IN THE HIGH COURT OF AUSTRALIA **No S28 of 2015**
SYDNEY REGISTRY

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT OF AUSTRALIA

BETWEEN: **YVONNE D'ARCY**
Appellant

AND: **MYRIAD GENETICS INC**
and
GENETIC TECHNOLOGIES LIMITED
Respondents

APPELLANT'S SUBMISSIONS

PART I: Publication

1. The appellant certifies that this submission is in a form suitable for publication on the internet.

PART II: Issues

2. This appeal presents the question whether an isolated human gene is a patentable invention, being a manner of manufacture within the meaning of s18(1)(a) of the *Patents Act 1990* (the **Act**). Claims 1-3 of the Patent[1] extend to nucleic acid sequences of "at least about five codons (15 nucleotides)"[2] and the patentability of those shorter sequences is also in issue.

3. As the primary judge said,[3] "*The issue that arises in this case is of considerable importance. It relates to the patentability of genes, or gene sequences, and the practice of 'gene patenting'.*"

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[1] Australian Patent No. 686004.
[2] Specification, p28 lines 6-10.
[3] *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65, [1].

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PART III: *Judiciary Act 1903*, s78B

4. The Appellant considers that notice in compliance with s78B of the *Judiciary Act 1903* should not be given.

PART IV: Citations

5. The Full Court decision (**FC**) is *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115, reported in (2014) 313 ALR 627; (2014) 107 IPR 478.

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6. The primary judge's decision (**PJ**) is *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65, reported in (2013) 99 IPR 567.

PART V: Facts

7. These proceedings were commenced by Cancer Voices Australia and Ms. Yvonne D'Arcy on 8 June 2010.[4] Because the applicants intended this to be a test case on the patentability of human genes, they challenged the validity only of claims 1-3 of Australian Patent No 686004,[5] and on limited grounds.

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8. The Patent describes the identification of "a human breast and ovarian cancer disposing gene (BRCA1)".[6] It refers to "mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast and ovarian cancer".[7]

9. Claim 1 is as follows:

> *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*
30 *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.*[8]

10. The sequence that is referred to in claim 1, "the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No: 1", is "a composite full length BRCA1

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[4] Cancer Voices Australia, a consumer advocacy organization, ceased to exist on 13 August 2012.
[5] The Patent was applied for on 11 August 1995. By s67, it expires on 11 August 2015.
[6] Patent specification p1 lines 7-9.
[7] Specification p1 lines 10-12. See FC at [2014] FCAFC 115, [1]-[2].
[8] Specification p185 lines 3-6.

cDNA" sequence.[9] This is the coding nucleotide sequence of the BRCA1 gene. It contains the exons that code for the amino acids that make up the BRCA1 polypeptide.[10] The sequence is set out as the bases of DNA (G, C, A or T) in groups of three (codons). The amino acid for which each codon codes is also shown. The Full Court explains this at FC [23]-[27].

11. Thus, the claim is to a product (isolated DNA or RNA) that codes for the whole or part of the BRCA1 polypeptide (protein). The claimed sequences possess specified mutations or polymorphisms "in comparison with" the normal (or wild type[11]) coding sequence for the BRCA1 gene (set out in SEQ.ID No: 1). The abnormalities were found in specific patients who had developed breast or ovarian cancer (Tables 12, 12A and 14[12]).

12. The nucleotide changes in the sequence of the gene lead to a mutated BRCA1 protein. Because the normal protein is a tumour suppressor, this mutation can lead to increased risk of cancer.[13] In addition, the polymorphisms of Tables 18 and 19[14] (that is, variations from the wild type of unknown clinical significance) were detected during the screening process described in the specification. See per the primary judge at PJ [58]-[70]; Full Court at FC [66]-[83].

13. At trial, the grounds were confined to the question whether claims 1-3 claimed a manner of manufacture within s18(1)(a) of the *Patents Act 1990*.[15] They claim isolated nucleic acids corresponding to all or part of a human gene.

14. Claims 2 and 3 are limited to DNA and relate to the mutations (claim 2) and polymorphisms (claim 3) respectively. These claims were also in issue at trial and on appeal but the subsequent claims of the Patent were not. The subsequent claims include claims to a probe (claim 4), vectors (claims 5-7), methods of producing mutant or polymorphic polypeptides (claims 8-9), preparations and polypeptides (claims 10-16) and various methods of diagnosis (claims 17-30).

