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The Pragmatic Approach: The Myriad Gene Patents Before the Australian Courts

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Quick View

The Full Court of the Federal Court of Australia in D'Arcy v Myriad Genetics Inc [2014] FCAFC 115[2] recently upheld the validity of Myriad Genetics' Australian BRCA1 gene patent over isolated DNA sequences.

The five judges who constituted the court in a joint judgment unanimously held that isolating a DNA sequence from its surrounding genetic material involves more than simply taking the nucleic acid out of the cell, and instead involves structural and functional changes that create a new composition of matter. The court thus took the view that the patent in question claims something other than subject matter that had previously existed in nature, and as such, the isolated nucleic acid, including cDNA, constitutes patentable subject matter.

The expressly court rejected the conclusion reached last year by the US Supreme Court in AMP v Myriad Genetics that isolated genes and the information they encode are not patent eligible. Instead, it adopted the reasoning of Judges Lourie and Moore in the Federal Circuit below, finding that isolated genes are not naturally-occurring substances but are "the products of man." At paragraph [212] the court said 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.

Although the court characterised isolated DNA as material derived from

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[2] D'Arcy v Myriad Genetics Inc [2014] FCAFC 115 (5 September 2014), http://www.austlii.edu.au/au/cases/cth/FCAFC/2014/115.html.

naturally occurring material, it held that this is not a reason for it to be excluded from patentability. In this regard, the court by reference to precedent explained the distinction between a discovery (and an idea in the abstract) and an invention at paragraphs [111] to [113]. The court thus took the view that in determining whether an invention is patentable subject matter, there is no requirement for a consideration of whether a claimed composition of matter is a "product of nature" or whether a microorganism is "markedly different" from something that already exists in nature. The court also noted at paragraph [155] that "the analysis should focus on differences in structure and function effected by the intervention of man and not on the similarities [with what is found in nature]."

The court, for the purposes of Australian law, sought to delineate patentable and non-patentable subject matter by stating that, "[a] mere discovery is not patentable and an idea is not patentable, but a "manner of manufacture", as that term has been developed, is." In doing so, the court rejected any suggested that there is a "product of nature" subject matter exclusion in Australian law.

Unlike the US Supreme Court, the Full Federal Court considered that the correct approach when determining patentable subject matter is to focus on the products of human ingenuity claimed (in this instance being the isolated nucleotide sequences) and not on the information that they contain. In this regard, the court criticised the US Supreme Court noting at paragraph [215] that:

> It is difficult to reconcile that Court's endorsement of the reasoning in Chakrabarty, with its rejection of isolated nucleic acid as eligible for patentability. With respect, the Supreme Court's emphasis on the similarity of 'the location and order of the nucleotides' existing within the nucleic acid in nature before Myriad found them is misplaced. It is the chemical changes in the isolated nucleic acid which are of critical importance, as this is what distinguishes the product as artificial and economically useful.

Unlike in places such as the United States and Canada where subject matter eligibility is defined by reference to enumerated classes of subject matter, the scope of patentable subject matter in Australia is defined by reference to whether an invention is a "manner of manufacture" of the kind envisaged by s 6 of the Statute of Monopolies 1623.

While it is difficult to fault the Full Federal Court's reasoning, it is unlikely that this will be the final chapter in Myriad's defense of its Australian patent. Rather, it is likely that the unsuccessful applicant in this instance will appeal to the High Court of Australia, Australia's final court of

appeal, and that that the High Court will give leave (a statutory equivalent to certiorari) to hear the appeal given the importance of the subject matter concerned.

Cited as:
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