

ISOLATING THE PATENTABILITY OF GENETIC MATERIALS: THE *D'ARCY V MYRIAD GENETICS SAGA*

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*D'Arcy v Myriad Genetics Inc (D'Arcy)*¹ thoroughly examined the patentability of isolated genetic sequences and laid scrutiny to the application of the 'manner of manufacture' test found in *National Research Development Corporation v Commissioner of Patents (NRDC)*.² In September 2014, a specially enlarged five member bench of the Full Federal Court ('Full Court') held that the isolated materials were patentable, with the case turning on whether those materials constituted an 'artificial state of affairs' or were the 'mere discovery' of a 'product of nature'.³ Whilst the Full Court affirmed the trial judgment, the matter was granted special leave to be heard by the High Court of Australia ('High Court') in June 2015.⁴

It is notable that the patent expires on 11 August 2015, and as such, will have little impact on Myriad Genetics Inc ('Myriad'). More broadly, the case will have ramifications for patent examiners' guidelines and, in the long run, forms a limited precedent for litigation. In addition to the commercial significance of the decision, on-going litigation in this area highlights the judiciary's difficulty in analysing technical products to discern patentability and, similarly, the legislative void surrounding the commercialisation of human biological materials. This case note provides up to date analysis as of 22 June 2014.

I FACTS

Myriad, an American molecular diagnostics company, obtained a standard Australian patent (Australian Patent 33212/95) in the field of human genetics for the 'methods and materials' used to locate and analyse the BRCA1 gene sequence in patient samples. These sequences can be used to determine a patient's predisposition to cancer, particularly ovarian and breast cancer.⁵ Claims 1–3 of the patent assert protection for the isolated coding sequences of 'typical', 'mutated' and 'polymorphic' BRCA1 genes.⁶ Myriad uses these isolated materials as comparison tools for diagnosing patient susceptibility to the respective cancers.

II DECISIONAL HISTORY

In 2010, Cancer Voices Australia ('CVA') joined with Yvonne D'Arcy to launch action against Myriad in the Federal Court, asserting that the patent's claims did not relate to patentable subject matter. It was argued that they were a 'discovery of the laws of nature' and thereby failed to satisfy the 'manner of manufacture' test in s 18 (1)(a) of the *Patents Act 1990* (Cth) ('*Patents Act*').⁷

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¹ (2014) 224 FCR 479 (*D'Arcy*).

² (1959) 102 CLR 252.

³ *D'Arcy* (2014) 224 FCR 479, 517-8.

⁴ *Ibid*; Transcript of Proceedings, *D'Arcy v Myriad Genetics Inc and Anor* [2015] HCATrans 12 (13 February 2015).

⁵ *D'Arcy* (2014) 224 FCR 479, 491 [66].

⁶ *Ibid*.

⁷ *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (*Cancer Voices*).

At first instance and subsequently upon appeal, CVA contended that the evolved product was not 'materially different' to the cellular form and, hence, is the equivalent of naturally occurring DNA, which is unpatentable.⁸ Conversely, the respondent (Myriad) argued that the claims satisfied the *NRDC* test for a 'manner of manufacture', in that the isolated product is 'chemically, structurally and functionally different' and thereby artificial.⁹

Nicholas J's analysis focused on the effect of the process of isolation to ascertain if the product was altered from its natural form. He rejected CVA and D'Arcy's argument, stating that 'an artificial state of affairs' was produced by virtue of the sequence being 'extracted from cells obtained from the human body and purged of other biological materials'.¹⁰ The primary judge further justified his decision with reference to the deliberately 'expansive language' used by the High Court in *NRDC* and the 'immense research and intellectual effort' involved to perform the isolation.¹¹

III JUDGMENT

In upholding the decision at first instance, Allsop CJ, Dowsett, Kenny, Bennet and Middleton JJ differed from the primary judge only by emphasising that the isolated BRCA1 sequence illustrated structural 'but more importantly ... functional differences because of isolation'.¹² The court stated that heritable information did not exist outside of the cell, which gave the 'chemical *in situ*' a distinct character from its cellular counterpart and facilitated its 'economically useful' application.¹³

