Australian *Myriad* appeal confirms patentabililty of genes

By Vaughan Barlow[1]

1. Introduction

The recent decision in *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) by the Full Court of the Federal Court confirms that isolated nucleic acids constitute patentable subject matter in Australia. In upholding the validity of the claims in question, the court explicitly rejected the reasoning of the United States Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc* 569 US 12-398 (2013), finding that the process of isolation involves structural and functional changes to nucleic acids. These changes were held to result in a new composition of matter that is not naturally occurring and therefore patentable.

2. Requirements for patentable subject matter in Australia

To encompass patentable subject matter under Australian law, an invention must satisfy section 18(1)(a) of the *Patents Act* 1990, which requires that a claimed invention be "a manner of manufacture". Previous Australian case law has long established that in order for an invention to be "a manner of manufacture", it must give rise to (1) an artificially created state of affairs that is (2) in a field of economic endeavour.[2] In making this assessment, and in contrast to other jurisdictions such as the United States, it has long been held that the patent office or courts will not enquire into matters of ethics or social policy.[3]

In order to satisfy the first requirement for "an artificially created state of affairs", claims encompassing naturally occurring biological materials must distinguish that material from the form in which it already exists in nature. Hence, in relation to genes, claiming "isolated" or "purified" nucleic acids or recombinant nucleic acids has traditionally been allowed by the Australian patent office on the basis that the act of isolating, purifying or cloning satisfies the

1. Vaughan is a partner of Pizzeys Patent and Trade Mark Attorneys: www.pizzeys.com.au;
2. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (the "*NRDC* case");
3. *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) 28 IPR 383;

requirement that a patentable invention give rise to "an artificially created state of affairs". The underlying rationale is that an isolated, purified or recombinant nucleic acid does not exist in nature, but rather, that nucleic acid only exists in nature in a different form, for example, as part of a chromosome. A similar rationale has generally been applied by the patent office to claiming other naturally occurring biological materials such as isolated proteins, which may only exist in nature as part of a cell or organism.[4]

In order to satisfy the second requirement that there be "a field of economic endeavour", the patent office has traditionally required that a claimed nucleic acid or amino acid should have a function or putative function ascribed to it, or be described as useful for a particular purpose, such as for methods of treatment or diagnosis.[5]

Under section 18(2) of the *Patents Act* (1990), there already exists a specific ban on patenting "human beings, and the biological processes for their generation". This has been interpreted by the patent office to include totipotent stem cells, but not pluripotent / multipotent stem cells, due to the difference in the potential of each of these cell types to create a human being.[6] Accordingly, section 18(2) cannot be regarded as precluding *per se* the patentability of other biological materials such as a nucleic acid or amino acid that cannot of itself give rise to a human being.

3. The Myriad case at first instance

The initial *Myriad* Federal Court case involved an allegation that claims 1-3 of Australian patent no. 686,004, drawn to isolated nucleic acids *per se*, were not for "a manner of manufacture" as required by section 18(1) of the *Patents Act* (1990). Both parties acknowledged that the claimed subject matter was "in a field of economic endeavour", and hence the question to be heard was whether claims to an isolated nucleic acid constituted "an artificially created state of affairs".

4. *Ranks Hovis McDougall Ltd's Application* (1976) AOJP 3915;
5. While the need to demonstrate functionality satisfies the requirement for isolated biological material to be in "a field of economic endeavour", a further requirement for functionality now also exists in the new separate patentability requirement for an invention as claimed to be "useful", per the new Section 18(c) of the *Patents Act* 1990, as amended by the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012, where Section 7A states that "an invention is taken not to be useful unless a specific, substantial and credible use for the invention (so far as claimed) is disclosed";
6. *Fertilitescentrum AB and Luminis Pty Ltd's Application* [2004] APO 19 (13 July 2004); *Woo-Suk Hwang* [2004] APO 24 (9 September 2004);

In finding that the claimed isolated nucleic acids constituted the requisite "artificial state of affairs", the court emphasized that the claimed composition of matter must be the result of some human intervention, but that there was no requirement to ask whether the composition of matter is a "product of nature" or "markedly different" to something that already exists in nature.[7] Accordingly, it was held that the requisite "artificial state of affairs" may be satisfied by removal of a nucleic acid from its natural environment and its separation from other cellular components, even if the physical properties of the material have not changed.[8]

4. The Myriad case on appeal

On appeal to the Full Court of the Federal Court, it was unanimously confirmed in *D'Arcy v Myriad Genetics Inc*[9] that isolated nucleic acids constitute patentable subject matter. In reaching this conclusion, the court took special care to first set out in detail its understanding of the biological context of naturally occurring nucleic acid, and the procedures involved in its isolation.[10] After then reviewing the specification and claims, the court emphasized that the governing *NRDC*[11] test (as discussed above) does not involve any enquiry into whether claimed subject matter is a product of nature or markedly different from that already existing in nature.[12] Indeed, the court reiterated the reference in the *NRDC* case to the United States decision in *Funk Brothers Seed Company* v *Kalo Inoculant Company*[13], adopting the reasoning that:

