D'Arcy v Myriad Genetics Inc

[2015] HCA 35; (2015) 258 CLR 334

High Court of Australia

[The High Court of Australia had the opportunity to revisit the subject matter test more recently in this case, where it was required to consider the patentability of isolated nucleic acid sequences (also referred to as nucleotide sequences, DNA sequences or gene sequences). The sequences related to the 'BRCA1' gene, mutations in which have been linked to breast and ovarian cancer. The equivalent US litigation concerned Myriad's US patents over the same 'BRCA1' gene sequences, as well as over 'BRCA2' gene sequences (it also involved a separate question of whether the methods of using the sequences for diagnostic purposes were patentable: the Federal Circuit Court of Appeals held that they were not, and this was not appealed to the Supreme Court).]

French CJ, Kiefel, Bell and Keane JJ (some footnotes omitted)**:**

INTRODUCTION

1. A human gene which codes for the production of a protein called BRCA1 may bear variations from the norm, characterised as mutations or polymorphisms, which are associated with susceptibility to breast and ovarian cancers. Like all genes, it is a functional unit of the deoxyribonucleic acid ('DNA') molecule found in the nucleus of the human cell. By a biochemical process within the cell involving ribonucleic acid ('RNA'), a gene gives rise to the production of the protein molecule or 'polypeptide', which is defined by, or is an 'expression' of, the sequence of components of the gene known as nucleotides. That sequence comprises 'the genetic code'. The BRCA1 gene is one of approximately 25,000 genes in the human DNA molecule, which consists of about 3.2 billion linked nucleotides. The isolation of any of

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a class of molecules bearing a sequence of nucleotides coding for a BRCA1 polypeptide is said by the first respondent, Myriad Genetics Inc ('Myriad'), to give rise to a patentable invention if the sequence carries certain mutations or polymorphisms indicative of susceptibility to cancer. The mutations and polymorphisms are set out in tables attached to the patent based on information derived from the DNA of human subjects.

2. The validity of the invention claimed in Myriad's patent was challenged by the appellant, Ms D'Arcy, in revocation proceedings, on the ground that it was not a patentable invention within the meaning of the *Patents Act 1990* (Cth) ('the Act'). That challenge was dismissed by a Judge of the Federal Court, as was an appeal from that decision to the Full Court of the Federal Court. Ms D'Arcy appeals to this Court by special leave from the decision of the Full Court. The second respondent, Genetic Technologies Ltd, holds the exclusive licence in Australia for the patent from Myriad.

3. The patent in suit contains 30 claims. The validity of the first three claims is in issue in this appeal. They are for:

1. 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.
2. An isolated nucleic acid as claimed in claim 1 which is a DNA coding for a mutant BRCA1 polypeptide, said DNA containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations set forth in Tables 12, 12A and 14.
3. An isolated nucleic acid as claimed in claim 1 which is a DNA coding for a polymorphic BRCA1 polypeptide, said DNA containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more polymorphisms set forth in Tables 18 and 19.

Each of those claims relates to 'an isolated nucleic acid'. That term is defined in the complete specification as including DNA, RNA or a mixed polymer and as 'one which is substantially separated from other cellular components which naturally accompany a native human sequence or protein, eg, ribosomes, polymerases, many other human genome sequences and proteins.' It embraces a nucleic acid sequence or protein removed from its naturally occurring environment and includes recombinant or cloned DNA isolates and chemically synthesised analogs or analogs biologically synthesised by heterologous systems. It seems to have been assumed by all parties that a nucleotide sequence derived from a nucleic acid originating in a human cell may itself appropriately be designated as a 'nucleic acid'. That assumption can be treated as taxonomical, and accepted for the purposes of this appeal.

...

