

D'Arcy v Myriad Genetics Inc* [2015] HCA 35: The plurality's new factorial approach to patentability rearticulates the question asked in *NRDC

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Abstract

This case note analyses the High Court's recent landmark decision in D'Arcy v Myriad Genetics Inc [2015] HCA 35. In three separate judgments ultimately united on the result, the High Court held that patent claims to isolated human DNA used in testing for breast cancer were not a 'manner of manufacture' within the meaning of s 6 of the Statute of Monopolies. The claims were therefore not patent-eligible subject matter in Australia. It is submitted that the plurality's new factorial approach to patentability for new classes of claims rearticulates the approach propounded in the High Court's seminal decision in NRDC. D'Arcy's new guiding factors therefore realign the subject matter inquiry with its true nature, which turns on, in the plurality's words, the 'historically contingent concepts of patent and invention'. The note concludes by examining three of the most pressing consequences of D'Arcy's reasoning for Australian patent law.

Introduction

D'Arcy v Myriad Genetics Inc ('D'Arcy') is a watershed decision in Australian patent law, as the High Court provided clear guidance on the approach courts and patent examiners should take when determining whether new inventions in emerging fields of technology should be protected by a patent monopoly. In *D'Arcy*, French CJ, Kiefel, Bell and Keane JJ (the plurality) held that the correct approach to determining whether such subject matter was patent-eligible does not rest on a formulaic or 'unduly narrow' application of the approach laid down in *National Research Development Corporation v Commissioner of Patents* ('NRDC'). Instead, the plurality propounded a number of new factors relevant to whether a grant of letters patent should be made where the claimed

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[2015] HCA 35 (7 October 2015).

Ibid 14 [22] (French CJ, Kiefel, Bell and Keane JJ).

(1959) 102 CLR 252. The approach propounded in *NRDC* is to ask the question: '[i]s 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*?' at 269 per Dixon CJ, Kitto and Windeyer JJ. See also ibid 11 [18] (French CJ, Kiefel, Bell and Keane JJ). See further Part 1.4 below.

N.b. Information about volumetric and EAP page numbering is set out on page ii of this issue.

invention involves a new method of manufacture.' The result of this new factorial approach is that for such claims, the plurality in *D'Arcy* rejected as too rigid the modern orthodox application of *NRDC* by some Australian courts.' By enumerating a set of guiding factors, the plurality realigned the subject matter inquiry for new classes of claims with the 'historically contingent concepts of patent and invention'. As such, the plurality therefore rearticulated the approach propounded in *NRDC*. However some commentators have argued *D'Arcy* has reformulated wholesale the test for patentable subject matter.' This case note submits that the plurality's propounded factors are in fact only a rearticulation of the approach propounded in *NRDC* and not a complete reformulation of the law.

The unanimous ratio of *D'Arcy* is that the patent claim to the isolated nucleic acid encoding the BRAC1 polypeptide (human DNA linked to an increased risk of breast cancer) did not fall within the concept of 'manner of manufacture' under s 18(1)(a) of the *Patents Act 1990* (Cth) ('the Act'). Therefore it was not patent-eligible subject matter. *D'Arcy* overturned the unanimous decision of the enlarged bench of the Full Court of the Federal Court in *D'Arcy v Myriad Genetics Inc* ('*Myriad*').² In Parts 2 and 3, this case-note seeks to, first, provide a contextualised analysis of the High Court's reasoning in *D'Arcy* and, second, canvass the significant consequences of the decision. It is submitted these consequences include: (i) the immediate effect of the decision on the

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- ² *D'Arcy* [2015] HCA 35 (7 October 2015) 18 [28] (French CJ, Kiefel, Bell and Keane JJ).
 - ³ This orthodox application of *NRDC* is when a court or patent examiner decides that for an invention as claimed is a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*, it must produce the binary result of: (i) an artificially created state of affairs and then; (ii) be of economic utility. For appellate authorities that have either propounded or applied this orthodox interpretation of *NRDC* see, eg, *Grant v Commissioner of Patents* (2006) 154 FCR 62, 64; *CCOM Pty Ltd v Jejing Pty Ltd* (1994) 51 FCR 260, 295 ('CCOM'); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1. See further Part 1.4 below.
 - ⁴ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [26] (French CJ, Kiefel, Bell and Keane JJ).
 - ⁵ See above n 3. For a detailed analysis of the approach propounded and the broader question asked in *NRDC* see Ann L Monnotti, 'The Scope of "Manner of Manufacture" Under the Patents Act 1990 (Cth) After *Grant v Commissioner of Patents*' (2006) 34 *Federal Law Review* 461. See also The Hon Justice Andrew Greenwood, 'Reflections on patentable subject matter in US and Australian patent law' (2010) 34 *Australian Bar Review* 54.
 - ⁶ David Fixer, 'High Court re-invents the test for patentable subject matter and finds the patent for isolated breast cancer gene invalid' on King & Wood Mallesons, *IP Whiteboard* (8 October 2015) <<http://ipwhiteboard.com.au/high-court-re-invents-the-test-for-patentable-subject-matter-and-finds-the-patent-for-the-isolated-breast-cancer-gene-invalid/>>; Kate Hay, Jack Mandelbaum and Shariqa Shaheed, 'A Myriad of Considerations: The High Court Finds Gene Patent Invalid' on Corrs Chambers Westgarth, *Corrs In Brief* (16 October 2015) <<http://www.corrs.com.au/publications/corrs-in-brief/a-myriad-of-considerations-the-high-court-finds-gene-patent-invalid/>>.
 - ⁷ See also the other two judgments: Gageler and Nettle JJ at 45–70 [97]–[172] and Gordon J at 71–93 [173]–[285].
 - ⁸ (2014) 224 FCR 479.

