Are Genes No Longer Patentable?

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In a much anticipated decision that has attracted the attention of pharmaceutical and biotech companies, medical researchers, physicians, attorneys and patients concerned about their risk for breast or ovarian cancer, Judge Robert W. Sweet of the U.S. District Court for the Southern District of New York ruled in favor of the plaintiffs on March 29, 2010 in *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al*. The Court granted partial summary judgment that the claims of patents related to *BRCA1* and *BRCA2* are invalid on the grounds that genes are products of nature and, thus, constitute unpatentable subject matter. In particular, the Court held that composition claims on isolated DNA sequences and method claims on the use of those sequences for diagnosing breast and ovarian cancer fail to qualify as patentable subject matter under 35 U.S.C. §101. The lawsuit filed against the University of Utah Research Foundation, its licensee Myriad Genetics, and the USPTO, in May 2009 was organized by the American Civil Liberties Union, patients, physicians, and medical researchers. The decision marks the first time that a court has held patents on genes to be invalid as directed to non-statutory subject matter and will continue to be the subject of intense debate and scrutiny. It is estimated that 20% of the genome has been patented, amounting to thousands of patents that claim compositions of matter and methods of using those compositions.

Compositions of Matter and Products of Nature

There is wide-spread agreement that DNA in the body is a “product of nature” and does not qualify as patentable subject matter. The debate turns on whether the “isolation” of genes makes them patentable. Plaintiffs argued that isolating the gene does not alter the structure of the DNA itself, and thus isolated genes remain a product of nature. The defendants asserted that the isolation of the *BRCA* genes and separation of the genes from the other DNA makes the genes patentable.

The PTO currently grants patents on DNA sequences provided that the sequences are claimed in the form of “isolated” DNA and the isolated DNA is novel (the particular sequence had not been previously described), is non-obvious and is useful. According to Judge Sweet, the basis of this policy was that DNA was being treated the same as any other chemical compound.

The 152 page opinion reviewed Supreme Court precedent, including *Diamond v. Chakrabarty* (holding that an engineered bacterium capable of degrading oil was patentable subject matter), *American Fruit Growers* (holding that a patent claim covering fruit whose skin had been treated with mold-resistant borax not patentable subject matter, because it did not

"possess a new or distinctive form, quality or property") and *Funk Brothers* (holding that a mixture of several naturally-occurring species of bacteria was not patentable, since the qualities of the bacteria "are the work of nature").

To substantiate its holding, the Court highlighted the similarities between DNA as it exists in nature and isolated DNA: both are chemical substances and both serve as physical carriers of information. According to Judge Sweet, since the same structural and functional qualities are identifiable in both native DNA and isolated DNA, isolated DNA is not "markedly different" from native DNA and thus does not constitute patentable subject matter under 35 U.S.C. §101. The Court acknowledged that "the identification of *BRCA1* and *BRCA2* gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that it is not the same as concluding that it is something for which they are entitled to a patent."

Diagnostic Method Claims

The boundaries of patent-eligibility for biotechnology processes, including diagnostics, has been the subject of recent debate and speculation following the In *re Bilski, Classen* and *Prometheus* decisions. For the method claims-in-suit, Judge Sweet relied on the Federal Circuit's decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), as "the definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself." Under this "machine or transformation" test, "[a] claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." Applying the *Bilski* test, the court held that the method claims-in-suit are directed only to the abstract mental processes of "comparing" or "analyzing" gene sequences and thus are not patent eligible subject matter.

Constitutional Claims

The court dismissed claims that the Patent and Trademark Office violated the Patent and Copyright Clause and the First Amendment to the Constitution by issuing the subject patents, invoking the doctrine of "constitutional avoidance." Judge Sweet wrote, "[w]ith the holding that the patents are invalid, the Plaintiffs have received the relief sought in the Complaint and the doctrine of constitutional avoidance precludes this Court from reaching the constitutional claims against the USPTO."

This is just the beginning of the debate on whether genes and, potentially, other molecules constitute patentable subject matter. Myriad has vowed to appeal the decision to the Court of Appeals for the Federal Circuit and it may ultimately reach the Supreme Court. This decision, along with *In re Bilski*, emphasizes the importance of careful drafting of process claims to tie the method steps to a machine or to otherwise "transform" a starting material into a different state or thing. To support the patent eligibility of molecules, such as DNA, patent applications should focus on "marked differences" between the claimed molecule and how it may exist in nature. The fact that a molecule is simply different (i.e., novel) may no longer suffice.