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[9] Specification p78 lines 29-31.
[10] PJ at [2013] FCA 65, [64]-[67].
[11] See, e.g., Specification p17 lines 6-26.
[12] Specification pp89, 92, 100.
[13] Specification pp1-3.
[14] Specification pp105, 106.
[15] The applicants abandoned an additional argument based on s18(2) of the Act.

15. The practical monopoly conferred by the claims in issue is broader than that of the subsequent claims. The evidence was that "the mutations in the patent would account for about 3% of all of the mutations that have been documented so far" and that, in South Australia, about 10% of women tested have a mutation of some sort.[16]

16. Thus, infringement will occur in fewer than one in three hundred cases but a practitioner who isolates a person's DNA to test for the presence of mutations in the gene will not know whether that act constitutes infringement until after the DNA has been sequenced. This inadvertent infringement can be contrasted, for example, with the making or use of the probe of claim 4.[17]

17. As the Supreme Court of the United States said, in the counterpart to the present case,[18]

> *Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes)...*

18. The primary judge, Nicholas J, dismissed the application. His Honour rejected the respondents' argument that the claimed nucleic acids were structurally, functionally and chemically different from those that occurred in nature. The chemical difference was said to be the breaking of chemical bonds.[19]

19. On 5 September 2014, the Full Court dismissed the appellant's appeal.[20] The Full Court also upheld the respondents' contention challenging the primary judge's finding as to structural, functional and chemical differences.[21]

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[16] Dr G *Suthers*, T80.3-36.
[17] Described at p29 line16 – p30 line 20 of the specification.
[18] *Association for Molecular Pathology v Myriad Genetics Inc* 133 S. Ct 2107 (2103) at 2113, (***Myriad***) referring also to the BRCA2 gene, the subject of other patents in suit in that case.
[19] PJ at [2013] FCA 65, [105]-[106], [135].
[20] By consent, the Court made no order as to costs.
[21] FC at [2014] FCAFC 115, [213].

PART VI: Argument

20. An isolated human gene is not patentable. This is because, by s18(1)(a) of the *Patents Act 1990*, a patentable invention must, so far as claimed in any claim, be "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". A naturally occurring gene, isolated or not, is not a manner of manufacture.

21. The legislature has continued to leave to the Courts the development of the scope of the permissible subject matter of letters patent. This process was explained by the High Court in *National Research Development Corporation v Commissioner of Patents* (***NRDC***).[22] It follows that legislative inaction on the present point is irrelevant.[23] Compare FC at [205].

22. At FC [218], the Full Court held that the isolated nucleic acid[24] of claims 1-3 "resulted in an artificially created state of affairs for economic benefit" and that the claimed product is properly the subject of letters patent. In doing so, the Full Court erred, principally as follows:

    (a) despite its having been rejected by the primary judge, the Court upheld the respondents' contention that the isolated nucleic acid of the claims was chemically, structurally and functionally different from the corresponding gene (or the shorter sequences of DNA or RNA that are also within claims 1-3) as it occurs or they occur in nature – and that this was determinative of the question of patentability,[25]

    (b) the Court wrongly regarded the decision of the High Court in *NRDC* as having "specifically rejected" an exclusion of products of nature from the concept of manner of manufacture in Australian patent law.[26] In this context, the Court erred in putting aside the reasoning of the Supreme Court of the United States in the counterpart case, and

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[22] (1959) 102 CLR 252
[23] See per French CJ in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 (***Apotex***); (2013) 304 ALR 1, [19]; [49]. See also per Hayne J at [138].
[24] The relevance of the fact that the claims include cDNA is discussed below.
[25] FC at [2014] FCAFC 115, [194], [201], [212], [214]-[216].
[26] FC at [2014] FCAFC 115, [115], [217].

(c) the Court failed to hold that, in the relevant sense – namely, "coding for" the mutant polypeptide – the isolated nucleic acids were identical to the corresponding sequences in nature and, thus, were not a manner of manufacture in terms of the Act.

