

PUBLICATION

Patent Protection for Isolated Genetic Sequences Upheld in Australia

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Last year in *AMP v Myriad Genetics*, the U.S. Supreme Court concluded that isolated, naturally occurring DNA are not patent eligible, which caused considerable consternation in the biotech community. However, this does not appear to be the death-knell for gene patents worldwide. On Friday, September 5, 2014, five judges in the Full Federal Court of Australia upheld the validity of Myriad Genetics' Australian patent directed to isolated DNA sequences covering the BRCA1 gene in *D'Arcy v Myriad Genetics Inc.*

The judges unanimously held that isolating a DNA sequence from its surrounding genetic material involves more than just taking the nucleic acid out of a cell. Rather, these sequence products are different compared to the gene comprising the nucleic acid sequence as it exists in nature, involving structural and functional changes that create a new composition of matter. Thus, an isolated nucleic acid, including cDNA, constitutes patentable subject matter.

The Full Federal Court expressly rejected the opposite conclusion reached by the U.S. Supreme Court in *AMP v. Myriad Genetics*. In that decision, the Supreme Court found that isolated genes and the information they encode are not patent eligible. In Australia, the Full Federal Court adopted a similar reasoning to that of the U.S. Federal Circuit, finding that isolated genes are not naturally-occurring substances but rather are "the products of man." The court stated that:

What is being claimed is not the nucleic acid as it exists in the human body, but the nucleic acid as isolated from the cell. The claimed product is not the same as the naturally occurring product. There are structural differences but, more importantly, there are functional differences because of isolation.

The Appellant has the right to appeal the decision to the High Court in Australia. If the decision is upheld, the biotech community should have renewed interest in seeking patent protection for gene patents in Australia and other countries that may follow its lead.

If you have any questions or want to discuss how this decision could impact your business, contact your Baker Donelson attorney or one of the attorneys in the Firm's Intellectual Property Group.