

# Alert

INTELLECTUAL PROPERTY



## High Court Rules on Gene Patents

### *D'Arcy v Myriad Genetics Inc*

By Alastair (Sandy) Donaldson

The High Court of Australia on 7 October 2015 delivered a judgment that many have been awaiting with great interest in the matter of *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

The Court found that patent claims for an isolated nucleic acid coding for a specific mutant or polymorphic polypeptide are not valid and ordered that the claims be revoked.

The patent held by Myriad Genetics Inc arose from the discovery that a sequence of nucleotides coding for a BRCA1 polypeptide which carries certain mutations or polymorphisms indicates a susceptibility to breast or ovarian cancer. The potential of the discovery for use in diagnosis and treatment of cancer is significant.

Proceedings claiming that the patent was invalid were instigated by the cancer advocacy group Cancer Voices Australia and Yvonne D'Arcy, who had suffered from breast cancer. These proceedings were not successful, and the patent was upheld by the Federal Court of Australia in an initial judgment, and on appeal to the Full Federal Court.

The High Court has reversed these earlier decisions. The decision of the High Court was unanimous, consisting of a joint judgment of Chief Justice French and Justices Kiefel, Bell and Keane, and a separate judgment of Gordon J.

The essential question for the Court was whether the subject matter of the initial claim of the patent for an isolated nucleic acid was an *invention*. The Court referred to its decision in *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67 in which it was said that "The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?'".

Myriad Genetics have argued that the claim was for an *isolated* nucleic acid, and that this was not a substance that was naturally occurring in the human body. In relation to this, the Court, among other comments in the joint judgment, said that:

"... although claim 1 is restricted to isolated nucleic acid comprising the mutated BRCA1 gene, claim 1 does not disclose any method of infusing the isolated BRCA1 gene with the specified mutations and polymorphisms or otherwise facilitating their presence. ...

Consequently, so far from being a claim for a manner of manufacture of isolated nucleic acid constituted of the mutated BRCA1 gene, claim 1 is in truth a claim for a monopoly over the right to apply long-established methods for the isolation and amplification of specific nucleotide fragments to the isolation

and amplification of a patient's naturally occurring BRCA1 gene, where and if it is found upon subsequent examination that the patient's BRCA1 gene happened to be afflicted by any of the specified mutations and polymorphisms.

That is not a valid claim of a manner of manufacture of a product. By definition, a manner of manufacture is an artificial thing or state of affairs which involves an element of inventiveness. Although the isolation of nucleic acid comprising the BRCA1 gene is a man-made process, it does not involve any element of inventiveness. It is no more than the application of a recognised diagnostic technique to a known purpose of examining fragments of human DNA."

The Court recognised that the discovery of the mutations or polymorphisms in the gene sequence leading to a likelihood of cancer was significant, but affirmed that this discovery was not an *invention*. The language of the Court in considering the effect of upholding the patent was robust saying in the joint judgment that, "*The inherent patentability of the invention as claimed would powerfully imply patentability of any claim for an isolated nucleic acid coding for a specified polypeptide.*" The Court went on to say, "*There is a real risk that the chilling effect of the claims, on the use of any isolation process in relation to the*

*BRCA1 gene, would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequence coding for the BRCA1 protein”.*

The decision of the High Court will undoubtedly have substantial ramifications for research in relation to genetics. The decision will bring Australian law more into line with that in the United States where the US Supreme Court has held in *Association for Molecular Pathology v Myriad Genetics Inc* 596 US 12-398 (2013) that isolated genes were not patentable subject matter, merely by reason of the isolation of the genes.



**MORE INFO**

**Alastair (Sandy) Donaldson** Director

p: +61 8 **8124 1954**

alastair.donaldson@dwfoxtucker.com.au

**DW Fox Tucker Lawyers**

L14, 100 King William Street, Adelaide, SA 5000

p: +61 8 **8124 1811** e: info@dwfoxtucker.com.au **dwfoxtucker.com.au**