A MANNER OF MANUFACTURE—RELEVANT PRINCIPLES

18. The legislative history of the requirement for patentability imposed by s 18(1)(a) of the Act has been set out in previous decisions of this Court [*Apotex Pty Ltd v Sanofi-Aventis Pty Ltd* [2013] HCA 50; (2013) 253 CLR 284 at 297–301 [10]–[16] per French J, 324–325 [71] per Hayne J, 356 [186]–[187] per Crennan and Kiefel JJ]. The question posed by the application of s 18(1)(a) may be framed as in *NRDC*:

> Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?

That question is to be answered according to a common law methodology under the rubric of 'manner of manufacture' as developed through the cases, but consistently with 'a widening conception of the notion [which] has been a characteristic of the growth of patent law' [*NRDC* (1959) 102 CLR 252 at 270]. That widening conception is a necessary feature of the development of patent law in the 20th and 21st centuries as scientific discoveries inspire new technologies which may fall on or outside the boundaries of patentability set by the case law which predated their emergence.

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19. The Court in *NRDC* upheld the validity of a patent for the use of previously unknown properties of a known chemical to effect a new purpose. The Court generalised what had come to be treated, erroneously, as a 'rule', that for a method or process to be a 'manner of manufacture' it should result in the production, improvement, restoration or preservation of a 'vendible product'. By treating the word 'product' as covering every end produced and the word 'vendible' as pointing to the requirement of utility in practical affairs, the vendible product 'rule' could be accepted as wide enough to convey the broad idea which a long line of authority on the subject had been shown to be comprehended by the Statute. The Court said of the method patent in suit before it [at 277]:

> The effect produced by the appellant's method exhibits the two essential qualities upon which 'product' and 'vendible' seem designed to insist. It is a 'product' because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic ...

20. The terminology of an 'artificially created state of affairs of economic significance' is to be understood in the context in which it was used in *NRDC*. It was not intended as a formula exhaustive of the concept of manner of manufacture. The Court made that point emphatically [at 271]:

> To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound.

Hayne J made it in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [(2013) 253 CLR 284 at 328 [83]]:

> Nothing said in the Court's reasons for decision in that case can be taken as an exact verbal formula which alone captures the breadth of the ideas to which effect must be given.

In similar vein, Crennan and Kiefel JJ, with whom Gageler J agreed, said [at 366 [224]] that:

> In Australian law, the starting point is the recognition in the *NRDC Case* that any attempt to define the word 'manufacture' or the expression 'manner of manufacture', as they occur in s 6 of the *Statute of Monopolies*, is bound to fail. (footnote omitted)

It is true that in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [(1994) 50 FCR 1 at 19] Lockhart J in the Full Federal Court, in a passage endorsed by Crennan and Kiefel JJ in *Apotex* [at 372 [241]], said:

> If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s 6 of the *Statute of Monopolies*. (citations omitted)

Importantly, however, his Honour used the word 'may'. Neither Lockhart J nor Crennan and Kiefel JJ should be read as holding that satisfaction of that formula would mandate a finding of inherent patentability. That is not to say that it will not suffice for a large class of cases in which there are no countervailing considerations.

21. In *CCOM Pty Ltd v Jiejing Pty Ltd* [(1994) 51 FCR 260], the Full Court of the Federal Court said the *NRDC* case 'requires a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the field of economic endeavour' [at 295]. As Professor Monotti wrote in an article in the *Federal Law Review* in 2006, the passage from the judgment in *NRDC* characterising the process claimed before the Court as a product consisting in an 'artificially created state of affairs' merely explained 'the qualities of the invention before the court' [Monotti, 'The Scope of "Manner of Manufacture" under the *Patents Act 1990* (Cth) after *Grant v Commissioner of Patents*' (2006) 34 *Federal Law Review* 461 at 465]. The Court could hardly have intended the phrase to be seen as a definition of manner of manufacture because it had already denounced the idea of an exact formula [Monotti at 465–466]. The formulation in *CCOM*, like the so-called vendible product 'rule', should be taken as a guide rather than as a rigid formula [Monotti at 465–466].