patentability of isolated gene sequences (both DNA and cDNA) in light of the Australian Patent Office's narrow reading of the decision;¹¹ (ii) the effect of the plurality's 'common law methodology'¹² reasoning on Australian patent law jurisprudence; and (iii) whether the plurality's factorial approach has introduced a degree of uncertainty into the law, particularly in respect to other types of subject matter at the 'borderline'¹³ of patentability.

1 Contextualising *D'Arcy*

This Part seeks to contextualise *D'Arcy* by explaining: (i) the applicable science at issue; (ii) *D'Arcy*'s factual matrix; (iii) the relevant Australian statutory requirements for patentability; and (iv) the approach laid down by the High Court's seminal decision in *NRDC*.

1.1 Short précis on applicable science

The claims in suit before the High Court related to DNA and cDNA that had been isolated and extracted from the human body. DNA (deoxyribonucleic acid) is the basic 'building block' of a cell, as it contains a set of nucleotides which 'incorporates a "genetic code" that defines the growth, development, maintenance and reproduction of the human body'.¹⁴ The DNA isolated by Myriad Genetics Inc contained a series of nucleotides which coded for polypeptide called the BRAC1 gene, which consisted of mutations said to indicate a predisposition to breast cancer.¹⁵

Myriad Genetics' breast cancer testing isolated a patient's DNA in accordance with accepted processes (breaking down the covalent bonds to extract the DNA) which enabled the determination of whether a patient had an elevated risk of breast cancer, a determination not able to be made if the DNA was left in its native state. Complementary DNA (cDNA), which is also able to be synthesised during these accepted processes, was also subject to challenge in *D'Arcy* due to its similarity with DNA.

¹¹ Australian Patent Office, *Examination Practice following the High Court decision in D'Arcy v Myriad Genetics Inc* (16 December 2015) Australian Patent Office <http://www.ipaustralia.gov.au/pdfs/consultation_submissions/20151214_Examination_practice_following_the_High_Court_decision_in_D'Arcy_v_Myriad_Genetics_Inc.pdf>.

¹² *D'Arcy* [2015] HCA 35 (7 October 2015) 3 [5] (French CJ, Kiefel, Bell and Keane JJ). See also *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 253 CLR 294, 297–303 [8]–[20] (French CJ) ('*Apotex*').

¹³ Kathy Bowrey et al, *Australian Intellectual Property* (Oxford, 2nd ed, 2015) 405.

¹⁴ *D'Arcy* [2015] HCA 35 (7 October 2015) 25 [41] (French CJ, Kiefel, Bell and Keane JJ).

¹⁵ *Ibid* 1 [1].

1.2 Factual background of D'Arcy

Myriad Genetics Inc filed 30 patent claims with a priority date of 12 August 1994, which expired on 11 August 2015. This expiry date rendered the specific claims of little value to Myriad. Commentary on the D'Arcy litigation has therefore been principally framed in terms of its wider implications for the Australian biotechnology industry.²⁸ As discussed in Part 3.1 below, the key issue following D'Arcy is the extent to which isolated DNA and cDNA are now ineligible subject matter. Of the 30 patent claims made by Myriad, claims 1–3 were ultimately the only claims in suit before the High Court in D'Arcy; they were worded as claims to '[a]n isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide'.²⁹

In D'Arcy v Myriad Genetics Inc ('Myriad') the enlarged bench of the Full Court of the Federal Court unanimously rejected an appeal from the trial decision of Nicholas J in *Cancer Voices Australia v Myriad Genetics Inc*.³⁰ In Myriad, Allsop CJ, Dowsett, Kenny, Bennett and Middleton JJ found that the Respondent's patent claim was to an isolated nucleic acid, and this isolated DNA and cDNA was structurally and functionally different to its naturally occurring counterpart.³¹ Yvonne D'Arcy was then granted special leave to appeal to the High Court.³²