It similarly clarified that the *NRDC* test asked whether the subject matter 'consist[ed]' of 'an artificial state of affairs' and not if it 'produc[ed]' one, thereby directing the court to focus on differences rather than similarities.¹⁴ The court also reasoned that the prohibition of all natural derivatives on this basis would prevent the patentability of other biological products such as antibiotics.¹⁵

IV HIGH COURT APPEAL

On 13 February 2015, D'Arcy (the appellant) was granted special leave to have the matter heard before the High Court.¹⁶ The Institute of Patent and Trademark Attorneys of Australia ('IPTA') also obtained leave to be heard as *amicus curiae*, providing constitutional and general analysis of the case's impact.

In her written submissions, the appellant challenged the Full Court's determinations on three grounds. It was claimed that the Full Court erred by finding that the isolated and the natural sequences were different, the interpretation of the *NRDC* test encompassed products of nature, and the claims constituted a 'manner of manufacture'.

It is notable that the appellant submitted that granting the patent would result in ambiguity for medical practitioners who may infringe the patent when performing routine testing, given that a significant proportion of the population will carry mutations and other

⁸ *D'Arcy* (2014) 224 FCR 479, 509 [162–3].

⁹ *Ibid.*

¹⁰ *Cancer Voices* [2013] FCA 65 (15 February 2013) [136].

¹¹ *Ibid* [107–9].

¹² *D'Arcy* (2014) 224 FCR 479, 517 [212].

¹³ *Ibid* 513 [191].

¹⁴ *Ibid* 508, 510.

¹⁵ *Ibid* 514 [196].

¹⁶ Please note that the following section refers to Appellant and Respondent submissions found on the High Court Website: High Court of Australia, *Case S28/2015* (7 April 2015) High Court of Australia <http://www.hcourt.gov.au/cases/case_s28-2015>.

polymorphic variants in this gene. It was also asserted that this patent would create a monopoly over the sequences of the individuals whose information is included in the claims. These arguments are valid considerations, but they are phrased in terms of a 'general inconvenience' exception, which involves the judiciary making a policy decision. The respondent countered with this analysis and it is likely that the High Court will endorse the Full Court's reluctance to make a ruling on these grounds, explicitly stating that such considerations are a legislative matter rather than a judicial one.¹⁷

A *Functional and Structural Differences*

The appellant's submission relied on the decision from the parallel US litigation, which found that the claim was expressed to assert protection for the genetic material itself and not the chemical change that evolved a product.¹⁸ It is notable that Nicholas J, endorsed by the Full Court, clarified that the claim did not grant protection for the written or digitised forms of the genetic information, or the cellular form.¹⁹ Following this line of argument, the respondent put forward that the claim seeks protection for 'a chemical compound' and on this basis the court should apply its most recent examination of the issue in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd*.²⁰

In resolving this issue, the High Court case will turn on two major interpretative matters:

1 'Coding For'

The parties to the matter dispute the meaning of the claim's phrase 'coding for', as a means of ascertaining the functional attributes of the isolated sequences. The appellant submitted that 'code for' is expressed to assert ownership of the information rather than a distinct product with commercial application. By contrast, the respondent submitted that the information in the product allows for the 'coding' of a specific type of nucleic acid (cDNA), which cannot occur within a cell and, on this basis, the information is altered from its natural state.

2 Structure

The parties also disputed the structural distinction between the isolated product and its natural form. D'Arcy submitted that the court should consider the 'substance' of the change to the chemical structure and that the alteration of the structure does not impact on its ability to produce cellular proteins. In response, Myriad argued that this is not contentious, given the expert evidence elicited at trial, in particular that the breaking of covalent bonds constitutes sufficient evidence that a chemical change has occurred. It was also asserted that the sequences are differentiated through the removal of its beginning and end 'tails', which prevent genetic degradation and assist with other 'cellular' functions.