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22. Counsel for Myriad posited 'the test' in *NRDC* for patentability of a product as—'is it an artificially created state of affairs of economic utility?'. Myriad's approach was accepted by the primary judge who derived from *NRDC* the proposition that:

> a product that consists of an artificially created state of affairs which has economic significance *will* constitute a 'manner of manufacture'. (emphasis added)

In similar vein, the Full Court said of *NRDC* that:

> The Court held that it is sufficient for a product to result in 'an artificially created state of affairs', leading to 'an economically useful result'.

That proposition underpinned the conclusion by the Full Court in the second last paragraph of its judgment that:

> The isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs for economic benefit. The claimed product is properly the subject of letters patent. The claim is to an invention within the meaning of s 18(1) of the Act.

Myriad's proposition and the approach of the primary judge and the Full Court, with respect, rested upon an unduly narrow characterisation of the effect of the decision in *NRDC*. It rested upon the premise that the claims were for a product well within existing conceptions of a 'manner of manufacture'.

23. This Court in *NRDC* did not prescribe a well-defined pathway for the development of the concept of 'manner of manufacture' in its application to unimagined technologies with unimagined characteristics and implications. Rather, it authorised a case-by-case methodology. Consistently with that approach, and without resort to the 'generally inconvenient' proviso in s 6 of the *Statute of Monopolies*, there may be cases in which the court will decide that the implications of patentability of a new class of invention are such that the invention as claimed should not be treated as patentable by judicial decision.

24. The Full Court disclaimed any consideration of 'whether, for policy or moral or social reasons, patents for gene sequences should be excluded from patentability.' The question for its determination, however, was not whether a claimed invention, prima facie patentable, should be denied patentability by judicial fiat. The question was whether the claimed invention lay within the established concept of a manner of manufacture and, if not, whether it should nevertheless be included in the class of patentable inventions as defined in s 18(1)(a) of the Act. Purposive and consequentialist considerations which, no doubt, could be classed as 'policy' reasons may play a part in answering the second limb of that question. As Professor Monotti percipiently remarked in her article in the *Federal Law Review*, which, of course, predated *Apotex*:

> Although it was important to expand patentable subject matter and remove artificial fetters on patentable subject matter at the time of *NRDC*, there is no consensus that we should continue to expand the scope of patentable subject matter into all fields of endeavour so as to remove the remaining fetters on patentable subject matter. The continuing debates on whether methods of medical treatment, business systems and genes should be patentable subject matter demonstrate that there is no universal acceptance of an approach that would accept that anything under the sun invented by man is patentable [Monotti at 467].

The proposition that patents should extend to 'anything under the sun that is made by man' was a statement of legislative intention attributed to Congress by the Supreme Court of the United States in *Diamond v Chakrabarty* [447 US 303 at 309 (1980)] in relation to 35 USC § 101 which provides:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

25. *NRDC* was decided in 1959. The Act in 1990 re-enacted, in s 18(1)(a), the definition of 'invention' in the *Patents Act 1952* (Cth), to which *NRDC* was directed. That re-enactment bore with it the judicial methodology for its application and the constraints attaching to that methodology. The

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proper function of the judicial branch was considered in an analogous, but not identical, context in two successive decisions of the Supreme Court of the United States in 1978 and 1980. In *Parker v Flook* [437 US 584 at 596 (1978)], the Court said that the judiciary 'must proceed cautiously when ... asked to extend patent rights into areas wholly unforeseen by Congress'. In *Chakrabarty*, Burger CJ, writing for the majority, and finding for patentability of a manufactured micro-organism as 'any new and useful ... manufacture, or composition of matter' under 35 USC § 101, said [at 315 citing *Marbury v Madison*, 5 US 137 at 177 (1803)]:

> It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is 'the province and duty of the judicial department to say what the law is'.

