

The U.S. Myriad Patents-Still an Unresolved Issue

The ruling by Judge Robert Sweet in the District Court of the Southern District of New York was that the Myriad patents, which claimed isolated genomic DNA, were invalid under 35 U.S.C. §101 for lack of patentable subject matter. However, this is not a final decision.

The Association of Molecular Pathology v. The United States Patent and Trademark Office, otherwise known as the Myriad case on BRCA₁ and BRCA₂, was recently appealed to the Court of Appeal of the Federal Circuit by Myriad.

The United States Justice Department submitted an *amicus curiae* brief, which contradicts the position of the U.S. Patent & Trademark Office, insisting that a change in policy be undertaken at the USPTO with respect to the patent eligibility of isolated genomic DNA.

The USPTO in the meantime is maintaining its position that isolated genomic DNA is still patentable subject matter. PTO Director Mr. Kappos recently said at the BIO International Convention:

“The USPTO has issued more than 20,000 patents claiming isolated DNA molecules, almost 4,000 of those which directly claim isolated human DNA encoding of protein.” So there is a lot of intellectual property, probably much of it owned by companies represented in this room and most probably most of it owned by companies represented at this conference that is already out there. The USPTO has also issued tens of thousands of patents on other types of isolated and purified chemicals all of which could be put at risk by the District Court’s decision.”

However, it will now be decided by the Court of Appeal for the Federal Circuit, whether isolated genomic DNA is patentable subject matter. The CAFC may address this issue or may not. An issue which is relevant to this case is whether The Association of Molecular Pathology, the ACLU and the other plaintiffs have standing to file the suit. If the CAFC rules that there is no standing, the patentability issue will probably not be part of the judgment.

Once the CAFC’s decision is made the losing party may appeal to the United States Supreme Court.

Therefore, the issue whether isolated genomic DNA is patentable in the United States remains an issue that will be resolved in the future.