B *A Product of Nature?*

The appellant's submissions were that a naturally occurring sequence is not an invention and information carried by the sequence is not changed by isolation. On the semantics of the *NRDC* principle, the appellant contended that removal from cellular processes is a negative attribute rather than a positive one, as described in *NRDC*. The respondent challenged that the High Court should not follow the US decision, given that the judgment in *NRDC*

¹⁷ *D'Arcy* (2014) 224 FCR 479, 502 [125].

¹⁸ *Association for Molecular Pathology v Myriad Genetics, Inc*, 596 US 12-398 (2013).

¹⁹ *Ibid* 497 [103].

²⁰ (2013) 304 ALR 1.

emphasises the product's difference from the naturally occurring substance and, more broadly, that the US patent system has evolved independently of Australian jurisprudence.

V ANALYSIS

The *D'Arcy* case highlights three main gaps in the current legislative and judicial approach to this area of law. Firstly, discerning the requisite standard for 'artificiality' is extremely difficult in the absence of solid prescriptions for what constitutes an 'artificial state of affairs'.²¹ Secondly, the existing law does not allow the judiciary to engage in policy considerations beyond evaluating the products for economic utility. Finally, in the absence of a solid legislative determination either way, there is no policy framework to assist with judicial analysis.

A Reform Discourse

In analysis of the issues before the court, both the trial and appeal substantially addressed the legislative 'consideration[s]' and 'refusal' to explicitly exclude isolated genetic sequences from attracting protection under the patent system.²² Whilst it is a valid comment that Parliament has considered the issue, the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth) failed to clear the committee stage and, hence, there has been no definitive ruling either way.²³ Currently, s 18(2) of the *Patents Act* prevents 'human beings, and their biological processes for the generation [of humans]' from being patentable, which clearly reflects the prohibition on human cloning and genomic ownership. However, distinct and direct drafting that excludes genetic patents would only provide a short-term solution by restricting the patentability of a single subject matter.

A more desirable legislative response would provide a more general and long-term interpretative framework that is dynamic and adaptable to unforeseen technological progress, particularly in an industry as vigorous as the life science sector.

1 Policy Considerations

The development of reform in this area involves balancing numerous factors, including: protecting legitimate research and development investments; incentivising innovation and domestic investment; treating life-threatening diseases; protecting the genetic materials of individuals; and solidifying the protection of existing products. The existing *NRDC* interpretation of 'manner of manufacture' has an inherently commercial bias with the 'artificial state of affairs' being required to produce economic benefit. It can be argued that such a test fails to acknowledge the aforementioned public policy rationales that concern patentability in this area, particularly where the patent involves the ownership of a patient's isolated BRCA1, which is the motivation that underpins Ms D'Arcy's case. Failure to rectify this issue will result in on-going litigation in this area.

2 International Obligations and Comparison

It is also significant that the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ('TRIPS')²⁴ does not clarify whether such patents should be prohibited. Rather, the

²¹ Tim Vines, 'Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65: Should Gene Patent Monopolies Trump Public Health?' (2013) 20 *Journal of Law and Medicine* 747, 756.

²² *D'Arcy* (2014) 224 FCR 479, 508–9.

²³ Vines, above n 22, 754–5.

²⁴ (Annex 1C to the Marrakesh Agreement establishing the World Trade Organisation), opened for signature 15 April 1994, 1869 UNTS 299 (entered into force 1 January 1995) ('TRIPS').

lack of legislative action in this area can be attributed to restrictions in TRIPS, with signatories being precluded from discriminating between patenting biotechnological and other scientific technologies.²⁵ On this basis, it is apparent that the Australian Myriad litigation is symptomatic of the broader vacuum on this issue in international law.