Chemically, structurally and functionally different?

23. The respondents argued that the claimed isolated nucleic acids differed chemically, structurally and functionally from the corresponding sequences as they occurred in nature. They submitted that this satisfied a test that was derived from *NRDC* at 102 CLR 277, of "an artificially created state of affairs".[27]

24. None of the asserted chemical, structural and functional differences plays any part in the definition of the invention "so far as claimed" in each of claims 1-3,[28] or in the description[29] of the invention in the specification.

25. Accordingly, the appellant submits that the response of the US Supreme Court[30] to a similar argument is apposite:

> *Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.* (emphases added)

26. The Supreme Court rejected the approach of the Court of Appeals for the Federal Circuit, which was based in part on "chemical changes". The appellant submits that the Full Court erred in preferring the reasoning of the Federal Circuit, at FC [155] and [214]-[217].

27. The Full Court's reasoning on chemical changes depended on its upholding the respondents' notice of contention, at FC [213]. But the Court gives no reason

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[27] See FC at [2014] FCAFC 115, [163].
[28] *Patents Act 1990*, s40(2)(b); s18(1)(a).
[29] *Patents Act 1990*, s40(2)(a).
[30] *Myriad* at 133 S. Ct. 2118.

why the primary judge erred, at PJ [105]-[106], in finding that "*it is not apparent from the evidence that* [the bonds broken in the course of isolating nucleic acids] *will necessarily include covalent bonds*". The primary judge said at PJ [135] that he took "*a different view of the facts to that taken by Judge Lourie*". It appears that, in upholding the respondents' contention at FC [213], the Full Court derived both reasoning and facts from the judgment of Lourie J in the Federal Circuit. See FC [215] and [216].

28. In fact, of the thirteen federal judges or justices who sat in the US proceeding, only Lourie J treated the chemical changes said to be involved in the breaking of covalent bonds as being significant.[31]

29. The appellant submits that the primary judge was right in saying at PJ[105] that "*the question of whether these substances constitute patentable subject matter does not depend upon the type of chemical bond that may have been broken in the process of isolating them*".

30. At FC [194] and [210]-[215], the Full Court focusses on "a chemical molecule" but the appellant submits that to view the claimed nucleotides as merely "a chemical molecule characterised in a certain way"[32] is to approach the claim at the wrong level of analysis.

31. The claims are to an isolated nucleic acid, "coding for" part or whole of the polypeptide for which the natural gene codes. When isolated, the nucleic acid does not act physically (or chemically) as a template for "dynamic processes that result in the production of the polypeptide";[33] it is useful for testing and other applications because it possesses the same code that, in the cell, acts as a template for the production of the BRCA1 polypeptide. When isolated, as the Full Court said at FC [8], it provides "*a state of knowledge for the person upon which to contemplate, or assess, treatment*".

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[31] *Association for Molecular Pathology v Myriad Genetics Inc* 689 F.3d 1303 (Fed. Cir. 2012) per Lourie J at 1328-1330. Although Moore J concurred in part, her Honour did not base her decision on chemical changes. See at 1341; cf 1343.
[32] FC at [2014] FCAFC 115, [194].
[33] FC at [2014] FCAFC 115, [194].

32. The claimed nucleic acids enable this assessment because they possess the code that, in nature, "codes for" a mutant, cancer-predisposing, polypeptide (e.g., as in table 12).

33. At FC [215], the Full Court says that:

> *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.*

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34. The appellant submits that it merely begs the question to say that the chemical changes (assuming the primary judge's finding to the contrary is put aside) distinguish the product as artificial. The question of manner of manufacture does not depend on the identification of an element of artificiality, however trivial. The question is one of substance. The Full Court appears to recognise that this might be the case, at FC [168]. Secondly, it is not the chemical changes that give the isolated nucleic acid its utility; it is its possession of the code that matches that in the human body. Nothing about the covalent bonds at the end of a sequence of nucleotides affects the attribute of "coding for" the
20 polypeptide in the relevant sense.

35. The process of isolation is described by the Full Court at FC [54]-[59]. The Patent does not describe how the nucleic acids are isolated and there was no dispute that this was well known.

