

March 30, 2010

DNA Ruled Not Patentable Subject Matter

The U.S. District Court for the Southern District of New York has ruled that claims to isolated DNA and methods of use for diagnosis do not qualify as patentable subject matter in *Assoc. for Molecular Pathology v. U.S. Patent and Trademark Office*, 09 Civ. 4515 (RWS), March 29, 2010. The court avoided a further ruling on whether the U.S. Patent and Trademark Office (USPTO) violated the First Amendment to the Constitution in issuing the patents.

This decision will likely have negative short-term implications for financing in the biotechnology sector, and hence the development of new diagnostics and therapeutics, unless it is overturned by the U.S. Court of Appeals for the Federal Circuit in the next one to two years. It had long been viewed that the sequencing of genes and disease-associated mutations for use in developing isolated diagnostic DNA probes and assays provides useful non-naturally occurring subject matter which should qualify for patentability under the statute (35 U.S.C. §101). The USPTO and most other foreign patent offices have issued thousands of such isolated DNA patents in the past.

This lawsuit was brought by the American Civil Liberties Union, certain doctors, medical researchers, and patients against the patent owner Myriad Genetics, the USPTO, and other defendants, over the validity of patents directed to BRCA1 and BRCA2 genetic mutations associated with breast and ovarian cancer. The broader goal of the lawsuit was to eliminate patentability of any isolated DNA. The plaintiffs fundamentally believe that the free use of information contained in DNA should not be restricted by patents, whereas the defendants principally believe in promoting the progress of science and commercially available DNA-based products by incentivizing inventors with patent rewards.

The court did not find that isolated DNA has been “markedly changed” to become a useful product under the requirements stated in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The court relied upon the Federal Circuit’s decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) requiring either the use of a machine or the transformation of a material to create patentable subject matter. It should be noted that the U.S. Supreme Court is expected to issue its own *Bilski* appellate decision, specifically addressing the patentability of business methods, any day now.

The District Court did not agree with Myriad’s argument that while native genes in the body are originally products of nature, the work in isolating portions of the DNA in order to perform diagnoses does transform the DNA both structurally and functionally into patentable subject matter. However, the court acknowledged that isolated and amplified fragments of DNA are able to be detected for a diagnosis in ways that the native DNA cannot.

According to Judge Sweet, the similarity that the isolated DNA has to the native molecule in carrying some of the same genetically coded information is more relevant to the issue of “transformation” than are the other structural and functional changes that the DNA undergoes through isolation. While it is, of course, true that the information contained in the nucleotide sequence of the DNA fragment remains the same, the court did not recognize that its transformation to an isolated form is what makes the DNA functional for hybridization and detection. It would appear to be more appropriate for the court to focus the “transformation” analysis on the fundamental changes to the article in question, rather than the remaining similarities.

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The court also held that the method of using the isolated DNA for comparison to make diagnostic determinations was not patentable subject matter. Judge Robert W. Sweet made the narrow distinction that the method claims in the present case are directed to abstract mental processes of “analyzing” or “comparing,” and are not sufficiently transformational in the same way that the claims in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009), were found by the Federal Circuit to be transformational for “determining” metabolite levels in the body.

The issue of whether recent progress in scientific techniques and knowledge has made the isolation of such DNA fragments unpatentable as either routine or obvious is a separate question, which was not at issue in this case. However, the legal precedent relied upon in arguments made by the court often blurred the distinction of the separate requirements for patentable subject matter with those for novelty and obviousness. According to Judge Sweet, the purification of DNA from the body using well-known techniques does not render it patentable because it has not been transformed into something fundamentally different in character.

With the holding that these DNA-based patents are invalid, the doctrine of constitutional avoidance precluded the court from reaching the First Amendment Free Speech claims against the USPTO. An appeal to the U.S. Court of Appeals for the Federal Circuit of this decision against patentability of DNA is expected.



If you have any questions regarding this alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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