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LIFE SCIENCES UPDATE:

Full Federal Court confirms isolated genetic material is patentable in Australia

In *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115, an expanded bench of five judges of the Full Federal Court of Australia has unanimously upheld Justice Nicholas' decision in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65, confirming that isolated nucleic acid sequences (i.e. DNA or RNA that has been isolated from the cell nucleus) are patentable subject matter in Australia.

Myriad's Australian Patent No. 686004 (Myriad Patent) includes a claim (claim 1) to isolated nucleic acid sequences coding for mutant or polymorphic BRCA1 polypeptides (proteins) which are described to indicate a predisposition to breast cancer and ovarian cancer. The claimed invention is of economic significance to the diagnosis and treatment of breast and ovarian cancers.

D'Arcy argued that isolated nucleic acids are not patentable subject matter because they are the same as those that exist naturally inside the cells of a human body, and that even in an isolated form they are a "product of nature" and therefore not a "manner of manufacture" for the purposes of section 18(1)(a) of the *Patents Act 1990* (Cth) (Patents Act).

The Full Court rejected D'Arcy's arguments, noting that under Australian law there is no limitation of patentability to exclude "products of nature", that the claims of the Myriad Patent are not directed to the mere genetic information of the BRCA1 gene, and that there are clear chemical, structural and functional differences between isolated nucleic acid sequences and those that exist naturally inside the cells of a human body. Applying the construction of the term "manner of manufacture" derived from the prescient High Court decision of *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, the Full Court affirmed Justice Nicholas' reasoning that isolated nucleotide sequences are indeed a "manner of manufacture" because they are an artificially created state of affairs that provides an economic benefit.

The Full Court noted that whether patents for gene sequences should be excluded from patentability

for moral, social or policy reasons was a matter for Parliament. The Full Court further noted that Parliament had indeed previously considered, and specifically declined, to exclude isolated nucleic acid sequences from the scope of patentable subject matter (instead only "Human beings, and the biological processes for their generation" are excluded from being a patentable invention for the purposes of a standard patent in Australia (s 18(2) of the Patents Act)).

The Full Court's decision contrasts with the United States Supreme Court's decision in *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics, Inc.* 569 US 12-398 (2013). In that case, the United States Supreme Court held that isolated nucleic acid sequences of a corresponding US patent were not patentable subject matter under United States law as they were *"products of nature"* which are an exception to patentability under United States law (as per *Diamond v Chakrabarty*, 447 US 303 (1980)).

The Full Court's unanimous decision is likely to further instil confidence in Australia as a jurisdiction that recognises and appropriately affords intellectual property rights for innovation in the life sciences sector.

Click here to view full text of this judgment.

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MORE INFORMATION

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