Controversy over gene patents

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A controversial decision on the patentability of human genes has been issued in the United States of America, which could have a significant impact on the biotechnology and pharmaceutical industries.

On 29 March 2010, a New York District Court held in the case of Association for Molecular Pathology v United States Patent and Trademark Office, that several claims relating to the BRCA1 and BRCA2 genes were invalid as they claimed non-patentable subject matter pursuant to US statute.

The decision concerns several patents owned by the defendant, Myriad Genetics, containing claims relating to the BRCA1 and BRCA2 genes associated with breast and ovarian cancer. Mutations in these genes correlate to an increased risk of developing these forms of cancer. The patents include claims to isolated DNA sequences encoding all or part of the BRCA1 and BRCA2 genes, as well as methods to detect the presence of mutations in the genes by comparing a patient's DNA sequence to that of a normal gene. The tests are

aimed at detecting a patient's predisposition to these forms of cancer.

The patents effectively give Myriad a monopoly over testing for mutations in the BRCA1 and BRCA2 genes. According to the plaintiffs, a patient seeking screening of the BRCA1 and BRCA2 genes had no option other than testing through Myriad. Tests are provided to the general public at a cost of approximately US$3,000. The plaintiffs argued that this cost is unaffordable for many women, and Myriad's monopoly over testing precludes the ability for patients to seek a second opinion on results. In Canada, where claims of this nature are not patentable, these tests are provided at a third of the cost charged by Myriad.

The plaintiffs brought this case to challenge the validity of Myriad's patents, and determine whether isolated human genes and sequence comparisons are patentable subject matter.

Are the claims valid?

The Judge held that claims for isolated DNA which have the exact sequence as occurs naturally in the human genome, are "products of nature" and therefore non-patentable subject matter.

The isolated DNA also failed to satisfy the standard of being “markedly different” from a product in nature to be patentable subject matter. Despite the fact that there are chemical differences between isolated DNA and that of the human genome, the Judge held that the information-bearing characteristic of DNA is unique and does not differ between DNA in a isolated form and that which occurs naturally. On this basis the two forms of DNA could not be considered “markedly different”.

The essence of this decision is that DNA sequences that occur naturally in the human genome are non-patentable, even if they are “isolated” as there are no fundamental differences either to the information encoded or the way it exists in the human body.

The Judge also held that the claims to “comparisons” and “analysis” of a patient’s DNA and native DNA are “abstract mental processes” and therefore “constitute unpatentable subject matter”.

Prior to this decision, the USPTO practice had been to grant patents for DNA sequences provided they are in an “isolated” form.

This decision will undoubtedly be appealed to the Federal Circuit, and possibly again to the Supreme Court. While the future of the patentability of human genes

is being determined, it is likely that the biotechnological and medical industries will be looking at the most advantageous strategies to protect their intellectual property in the wake of this recent decision.