36. The Full Court refers to structural and functional differences at FC [212]. The structural difference is a consequence of isolation from the cell, where the DNA is wrapped tightly around spooling proteins called histones.[34] These are removed in the process of isolation.[35] In the relevant sense, however, the
30 nucleic acids claimed are structurally the same – they possess the naturally occurring nucleotides, in the same sequence. The result is that the codons of the claim code for the same (mutant or polymorphic) polypeptide as that for which the natural sequence codes.

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[34] FC at [2014] FCAFC 115, [31].
[35] FC at [2014] FCAFC 115, [57]-[58].

37. The Full Court places emphasis on the functional differences, at FC [212]-[213]. This amounts to no more than that the isolated nucleic acid is "in hand".[36] The appellant submits that the nucleic acids claimed are not functionally different in the sense that is essential to the claims: they code for the same polypeptide as that for which the gene encodes in nature. The fact, noted at FC [201], that the isolated nucleic acid is not the subject of cellular processes[37] is not an attribute that makes it a manner of manufacture. This is the absence of an effect of the type referred to in *NRDC* at 102 CLR 277.

Products of nature

38. What is described and claimed is a sequence of nucleotides, "coding for" a BRCA1 polypeptide. There are many such sequences.[38] They possess one of the mutations or polymorphisms – set out in the tables – that were naturally present in the cells of particular human beings. The appellant submits that such a naturally occurring sequence does not come within the concept of an invention. The addition of "isolated" makes no difference, at the correct level of analysis.

39. The attribute that defines the inventions claimed in each of claims 1-3 is that the isolated nucleic acid contains the same sequence of nucleotides, carrying the same information. This is part or all of the code of the mutated gene as occurs in nature, for example in the DNA of patient BT106, who was diagnosed at age 24 with breast cancer.[39] The mutation that she possessed is shown in table 12.[40] The fact of isolation does not affect the information carried by the DNA but the isolation of her DNA in Australia would infringe the claims.

40. The Full Court erred in holding that the isolated DNA was patentable because it comprised an "artificial state of affairs". Although the phrase is derived from *NRDC,* it is inapposite here - because the information claimed is precisely the same as that found in the DNA or RNA inside the body. If not, for example,

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[36] FC at [2014] FCAFC 115, [212], quoting Lourie J.
[37] Although it can be used to make proteins *in vitro*: see Specification p26 lines 7-11.
[38] At p28, lines 6-8, the Patent defines the DNA sequences as comprising "at least about five codons (15 nucleotides)".
[39] Specification p90 lines 10-11.
[40] Specification p89.

diagnostic testing using the information (as is claimed in later claims) would not be valid. The information claimed is not artificial in the required sense.

41. The present claims are defined by an attribute of the product, namely, that it codes for the (mutant) polypeptide. That attribute is not artificial; the genetic coding information is the same in both isolated and natural forms. Neither the DNA itself, nor the genetic coding information, has been artificially created (except in the crude sense that the naturally occurring DNA was separated out from other DNA and cellular material by the routine process of isolation). Scientific intervention merely enabled the genetic coding attributes of the DNA to be located and analysed, through the process of isolation.

42. At FC [215]-[217] and elsewhere,[41] the Full Court puts aside the reasoning of the Supreme Court in *Myriad* on the basis that expressions such as "the work of nature" or "laws of nature" are not found in the Australian Act and are not useful tools of analysis. The phrase, "artificial state of affairs" is, however, used in *NRDC* as the antithesis of a product of nature.[42] The Full Court itself analyses the isolated nucleic acid with reference to its differences from the DNA in the human body (being "the work of nature"), including as to chemical bonds.

43. This is a distinction that has been recognised for centuries. For example, at FC [112], the Full Court refers to recent statements of the House of Lords[43] and the High Court[44] that acknowledge a "*distinction between a discovery of one of nature's laws and the application of that discovery to a new and useful purpose*".[45] These statements echo the US Supreme Court's discussion of the "rule against patents on naturally occurring things".[46] A discovery of a naturally occurring thing, without more, has never been patentable; the application of that discovery can be. In this context, the Full Court at FC [215]-

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[41] E.g., FC at [2014] FCAFC 115, [13] and [114].
[42] See 102 CLR 268-277.
[43] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9, at [77].
[44] *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171, [34].
[45] *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171, at [34].
[46] *Myriad* at 133 S. Ct. 2107, 2116.

