Monday, February 16, 2015

This is an update to our September 5, 2014 post reporting the unanimous decision of the Full Court of the Federal Court of Australia (Full Court) in Yvonne D’Arcy v Myriad Genetics Inc., holding that isolated DNA and RNA constitute patent eligible subject matter. On February 13, 2015, the High Court of Australia (High Court) granted Special Leave to Appeal to Ms D’Arcy.

At first instance, Justice Nicholas found Australian Patent No. 686004 (Patent) covering the BRCA1 gene valid holding that the claimed invention constituted a “manner of manufacture”. The Full Court dismissed the application to revoke the Patent. Specifically, the Full Court agreed with Justice Nicholas that the Patent was valid and dismissed the appeal. In its decision, the Full Court confirmed the test set out in National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252 for determining whether or not an invention constitutes a manner of manufacture. Specifically, according to the test, an invention is a manner of manufacture if it results in an artificial state of affairs providing a new and useful effect that is of economic significance.

Ms. D’Arcy contested Full Court’s decision arguing that isolating a gene from the human body is not a form of “manufacture”, but instead constitutes a product of nature as determined by the U.S. Supreme Court. As discussed in our September 5th post, the Full Court was highly critical of the U.S. Supreme Court’s decision in Association for Molecular Pathology v. Myriad Genetics, Inc. stating:

The U.S. Supreme Court rejected the claim over isolated nucleic acids for much the same reasons as those pressed by the applicant in this case. 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.

The fact that the High Court is interested in hearing this case in view of the unanimous decision of the Full Court clearly indicates that the High Court believes this case warrants serious consideration. A subsequent decision adverse to Myriad could be devastating for the biotechnology industry in Australia.

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