D'ARCY v MYRIAD GENETICS INC & ANOR (S28/2015)

Court appealed from: Full Court of the Federal Court of Australia
[2014] FCAFC 115

Date of judgment: 5 September 2014

Special leave granted: 13 February 2015

The First Respondent ("Myriad") owns Australian Patent Number 686004 ("the Patent"). The Patent is over the invention of certain methods of detecting the gene BRCA1 and of using components and mutations of that gene in the diagnosis of predisposition to breast cancer and ovarian cancer.

The Patent has 30 different claims, the validity of three of which ("the disputed claims") was challenged by Ms Yvonne D'Arcy in the Federal Court. This was on the basis that the disputed claims involved naturally occurring nucleic acids that had merely been isolated, without a "manner of manufacture" as required by s 18(1)(a) of the *Patents Act* 1990 (Cth) ("the Act").

On 15 February 2013 Justice Nicholas dismissed Ms D'Arcy's application. His Honour found that the disputed claims pertained not to nucleic acids as they existed within human cells but to nucleic acids which had been extracted from such cells and purged of associated biological materials. Justice Nicholas held that each of the claims was to a "manner of manufacture" as that expression had come to be understood in Australian patent law.

On 5 September 2014 the Full Court of the Federal Court (Allsop CJ, Dowsett, Kenny, Bennett & Middleton JJ) unanimously dismissed Ms D'Arcy's appeal. Their Honours found that the isolated nucleic acids, as described in the disputed claims, were chemically and functionally different from those which occurred in nature. Only once those acids had been isolated could they be used for the described comparison with tables of coding (which had resulted from extensive epidemiological research) to determine the presence of any mutations in BRCA1 polypeptides that would indicate a likelihood of cancer. The Full Court held that the isolated nucleic acids resulted in an artificially created state of affairs for economic benefit and that accordingly the disputed claims involved a "manner of manufacture" within the meaning of the Act.

On 13 March 2015 the Institute of Patent and Trade Mark Attorneys filed a summons, seeking leave to intervene as amicus curiae in this proceeding. On 31 March 2015 it also filed a notice of a constitutional matter. The Attorney-General of the Commonwealth has intervened in this matter.

The grounds of appeal include:

- The Full Court erred in holding that the isolation of the nucleic acid was sufficient to render the claims as being claims to an "artificially created state of affairs for economic benefit" and hence to a manner of manufacture.