[216] criticises the US Supreme Court's drawing of a distinction[47] between the *Myriad* case and its decision in *Diamond v Chakrabarty*.[48] *Chakrabarty*, however, related to a plainly artificial, "human-made genetically engineered bacterium".[49] In that case, the Supreme Court said,[50]

> *The laws of nature, physical phenomena, and abstract ideas have been held not patentable ... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter ...*

10 44. The Full Court erred in regarding the exclusion from patentability of a "product of nature" as having been specifically rejected in *NRDC*.[51]

45. In *NRDC* at 102 CLR 261-262, the High Court identified two aspects of the expression "manner of new manufacture". At 102 CLR 263-264, the Court dealt first with an argument as to one of these aspects, derived from *Commissioner of Patents v Microcell Ltd*,[52] that the Commissioner is not obliged to accept the allegation of a patent applicant that an invention is new, "if it is apparent on the face of the specification, when properly construed, that the allegation is unfounded".[53] In that context, the quotation from Frankfurter J's
20 reasons in *Funk Brothers Seed Company v Kalo Inoculant* Company,[54] referred to by the Full Court at FC [115], is discussed in *NRDC* at 102 CLR 263-264. Those observations were relevant to the argument based on *Microcell*.

46. The argument based on *Microcell* was entirely distinct from the other aspect, the "central question" that is discussed in the Court's judgment in *NRDC* from 102 CLR 268:[55] namely, whether the claims in suit were within the concept of a manufacture, that is, as being for "*a proper subject of letters patent according to the principles which have been developed for the application of s6 of the Statute*

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[47] *Myriad* at 133 S. Ct. 2116-2117.
[48] *Diamond v Chakrabarty* 447 U.S. 303.
[49] At 447 U.S. 305.
[50] At 447 U.S. 309, per Burger CJ, Stewart, Blackmun, Renquist and Stevens J joining.
[51] See FC at [2014] FCAFC 115, [217], [115].
[52] (1959) 102 CLR 232.
[53] At 102 CLR 262.
[54] 333 US 127 (1948).
[55] This structure of the Court's reasons was discussed by Hayne J in *Apotex* at [86].

of Monopolies".[56] In answering the Commissioner's argument that a manner of new manufacture had to be a "vendible product", the Court broadened that idea to an "artificial effect" of "economic utility", at 102 CLR 276-277. The Court did not reject the exclusion of products, or principles, of nature.

47. The provenance of vendible product is shown at 102 CLR 270 and ff. At 102 CLR 270, the High Court quoted from a passage in the judgment of Eyre CJ in *Boulton and Watt v Bull*,[57] referring to the "new results of principles carried into practice". This was significant in that case because James Watt had described his invention as consisting "of the following principles".[58] Heath J said that, "*The patent decides the question. It must be for the vendible matter, and not for the principle*".[59] Eyre CJ said,

> *Undoubtedly there can be no patent for a mere principle, but for a principle so far embodied and connected with corporeal substances as to be in a condition to act, and to produce effects in any art, trade, mystery, or manual occupation, I think there may be a patent.*

48. In *Apotex,* French CJ referred to *Boulton v Bull* as "the first case in which so-called 'inherent patentability' received close consideration".[60] As his Honour said, this is a "common law question".[61]

49. In the present case, the Full Court correctly drew the distinction between the discovery of a principle of nature, or information about a product of nature, which is not a manner of manufacture, and the practical application of that information, which can be.[62] Contrary to FC [181], however, the words "and utilised" do not appear in claims 1-3, nor do those claims relate to "the treatment of breast and ovarian cancers", cf FC [214]. The US Supreme Court held that the proposition that the practical application of a principle is patentable did not apply to claims of the present type:

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[56] At 102 CLR 269.
[57] *Boulton and Watt v Bull* 2H. Bl. 463; 126 ER 651 (1795).
[58] At 2H.Bl. 465; 126 ER 652.
[59] At 2H.Bl. 482; 126 ER 661.
[60] [2013] HCA 50, at [11].
[61] [2013] HCA 50, at [17]-[20].
[62] [2014] FCAFC 115, [110]-[112].

