

Biotechnology breathes a sigh of relief: *Isolated gene sequences are patentable subject matter*

Intellectual Property Update

Case note in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65.

On 15 February 2013, the Federal Court of Australia dismissed an application to invalidate a patent claim over the BRCA 1 breast and ovarian cancer gene.

The case is one of considerable importance in patent law, particularly as it applies to biotechnology. Biotechnology patents, particularly gene sequence patents, are now less vulnerable to a finding that they do not satisfy section 18(1)(a) of the *Patents Act 1990*.

In order to justify investing resources into products derived from genes or gene sequences, the biotechnology industry has long needed certainty that the patents protecting its intellectual capital are valid. This case goes a long way to creating that certainty. The case has answered the question of whether genes and gene sequences **"isolated"** from living things can be patentable subject matter.

The Court accepted that **"isolated"** genes and gene sequences are not materially different to naturally occurring (and unpatentable) genes and gene sequences. Despite this finding, the Court found that the **"isolated"** BRCA 1 gene sequence was patentable subject matter. The Court found that s18 (1)(a) (the manner of manufacture test) was satisfied by the asking the following question:

Whether there is an artificially created state of affairs, providing a new and useful effect that is of economic significance.

The key issue was whether an **"isolated"** gene sequence was an artificially created state of affairs. The following factors were important to this finding:

- naturally occurring nucleic acid (of which genes are composed) does not exist outside the cell;

Who does this affect?

- Stock brokers
- Biotechnology researchers and organisations
- Patent attorneys

Article Highlights

- Genes and gene sequences can be considered patentable subject matter



- **"isolated"** nucleic acid does not exist inside the cell; and
- isolation of a gene sequence may require immense research and intellectual effort.

This case creates an important precedent that the act of isolating a gene sequence is sufficient to create a sufficient artificial state of affairs to satisfy the first limb of the manner of manufacture test of patentability.

If you would like any further information on this important case, please contact Dr David Cox at dcox@jacmac.com.au.

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