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Life Sciences Alert

Full Court confirms isolated DNA is patentable in Australia

D'Arcy v Myriad Genetics Inc [2014] FCAFC 115

WHAT YOU NEED TO KNOW

- In a unanimous and significant decision, a five-member bench of the Full Court of the Federal Court of Australia (Allsop CJ, Dowsett, Kenny, Bennett and Middleton JJ) has confirmed that a claim covering naturally occurring deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), which has been isolated, can be a "manner of manufacture" and therefore a patentable invention.
- The Full Court reached a contrary conclusion to the US Supreme Court, which, in relation to the corresponding US patent, held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.
- The decision continues a trend in which Australian courts have shown reluctance to exclude inventions in the medical sphere from patentability (on the basis of not being a "manner of manufacture") where Parliament has declined to do so.

Background

In *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (***Cancer Voices***), Nicholas J dismissed an application by Cancer Voices Australia and Yvonne D'Arcy to revoke claims 1 to 3 of Australian Patent No. 686004 (the **Patent**) on the ground of lack of "manner of manufacture". The Patent concerns the BRCA1 gene, mutations in which cause a predisposition to breast and ovarian cancer, as well as use of the BRCA1 gene in the diagnosis of predisposition to breast and ovarian cancer.

We have previously reported on *Cancer Voices* and the US decisions on Myriad Genetics' corresponding US patent in the 12 May 2010, 30 August 2011 and 14 October 2013 editions of *Life Sciences Update*.

Ms D'Arcy appealed from Nicholas J's decision, and the Full Court has now dismissed the appeal with no order as to costs.

The invention claimed

The appeal before the Full Court focussed on claim 1 of the Patent, which is to:

> *An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.*

A number of features of the claim may be observed:

- it is to a compound, an "isolated nucleic acid", ie, tangible material and not genetic information;
- the isolated nucleic acid:
  - is substantially separated from the other cellular components that naturally accompany native DNA or RNA; and
  - codes for a mutant or polymorphic protein;
- "SEQ.ID No:1" is a sequence listing for the BRCA1 wild-type (or typical) gene and represents the coding sequence of a nucleic acid, being cDNA (or "complementary DNA" synthesised from a species of RNA known as messenger RNA), which encodes the BRCA1 polypeptide; and

- the "isolated nucleic acid" contains a sequence identified by comparison with tables which record the mutations or polymorphisms as variations in the encoding sequence shown in SEQ.ID No:1.

The issue

The single issue for determination was whether or not the claims to an "isolated nucleic acid" are for a "manner of manufacture", as required by section 18(1)(a) of the *Patents Act 1990* (Cth). In this regard the phrase "manner of manufacture" refers to an artificially created state of affairs whose significance is economic. These principles were set out in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, which was applied in this case.

Ms D'Arcy's submissions and the US Supreme Court decision

Ms D'Arcy admitted that the claimed invention has economic significance, but said this was insufficient to make it a "manner of manufacture" and pressed three main points:

- "a human being's DNA is not the thing we patent, unless isolation makes a difference";
- isolation does not make a difference because the resulting product (the isolated nucleic acid) has the same coding as in nature. This is not an "artificial effect" or a sufficiently "artificial effect"; and
- the claims arise out of a discovery of "laws of nature", which are not patentable.

As noted by the Full Court, Ms D'Arcy's submissions were similar to the reasons why the US Supreme Court rejected the claim to isolated nucleic acids in the corresponding US patent in *Association for Molecular Pathology v Myriad Genetics, Inc*, 596 US 12-398 (2013).

The US Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. The Full Court was unpersuaded by this decision, preferring the reasoning of the majority of the US court below in *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics, Inc*, 689 F.3d 1903 (2012), which held that the isolated DNA sequences were "markedly different" to native DNA and therefore patent-eligible.

Full Court's decision

In contrast to Ms D'Arcy's and the US Supreme Court's focus on the similarity between isolated and naturally occurring nucleic acid, the Full Court said "the analysis should focus on differences in structure and function effected by the intervention of man and not on the similarities". Consistent with this, in rejecting Ms D'Arcy's submissions, the Full Court found:

- the challenged claims were not to the nucleic acid as it exists in the human body, but the nucleic acid as isolated from the cell;
- there are structural differences, but, more importantly, there are functional differences because of isolation. For example, without manipulation, isolated DNA cannot code for a protein or polypeptide, this being a function that occurs naturally within the cell; and
- while the gene that contains the mutation or polymorphism exists in nature, until it was isolated, it could not be used to identify the mutation or polymorphism. Once isolated, the presence of the mutation or polymorphism that indicates a likelihood of cancer could not be determined without comparison with the tables of the Patent. This reflects a difference between the gene in its natural state and after isolation.

Accordingly, the Full Court decided in favour of Myriad Genetics, holding that the isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs for economic benefit, ie, a "manner of manufacture".

Conclusion

Like the decision of the primary judge in *Cancer Voices*, the Full Court's decision no doubt will cause controversy. Not only does it concern technology of particular public concern in the field of cancer research, diagnosis and treatment, but it tilts the balance in favour of patentability of a vast number of Australian patents for isolated gene sequences.

However, it would be difficult to sustain an argument that the decision is authority for the proposition that any isolated nucleic acid is a "manner of manufacture". The isolated nucleic acid of the Patent was defined by specific mutations or polymorphisms that the Patent taught indicated a predisposition to cancer. While the decision is contrary to the US Supreme Court's decision on the corresponding US patent, the Full Court noted that the Australian

Parliament had considered and chosen not to exclude gene sequences from patentability.

Ms D'Arcy has 28 days from 5 September 2014 within which to file a special leave application to the High Court of Australia. If the High Court hears the appeal, dismissal would not be surprising, particularly given the importance recently accorded by the High Court in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 304 ALR 1 (reported in the 9 December 2013 Life Sciences Alert) to the circumstance that Parliament had not excluded methods of medical treatment from patentability. It appears that substantive change to the patent eligibility of gene sequences in Australia in the near future, if it is to come at all, will come from Parliament and not the judiciary.

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