I don't know what is.

For those of you interested in a more extended discussion of the merits of gene patents, please see my article at <http://www.genengnews.com/articles/chitem.aspx?aid=2052&chid=0>.

I'm sure I'll be writing more about this case and the efforts of the anti-patent cabal to destroy gene patents. But this is it for now.