

## Status Quo Restored? - the patentability of gene sequences

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Last year a court in the United States invalidated the claims of several patents for being directed to non-patentable subject matter.<sup>1</sup> The claims in question were directed to isolated human nucleic acids.

This year the judges hearing the appeal have reversed the first decision, deciding that the claims are valid. So is this the end of the debate?

### The Background

The claims at the heart of the court cases are for isolated (extracted from the genome without further alteration) human gene sequences related to the BRCA1 and BRCA2 genes.

Mutations in the BRCA genes correlate with an increased risk of breast and ovarian cancer. It is estimated the average woman in the United States has around a twelve to thirteen percent risk of developing breast cancer. Women with BRCA mutations, by contrast, have a fifty to eighty percent risk of developing breast cancer and twenty to fifty percent risk of developing ovarian cancer.

Myriad Genetics Inc. (that own or licence the rights to the patents in question) provides testing to patients for mutations in the BRCA1 and BRCA2 genes.

The case was brought to the courts by the American Civil Liberties Union and the Public Patent Foundation representing a number of parties including doctors, patients and researchers. The group argued that the patents provide Myriad with a monopoly over the testing and therefore the ability to set the price and accessibility of the testing. They believe the testing should be made more readily available and at a lower cost.

### The Decisions

The first court (the New York District court) held that the claims for isolated gene sequences were for products which were not markedly different from products of nature and were therefore ineligible for patent protection.

The Court of Appeals overturned most aspects of the decision, deciding that isolated genes are eligible for patent protection. However, the decision of the Court of Appeals was not unanimous. Two of the judges came to the same conclusion (that isolated gene sequences are patentable subject matter) but for slightly different reasons. The third judge did not agree that isolated gene sequences in general are eligible for patent protection.

The dissenting judge gave the following summary of the technical arguments for and against the patentability of isolated gene sequences:

*In its simplest form, the question in this case is whether an individual can obtain patent rights to a human gene.*

*From a common-sense point of view, most observers would answer, "Of course not. Patents are for inventions. A human gene is not an invention." The essence of Myriad's argument in this case is to say that it has not patented a human gene, but something quite different—an isolated human gene, which differs from a native gene because the process of extracting it results in changes in its molecular structure (although not in its genetic code). We are therefore required to decide whether the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention. The court concludes that it does; I conclude that it does not.*

While the Court of Appeals' decision was in favour of patentability of isolated nucleic acid sequences, it seems this subject is nonetheless splitting the opinions of judges, lawyers, scientists and the general public.

### Patent Office Practice

One of the factors considered by the Court of Appeals was the way the United States Patent Office has been dealing with patent applications to date. The Patent Office has been granting patents covering human gene sequences since around the early 1980's. The judgement of the Court of Appeals states an estimated 2,645 United States patents have been granted covering various isolated genes. In the wake of the original judgement there was uncertainty over whether any of these patents were valid and whether the monopolies they defined could be enforced.

One of the appeal judges clearly took this into consideration stating:

*The settled expectations of the biotechnology industry—not to mention the thousands of issued patents—cannot be taken lightly and deserve deference....I believe leaving intact the settled expectations of property owners is particularly important in light of the large number of property rights involved, both to isolated DNA and to purified natural products generally.*

One group that would lose out if a Court held that patents for gene sequences were not allowed would be the owners of the patents currently on the register. These patents were filed in good faith and were granted by the United States Patent Office.

### Patents, a Reward for Innovation

The argument for patent protection (of any form) is that it rewards innovation. Research and development costs can be enormous, particularly in the biotech and pharmaceutical fields. If a competitor can immediately copy the end result of the research for a fraction of the cost, will companies continue with their research and development programs?

While the decision of the Court of Appeals supports the granting of patents for nucleic acids, there is significant ongoing political and social debate around this topic world-wide, and the Courts' decision is not likely to mark the end of the issue.

### What does the Future Hold?

Considering the importance and potential implications of the judgement, it is very likely the case will be appealed to a higher court and will be watched with interest by all concerned.

Other countries are also considering the social implications of the granting of patents to isolated nucleic acids, particularly those from humans. In Australia, this has led to a private members bill being introduced into Parliament which, if passed, would see the end of granting patents for any biological material which is identical or substantially identical to such materials as they exist in nature.

If you are considering filing a patent application for a gene sequence, we recommend proceeding as usual ensuring that you include as much detail as possible in your

application about how the gene sequence(s) differ(s) from any equivalent sequence(s) found in nature (for example, mutations or alterations, functionality) and be sure to include claims to other aspects of the invention, for example: hybrid nucleic acids (such as vectors or constructs), cDNAs, recombinant cells (or organisms) including the nucleic acids, and the methods by which the gene sequences are used.<sup>2</sup>

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact:

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### References

1. United States District Court for the Southern District of New York, Case No. 09-CV-4515, Senior Judge Robert W. Sweet.
2. Association of Molecular Pathology v. U.S. Patent and Trademark Office (Myriad), No. 2010-1406, 8 (Fed. Cir. July 29, 2011).



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