The majority rejected the proposition that the claim before them was a matter of high policy for resolution within the legislative process, saying that the contentions to that effect should be pressed on the political branches of government and not on the courts. Brennan J, who was joined in dissent by White, Marshall and Powell JJ, put the other side of the argument [at 322]:

> It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

The debate about institutional competency in *Chakrabarty* was resolved by the majority on the basis that the statutory authority conferred on the courts by Congress under 35 USC § 101 required an approach to patentability unconstrained by policy considerations. In Australia, the Parliament has left it to the courts to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy.

26. The term 'manner of manufacture', and the concept it embodies, was and is no more pregnant with rules and applications awaiting discovery, than is the common law. Its statutory origin in 1624 is embedded in historically contingent concepts of patent and invention. It has been described as an act of economic policy the objectives of which were the 'encouragement of industry, employment and growth, rather than justice to the "inventor" for his intellectual percipience' [Cornish, Llewelyn and Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8th ed (2013) at 123 [3–05]]. It has also been characterised, persuasively, as a 'political compromise' [Dent, '"Generally Inconvenient": The 1624 *Statute of Monopolies* as Political Compromise' (2009) 33 *Melbourne University Law Review* 415 at 451–453]. That characteristic and the relative inaccessibility, nearly four centuries after its enactment, of contemporary understandings of patent and invention no doubt played a part in its application as a general common law concept, rather than as a well-defined statutory category. The modest and constrained role of courts in the common law tradition was spoken of in *Breen v Williams* [(1996) 186 CLR 71] by Gaudron and McHugh JJ. Their Honours, nevertheless, acknowledged the necessity, from time to time, to reformulate existing legal rules and principles to take account of changing social conditions. Their Honours said [at 115]:

> But such steps can be taken only when it can be seen that the 'new' rule or principle that has been created has been derived logically or analogically from other legal principles, rules and institutions.

The question whether a propounded application of a general concept amounts to an extension of that concept is often debatable. In some cases, the distinction between a new application and an extension is likely to be a distinction without a practical difference.

27. Myriad submitted that the Court ought to treat the impugned claims as claims for a chemical compound. It argued that there was 'no jurisprudential basis or normative principle upon which claims to isolated nucleic acids should be treated differently from any other product claims.' The Court should look to their subject matter and determine the question of patentability according to the principles in *NRDC* which had been affirmed in *Apotex*. That submission sought to locate the claims well within the established

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understanding of 'manner of manufacture' in a way that would make normative considerations, which might inform the development of that concept, irrelevant. Properly construed, however, the claims are not within the established boundaries and wider considerations than Myriad's characterisation of them as an 'artificially created state of affairs of economic utility' come into play.

28. A number of factors may be relevant in determining whether the exclusive rights created by the grant of letters patent should be held by judicial decision, applying s 18(1)(a) of the Act, to be capable of extension to a particular class of claim. According to existing principle derived from the *NRDC* decision, the first two factors are necessary to characterisation of an invention claimed as a manner of manufacture:

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action.
2. Whether the invention as claimed has economic utility.

When the invention falls within the existing concept of manner of manufacture, as it has been developed through cases, they will also ordinarily be sufficient. When a new class of claim involves a significant new application or extension of the concept of 'manner of manufacture', other factors including factors connected directly or indirectly to the purpose of the Act may assume importance. They include:

3. Whether patentability would be consistent with the purposes of the Act and, in particular:
   3.1. whether the invention as claimed, if patentable under s 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;
   3.2. whether the invention as claimed, if patentable under s 18(1)(a), could, because of the content of the claims, have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;
   3.3. whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.
4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability.
5. Relevantly to Australia's place in the international community of nations:
   5.1. Australia's obligations under international law;
   5.2. the patent laws of other countries.
6. Whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by the legislature.

Factors 3, 4 and 6 are of primary importance. Those primary factors are not mutually exclusive. It may be that one or more of them would inform the 'generally inconvenient' limitation in s 6 of the *Statute of Monopolies*. It is not necessary to consider that question given that no reliance was placed upon that proviso. They are nevertheless also relevant to the ongoing development of the concept of 'manner of manufacture'.