> *Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."*[63]

50. It is the subsequent claims of this Patent that "tell people how [the discovery of the coding sequence of the BRCA1 gene] can be usefully employed".[64] Claims 1-3 do not do this. They are claims to the same genetic information as occurs in nature.

Coding for the polypeptide

51. As noted, the BRCA1 gene sequence in SEQ.ID No: 1[65] (i.e., the "normal" gene) sets out its sequence of nucleotides conventionally, showing groups of three bases – that is, as "codons". The amino acid that each codon "codes for" is also set out. That correspondence is the genetic code.[66] The claim calls the sequence, the BRCA1 "encoding" sequence.

52. The "BRCA1 polypeptide encoding sequence set forth in SEQ.ID No: 1", referred to in claim 1,[67] is the coding nucleotide sequence of the BRCA1 gene; it codes for the BRCA1 polypeptide. Coding is the central concept of the claim.

53. The Full Court said that "*to identify the invention as being in the concept of information said to be embodied in a sequence of nucleotides ignores the language of the claim*".[68] To the contrary, the crucial phrase in the claim is that the claimed nucleic acid is "**coding for**" the BRCA1 polypeptide. "Coding" refers to the possession of the code – not the making of a polypeptide. Because the nucleic acid is isolated (from the body and from surrounding cellular material), it does not physically produce the polypeptide.

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[63] *Myriad* at 133 S. Ct 2120.
[64] FC at [2014] FCAFC 115, [111], citing *Genentech Inc's Patent* [1987] RPC 553, 556.
[65] Specification p119 line 33.
[66] As explained by the Full Court at [2014] FCAFC 115, [26]-[53].
[67] Specification p78 lines 29-31.
[68] FC at [2014] FCAFC 115, [194].

54. The mere isolation of the nucleic acid is not sufficient to convert information, which can never be a manner of manufacture, into a patentable invention. The specification makes no suggestion that there is anything inventive in the technique of isolation[69] – as noted, the method used is not even described. With respect to the defining attribute of "coding for" the mutant polypeptide, there is no difference between the isolated nucleic acid and the sequence of nucleotides that exists in the cell. The Full Court's earlier statement, quoted above, that the claimed sequence provides "*a useful effect, being a state of knowledge for the person upon which to contemplate, or assess, treatment*",[70] recognises the function of the claimed sequence as conveying information. Compare FC [214]-[215].

55. The specification reflects the same distinction between possession of the code and its role in the dynamic processes in the cell:[71]

> ***Encode***. *A polynucleotide is said to "encode" a polypeptide if, in its native state or when manipulated by methods well known to those skilled in the art, it can be transcribed and/or translated to produce the mRNA for and/or the polypeptide or a fragment thereof.*
>
> (emphasis added)

56. The Full Court erred in drawing a distinction at FC [175] between *"code for" – "(passive; having the **potential** to produce the polypeptide)"*, and *"encode" – "means actually to produce the polypeptide (the active)"*. The claim uses the former sense – and the Full Court overlooks the fact that the definition of "encode" is not limited to a polynucleotide that acts "actually to produce the polypeptide". The Full Court's misreading of the definition first appears at FC [85], where the Court emphasises "**can be** transcribed and/or translated". The Patent's definition[72] refers to a case where, if the polynucleotide were in its native state, it could be transcribed and/or translated. That is, it possesses the code.

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[69] FC at [2014] FCAFC 115, [187], noting the appellant's submission.
[70] FC at [2014] FCAFC 115, [8].
[71] Specification at p26 lines 7-9, emphasis added.
[72] Specification at p26 lines 7-11.

57. The distinction drawn by the Full Court relates to something that the nucleic acid sequence cannot do when isolated – that it can do in nature. Although the isolated nucleic acid lacks that natural attribute, that deficiency is hardly a sensational advantage of the type referred to in *NRDC*.[73] The economic utility of the isolated nucleic acid is not its inability to make proteins; it is its ability to carry the code – as it does in nature – so that it can be analysed for the possession of cancer-predisposing mutations.