> "[I]t confuses the issue to use such terms as 'the work of nature' and the 'laws of nature'. It is not decisive or helpful to point out that the suggestion is that nature, in its newly ascertained aspect, be allowed to work in its own way. Expressions such as the 'work of nature' or the 'laws of nature' could fairly be employed to challenge almost any patent."[14]

The court went on to reference several other case law precedents, citing the following passage by way of analogy from *Hill v Evans*,[15] which it described as "part of the bedrock of patent law"[16]:

7. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 103;
8. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 104;
9. [2014] FCAFC 65 (5 September 2014);
10. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) pages 4-14;
11. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (the "*NRDC* case");
12. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 114;
13 333 US 127 (1948);
14. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 115;
15. 1A IPR 1 at 7;
16. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 122;

> "The reason is manifest, because much further information, and therefore much further discovery, are required before the real truth can be extricated and embodied in a form to serve the use of mankind. It is the difference between the ore and the refined and pure metal which is extracted from it... (emphasis added)"

Significantly, the court explicitly rejected the reasoning of the United States Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc*[17], finding that the process of isolation involves structural and functional changes to nucleic acids. These changes were held to result in a new composition of matter that is not naturally occurring and therefore patentable. In coming to this conclusion, the court summarized both the US Supreme Court decision in *Association for Molecular Pathology v Myriad Genetics, Inc* and the earlier US Court of Appeal decision in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*,[18] noting that the Supreme Court focused on the information contained in the nucleic acid rather than the product itself.[19] In defending the decision of Lourie J in the earlier US Court of Appeal decision, and drawing similarities to His Honour's reasoning with the established Australian principles enunciated in the *NRDC* case, the court agreed that:

> "The subject matter of the claims is a chemical compound, not pure information content…[T]he isolated DNA molecule is a distinct chemical entity. It is not a purified form of a natural material."[20]

In further reference to the earlier US Court of Appeal decision, the court also agreed with the reasoning of Moore J, noting that:

> "…DNA is a polymer, made up of repeating monomer units connected by chemical bonds to form one larger molecule. The process of polymerisation of the monomer units results in a new molecule, as polymerisation changes the monomers to result in a molecule with a different molecular charge, different chemical bonds and a different chemical composition as compared to the monomers in aggregate. A fragment of a DNA sequence has different properties to that of the parent molecule from which it is derived … [T]he appropriate course was to consider whether the differences impart a new utility which makes the molecules markedly different from nature."[21]

Regarding the reasoning of Bryson J in the earlier US Court of Appeal decision, the court asserted:

17. 569 US 12-398 (2013);
18. *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 10-1406 (Fed. Cir. Aug. 16, 2012). Cert. granted 16 August 2012;
19. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 138;
20. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 143;
21. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at paras 146 and 149;

> "Bryson J (dissenting) drew on a metaphor, likening an isolated nucleic acid and a branch being snapped off a tree. That is inapposite. The branch has not changed - it is simply divorced from the tree, whereas the chemical and physical makeup of the isolated nucleic acid renders it not only artificial but also different from its natural counterpart."[22]

In concluding on the position in the United States, the court held:

> "[W]e find the reasoning of Lourie J and Moore J, based on an analysis of the products as products and not on the information that they contain, to be consistent with [Australian] patent law, and persuasive. Similarly, we agree that, consistent with *NRDC* and Australian law, the analysis should focus on differences in structure and function effected by the intervention of man and not on the similarities."[23]

Upon then applying the principles of the *NRDC* case to the facts at hand and finding that the isolated nucleic acid "is properly the subject of letters patent",[24] the court took special care to again emphasize that:

> "This case is not about the wisdom of the patent system … It is not about whether, for policy or moral or social reasons, patents for gene sequences should be excluded from patentability … This case is about whether, under Australian law and the concept of patentable invention as discussed by the courts … the challenged claims of the patent are to patentable inventions.
>
> 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."[25]

Finally, in criticizing the US Supreme Court decision in *Association for Molecular Pathology v Myriad Genetics, Inc*[26] the court pointed out 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.

22. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 211;
23. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 155;
24. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at para 218;
25. *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 65 (5 September 2014) at paras 204, 205, 206 and 212;
26. 569 US 12-398 (2013).

Given the court's reliance on the critical importance of the chemical changes to nucleic acid brought about through the process of isolation, it is interesting to query how well this reliance sits with the governing principles of the *NRDC* case, which assert that the test does not involve any enquiry into whether claimed subject matter is a product of nature or markedly different from that already existing in nature. It therefore appears to be more the functional changes that are relied upon, for consistency with the *NRDC* test. It is also interesting to query whether such reliance would extend to claims encompassing isolated proteins, for example, such as antibodies, where potentially no such structural or functional differences *per se* may result from the process of isolation.

4. Conclusion

The decision in *D'Arcy v Myriad Genetics Inc* provides further assurance that isolated nucleic acids remain patentable under Australian law. It is however to be noted that within two weeks of this latest decision being handed down by the Full Court of the Federal Court, an application was launched for special leave to appeal to the High Court, being Australia's final court of appeal. It therefore appears that the *Myriad* litigation is not over in Australia, although many doubt that this most recent decision will be overturned.