In comparing the varying global approaches, the Australian determination is a more expansive acceptance of gene patentability whereas the US has definitively rejected this subject matter.²⁶ The tradeoff of this diametric outcome is between attractiveness of the jurisdiction for commercialisation, and the integration of non-economic policy considerations such as an individual's intellectual property rights. Whilst Australia becomes commercially attractive, an absolute acceptance ignores the nuances of the types of products being commercialised and the public policy repercussion of each type.²⁷ By contrast, the European Union ('EU') has implemented a more moderate approach under Article 5(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions. Under this scheme, the structural similarity of the gene is immaterial (thereby addressing artificiality) and the patentability of the product is more reliant on the commercial application of the information. Similarly, EU case law has developed to limit the protection of genetic sequences to the function that it was patented.²⁸ Arguably, this provides greater clarity for balancing commercial interests and the broader neutrality of the information in line with the limitations prescribed by Nicholas J.

B *Impact*

1 *Scope of the Decision*

It has been widely noted that these proceedings have been deliberately framed to focus on the core issue of patentability as a test case for genetic patents.²⁹ The patent's claims have not been disputed on other grounds such as novelty, inventiveness and the patent's economic benefit. Arguably, the claims for diagnostic and analytical methods may not satisfy the requisite inventiveness as a result of common usage in the scientific community.³⁰ Narrow framing of this case substantially limits its usefulness in developing general patent law.

2 *Practical Effects*

Irrespective of the outcome of the High Court challenge, patent enforcement occurs where large-scale infringement derives substantial profit. It is well known that laboratory scientists regularly infringe patents in the course of their work and are protected from sanction through the experimental usage exception in the *Patents Act*.³¹ In a commercial context, fears have been raised that monopolising this product will severely restrict competition through the ability to charge monopoly prices and prevent entry of rival providers in refusing to grant licences. This is particularly concerning given that the patented product can be widely applied to developing diagnostic technologies and gene-based therapies.³² Whilst a

²⁵ Belinda Huang, 'Biotech Patents in Australia: Raising the Bar on the Generally Inconvenient Exception' (2013) 24 *Australian Intellectual Property Journal* 40, 51.

²⁶ Adam Denley et al, 'Intellectual Property: Isolated Nucleic Acids: Now Patentable in Australia' (2014) 6(1) *Law Society of NSW Journal* 82, 82
<<http://search.informit.com.au/documentSummart;dn=786172139466178;res=IELHSS>>.

²⁷ *Ibid* 82–3.

²⁸ *Monsanto Technology v Cargill International* [2007] EWHC 2257 (Pat) (10 October 2007).

²⁹ *D'Arcy* (2014) 224 FCR 479, 516 [206].

³⁰ *Ibid* 504; *Patents Act* ss 18(1)(b)(i), (ii).

³¹ *Patents Act* s 119C.

³² Huang, above n 26, 43.

valid concern, this argument fails to take into account the 20-year limitation period on standard patents and the compulsory licencing and government usage provisions of the *Patents Act*.³³ Similarly, as a precedent, this case is unlikely to have a great impact on new patent applications with the prior art base growing due to 'second generation genome sequencing of other organisms'.³⁴

3 *Finding Otherwise*

Pending the High Court challenge, an adverse determination will impact beyond the diagnostics industry. The ramifications of the US decisions have been seen with the United States Patents and Trademark Office ('USPTO') issuing guidelines for the examination of isolated genetic sequences in addition to chemicals derived from nature sources, foods and natural metallic compounds.³⁵

VI CONCLUSION

In the absence of any new argument advanced by either party, it is likely that the High Court will endorse the Full Court's determination and find that genetic sequences are patentable given the current limitations of Australia's patent legislation and self-imposed judicial restraint. The current Australian position remains that genetic sequence patents are patentable. However, this saga is unlikely to adduce a holistic solution especially where the aforementioned gaps in the *D'Arcy* case are yet to be tested.

³³ Ibid ss 133, 163.

³⁴ Denley et al, above n 27, 83.

³⁵ Ibid.