Apotex Pty Ltd v Sanofi-Aventis[74]

58. In *Apotex*, in the context of a claim for a medical treatment, using a particular drug, the focus of the Court's analysis was on the effect on the patient, artificially created by the medical treatment.[75]

59. Crennan, Kiefel and Gageler JJ derived from *NRDC* a test, applicable to the instant case, of "an artificially created state of affairs" providing "economic utility".[76] Crennan and Kiefel JJ also said, at [283], that the test in *NRDC* requires that the process [or product] "effects an artificially created improvement in something" (emphasis added). This does not apply to the present claims. In terms of the definition of "encode" set out at FC [84], the claimed nucleic acids are precisely the same as occur in nature.

60. The mere fact that the isolated DNA product may be characterised as itself artificial, in that it has been separated from the surrounding cellular material in which the DNA is to be found in the body, is not sufficient to satisfy the requirements of manner of manufacture as explained in *NRDC* and *Apotex*. Here, the only relevant attribute of the claims in respect of the isolated DNA - the genetic coding information - is in no real sense artificial, because it is the same as that of the DNA in its natural state. Its movement from the cell to being "in hand"[77] (i.e., in a test tube) does not change this.

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[73] At 102 CLR 277.
[74] [2013] HCA 50; (2013) 304 ALR 1.
[75] Per Crennan and Kiefel JJ at [2013] HCA 50, [282]; Hayne J at [2013] HCA 150, [157], [161].
[76] Per Crennan & Kiefel JJ at [2013] HCA 50, [235]-[236], [240]-[241]; per Gageler J at [2013] HCA 50, [307].
[77] Cf FC at [2014] FCAFC 115, [212].

61. The reasoning of Crennan and Kiefel JJ[78] answered submissions derived from *obiter dicta* in *NRDC* that the possible exclusion of methods of medical treatment was because the subject was "essentially non-economic".[79] Their Honours' reasons include that the subject-matter of a patent must have some useful application, hence economic utility.[80] In *Apotex*, that utility was defined in the particular claim as the treatment of psoriasis.[81] The reasoning in *Apotex* principally concerned this question of economic utility, rather than whether there was an artificial effect. The present case is the obverse.

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62. The consideration referred to by Gageler J[82] of a "judicially sanctioned orthodoxy", is inapplicable here. As the submissions below illustrate, this is also not a case where a lack of harmony among trading partners would be introduced by recognizing the present exception.[83]

63. The decision in *Apotex* did not apply the *NRDC* case in a way that determines this case: cf FC at [129]. The appellant has always accepted that the isolated nucleic acid here is useful.[84] Because it possesses the code, the nucleic acid can usefully be assessed for the presence of mutations that confer a susceptibility to
20 cancer. Unlike the exception propounded in *Apotex,* the exception from patentability of natural products or principles does have "a stable, logical or normative foundation"; it does not depend upon "nice distinctions for its maintenance".[85] To recognise the exclusion would serve "the application of the rubric 'manner of new manufacture' in a logically and normatively coherent way".[86]

64. Crennan and Kiefel JJ referred to the Supreme Court's decision in *Myriad* at [2013] HCA 50, [269], including its application of the "laws of nature exception to patentability". At [269], their Honours drew the distinction – also significant

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[78] At [2013] HCA 150, [276]-[288].
[79] *NRDC* at 275; see also 270-271.
[80] At [2013] HCA 50, [278].
[81] See per Crennan and Kiefel JJ at [2013] HCA 50, [289]-[292].
[82] At [2013] HCA 50, [315].
[83] Per Crennan and Kiefel JJ at [2013] HCA 50; [280].
[84] This is noted by the primary judge at [2013] FCA 65, [8]
[85] Per French CJ at [2013] HCA 50, [44].
[86] Per French CJ at [2013] HCA 50, [50]. See also per Crennan and Kiefel JJ at [281].

in the *Apotex* case[87] – between the description of a law of nature and its application. Their Honours regarded as significant the fact that products for therapeutic use were patentable; there was no valid distinction between claims for such products and for methods for such uses.[88] There is no such contradiction here.

cDNA

65. Section 18(1)(a) of the Act reflects the requirement that a claim must be valid across its whole scope.[89] The Full Court thus erred in giving significance to the artificiality of the cDNA of SEQ ID No: 1. See, e.g., FC [179], [218]. The cDNA sequence is the coding sequence of the natural gene, the exons, without the (non-coding) introns. The process of its construction is described in Example 8 of the specification at pp78-79. The claims also encompass isolated genomic DNA and RNA. If they are not patentable, the claims are invalid. The primary judge noted the parties' agreement as to this at PJ [8].

