HIGH COURT OF AUSTRALIA

7 October 2015

D'ARCY v MYRIAD GENETICS INC & ANOR

[2015] HCA 35

Today the High Court unanimously allowed an appeal from a decision of the Full Court of the Federal Court of Australia. The High Court held that an isolated nucleic acid, coding for a BRCA1 protein, with specific variations from the norm that are indicative of susceptibility to breast cancer and ovarian cancer, was not a "patentable invention" within the meaning of s 18(1)(a) of the *Patents Act* 1990 (Cth) ("the Act").

The term "nucleic acid" includes two kinds of molecules, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), which are found inside a human cell. A gene is a functional unit of DNA which encodes a particular protein produced by the cell. The protein produced depends on the sequence of nucleotides. The BRCA1 gene codes for the production of a protein called BRCA1.

The first respondent filed a patent which contained 30 claims. Relevantly, Claims 1 to 3 concerned a nucleic acid coding for a BRCA1 protein, and with one or more specified variations from the norm in its nucleotide sequence, isolated from its cellular environment. Those specified variations, characterised as mutations or polymorphisms, are indicative of susceptibility to breast cancer and ovarian cancer.

Section 18(1)(a) of the Act requires that, for an invention to be patentable, it must be "a manner of manufacture" within the meaning of s 6 of the *Statute of Monopolies*. The appellant commenced proceedings in the Federal Court of Australia challenging the validity of Claims 1 to 3 on the basis that the invention claimed did not meet the requirement of s 18(1)(a).

The primary judge dismissed the appellant's challenge, holding that the invention fell within the concept of a "manner of manufacture". The Full Court dismissed an appeal from that decision. The Full Court held that an isolated nucleic acid was chemically, structurally and functionally different from a nucleic acid inside a human cell. The invention was a manner of manufacture because an isolated nucleic acid with the characteristics specified in Claims 1 to 3 resulted in an artificially created state of affairs for economic benefit.

By grant of special leave, the appellant appealed to the High Court. The Court unanimously allowed the appeal, holding that the invention claimed did not fall within the concept of a manner of manufacture. The Court held that, having regard to the relevant factors, an isolated nucleic acid, coding for the BRCA1 protein, with specified variations, is not a manner of manufacture. While the invention claimed might be, in a formal sense, a product of human action, it was the existence of the information stored in the relevant sequences that was an essential element of the invention as claimed. A plurality of the Court considered that to attribute patentability to the invention as claimed would involve an extension of the concept of a manner of manufacture which was not appropriate for judicial determination.

- *This statement is not intended to be a substitute for the reasons of the High Court or to be used in any later consideration of the Court's reasons.*

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