[Ultimately the plurality determined that the manner of manufacture test was not satisfied in this case. Understanding this requires going back to earlier paragraphs in the plurality's reasoning:]

5. This Court in [*NRDC* at 269] held that the terminology of 'manner of manufacture' taken from s 6 of the *Statute of Monopolies* was to be treated as a concept for case-by-case development. It thereby mandated a common law methodology for its application. It did not confine that methodology to the use of any verbal formula in lieu of 'manner of manufacture'. Nor, in the case of a new class of claim, did the decision of the Court in *NRDC* preclude consideration of policy factors informed by the purpose of the Act and considerations of coherence in the law.

6. Claims 1 to 3 are formally expressed as product claims. The class of products claimed is derived from naturally occurring sequences of nucleotides in the bodies of individual human beings. An essential integer requires that the isolated nucleic acid must code for all or part of a mutant or polymorphic BRCA1

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polypeptide. It must therefore reproduce a relevant sequence of nucleotides existing in the body of the human being from which it is derived. The sequence so reproduced is isolated from structural and discrete components which would enliven its functionality in the human cell. Despite the formulation of the claimed invention as a class of product, its substance is information embodied in arrangements of nucleotides. The information is not 'made' by human action. It is discerned. That feature of the claims raises a question about how they fit within the concept of a 'manner of manufacture'. As appears from s 6 of the *Statute of Monopolies*, an invention is something which involves 'making'. It must reside in something. It may be a product. It may be a process. It may be an outcome which can be characterised, in the language of *NRDC*, as an 'artificially created state of affairs'. Whatever it is, it must be something brought about by human action [at 276–277]. The requirement, in each claim, that the sequence in the isolate bear specified mutations or polymorphisms raises the same problem in a particular way. Satisfaction of that integer depends upon a characteristic of the human being from whom the nucleic acid is isolated, a characteristic which is not shared by all human beings. It has nothing to do with the person who isolates the nucleic acid bearing the mutant sequence.

7. The proposition that a broad statutory concept applies to a new class of case on the boundaries of existing judicial development of that concept requires consideration of the limits of judicial law-making inherent in common law methodology. Where an affirmative application of the concept is likely to result in the creation of important rights as against the world, to involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination. The patentability of nucleotide sequences derived from human DNA is in that category. The inherent patentability of the invention as claimed would powerfully imply patentability of any claim for an isolated nucleic acid coding for a specified polypeptide.

8. Claims 1 to 3 include the products of applying any process, known or unknown, to the cells of a human being which extracts or replicates from them nucleotides which code for mutant or polymorphic BRCA1 in the sequences specified in the Patent, whether or not the isolate contains other components and sequences. The size of the class of the products as defined is large. No upper limit was suggested in argument. The boundaries of the class are not defined by a limiting range of chemical formulae. There is a real risk that the chilling effect of the claims, on the use of any isolation process in relation to the BRCA1 gene, would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the BRCA1 protein. The infringement of the formal monopoly would not be ascertainable until the mutations and polymorphisms were detected. Such a result would be at odds with the purposes of the patent system. As Cornish, Llewelyn and Aplin observed generally in the 8th edition of their well-known work on intellectual property [*Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8th ed (2013) at 915 [21–21]]:

> A patent over a single gene may prove to set up a barrier against its use in a quite distinct genetic procedure for a different medical condition which is worked out only subsequently.

They further observed, in the context of the *Patents Act 1977* (UK) but relevantly to the present case [at 915 [21–21], fn 85]:

> The question of what activity by an unauthorised person actually amounts to infringement of these claims is a problematic one, raising the issue when does that person 'make the patented product' in the sense of PA 1977 s 60.

9. Those features of the invention as claimed in Claims 1 to 3, and its substance as an invention relating to sequence information, lead to the conclusion that its patentability would not serve the purposes of the concept of 'manner of manufacture' in s 18(1)(a) of the Act or of the Act itself. It should not be brought, by analogy or otherwise, within that concept. The contested claims do not meet the requirement of s 18(1)(a).

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