Other jurisdictions

United States of America

66. The law of the United States, applied by the Supreme Court in *Myriad*, is not relevantly different from that of Australia: 35 U.S.C. § 101 broadly corresponds with s18(1) of the *Patents Act 1990* and the concept of what is a patentable invention ("patent eligible subject-matter") has been developed by the US Courts in a similar way to that described by the High Court in *NRDC* at 102 CLR 269. Recent decisions of the Supreme Court, including that in the counterpart case to the present illustrate that process.[90] They also illustrate the proposition that the present question is approached as a matter of substance.

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[87] See, e.g., at [2013] HCA 50, [289].
[88] At [2013] HCA 50, [282].
[89] *AstraZeneca AB v Apotex Pty Ltd* [2014] FCAFC 99. This was common ground in the present case. See per the primary judge at [2013] FCA 65, [8].
[90] See also *Bilski v Kappos* 561 U.S. 593 (2010); *Mayo Collaborative Services v Prometheus Laboratories Inc* 132 S. Ct. 1289.

UK and Europe

67. The *EC Directive on the Legal Protection of Biotechnological Inventions*,[91] Article 5, provides:

> *1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*
>
> *2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*
>
> *3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*

68. The requirement in Article 5(3) is that the industrial application must be disclosed in the patent application. These submissions focus instead on the application of the sequence of gene in the claim, as do the reasons of the US Supreme Court. The present claims are not limited by the application of the sequence – although later claims are. To adapt the phrase of the *Directive*, claims 1-3 do not "disclose" any application.

69. In *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9, referred to by the Full Court at FC [112], Lord Hoffman says that "an invention is a practical product or process, not information about the natural world".[92] The information to which his Lordship was referring was that in Table VI – the full DNA sequence coding for erythropoietin (EPO) in humans.[93] This, his Lordship agreed, "could not have been the invention".[94]

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[91] *Directive 98/44 of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions.*
[92] At [2005] RPC 9, [77].
[93] At [2005] RPC 9, [12].
[94] At [2005] RPC 9, [76].

New Zealand

70. The New Zealand *Patents Act 2013*, s14(1) continues to invoke "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". The Courts of New Zealand follow *NRDC* in the development of that concept.[95]

Canada

71. It appears that a case raising issues that include the present issue has recently commenced in the Federal Court of Canada: *Children's Hospital of Eastern Ontario v University of Utah Research Foundation & Ors*, No. T-2249-14 (Toronto Registry). It concerns patents for genes associated with "Long QT Syndrome", an inherited cardiac disorder. The Supreme Court of Canada discussed the patentability of "higher life forms", in the context of a genetically engineered mouse, in *Commissioner of Patents v Harvard College* [2002] 4 S.C.R. 45.

PART VII: Applicable provisions of the *Patents Act 1990*

72. The following provisions are still in force, in the same form.

73. **S18(1)(a)**:

> *Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the meaning of s6 of the Statute of Monopolies; ...*

74. **S18(2)**:

> *Human beings, and the biological processes for the generation, are not patentable inventions.*

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[95] See, e.g., *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104; [2005] 1 NZLR 362, [3]; *Apotex v Sanofi-Aventis* [2013] HCA 50, [36].

75. **Schedule 1 – Dictionary**:

> ***invention*** *means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.*

10 **PART VIII: Orders sought by the appellant**

76. The appellant seeks the following orders:

(a) That the appeal be allowed.

(b) That Order 1 made by the Full Court of the Federal Court of Australia on 5 September 2014 be set aside.

(c) That claims 1, 2 and 3 of Australian Patent No 686004 be revoked.

77. The parties agree that there should be no order as to costs.

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PART IX: Estimate of time

78. It is estimated that 3.5 hours will be required for the presentation of the appellant's oral argument; 15 minutes more if there is an intervener, as has been foreshadowed.

Date: 9 March 2015

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