The counterpoint to the Australian D'Arcy litigation is the parallel set of Myriad litigation in the United States. In *Association for Molecular Pathology v Myriad Genetics Inc*, ('AMP')³³ the US Supreme Court held that the claim to the isolated nucleic acid was not patentable. On very similarly worded claims, the High Court in D'Arcy ultimately came to the same conclusion as the US Supreme Court in AMP. It must be noted however that the Full Court of the Federal Court in Myriad rejected the reasoning of the US Supreme Court in AMP,³⁴ leading Sherman to comment that (the Australian Full Federal Court decision in) Myriad 'occasionally reads as if it is an appeal from the US Supreme Court'.³⁵

²⁸ See Mark Summerfield, 'Australian High Court Nukes Biotech Industry from Orbit: 'It's the Only Way to be Sure' on Mark Summerfield, *Patentology.com.au* (9 October 2015) <<http://blog.patentology.com.au/2015/10/australian-high-court-nukes-biotech.html>>.

²⁹ D'Arcy [2015] HCA 35 (7 October 2015) 2 [3] (French CJ, Kiefel, Bell and Keane JJ).

³⁰ [2013] FCA 65 (15 February 2013) ('Cancer Voices'). See Matthew Rimmer, 'The Empire of Cancer: Gene Patents and Cancer Voices' 22(2) *Journal of Law, Information and Science* EAP1 <<http://www.scribd.com/doc/201097103/The-Empire-of-Cancer-Genes-Patents-and-Cancer-Voices>>.

³¹ Myriad (2014) 224 FCR 479, 508 [155].

³² D'Arcy v Myriad Genetics Inc [2015] HCATrans 146–7 (16–7 June 2015).

³³ 569 US 1 (2013).

³⁴ Myriad (2014) 224 FCR 479, 508 [155].

³⁵ Brad Sherman, 'Before the High Court: D'Arcy v Myriad Genetics Inc: Patenting Genes in Australia' (2015) 37 *Sydney Law Review* 135, 140.

1.3 The s 18(1)(a) requirement for patentability in Australia

In Australia, s 18(1)(a) of the *Patents Act 1990* (Cth) provides that an 'invention' is patentable if it is 'a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*'. The entry into force of the English *Statute of Monopolies*²⁴ in 1623 marks the birth of the modern body of Anglo-Australian jurisprudence²⁵ on the 'meaning and operation'²⁶ of the letters patent prerogative. This wide body of common law jurisprudence has developed to provide parameters as to what is a 'manner of manufacture' within the meaning of s 6. As such s 18(1)(a) operates to confer a broad statutory grant of discretion upon Australian courts to develop the concept of 'manner of manufacture'.

1.4 The relevance of the approach propounded in *NRDC*

NRDC has been described as a 'vanguard'²⁷ and 'watershed'²⁸ decision in Australian patent law. At issue in *NRDC* was whether a method of horticulture was patent-eligible subject matter. The most important aspect of the High Court's reasoning was the approach the Court propounded for determining whether subject matter was patent-eligible. This approach is to ask the broad question: '[i]s 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*?'²⁹ These developed principles are determined by looking at the manner of manufacture jurisprudence. *NRDC* therefore propounded a 'concept for case-by-case development'.³⁰

It is the subsequent application of this concept by Australian courts which has culminated in *D'Arcy*'s strong re-articulation of *NRDC*. It is submitted that instead of attending to the question asked in *NRDC*, a significant number of Australian courts and patent examinations have effected what this case note terms the 'orthodox binary application of *NRDC*'. As submitted above, this orthodox application of *NRDC* is when a court or patent examiner decides that for an invention as claimed is a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*, it must produce the binary result of: (i) an artificially created state of affairs and then; (ii) be of economic utility. It is submitted that this compound concept had, prior to *D'Arcy*, attained the status of a 'rule' capable of rigid application to determine whether subject matter was patentable under Australian law.³¹ Monnotti refers to the orthodox application

²⁴ (1623) 21 Jac 1 c 3.

²⁵ See further Justine Pila, 'Inherent patentability in Anglo-Australian law: A history' (2003) 14 *Australian Intellectual Property Journal* 109 for a comprehensive history of this rich Anglo-Australian jurisprudence.

²⁶ David J Brennan and Andrew F Christie, 'Patent claims for analogous use and the threshold requirement of inventiveness' (1997) 25 *Federal Law Review* 237, 238.

²⁷ Pila, above n 25, 165.

²⁸ *Joos v Commissioner of Patents* (1972) 126 CLR 611, 616 (Barwick CJ).

²⁹ (1959) 102 CLR 252, 269 (Dixon CJ, Kitto and Windeyer JJ).

³⁰ *D'Arcy* [2015] HCA 35 (7 October 2015) 3 [5] (French CJ, Kiefel, Bell and Keane JJ).

³¹ Monnotti, above n 7, 465.

as the 'CCOM Rule'; CCOM can be identified as the case that coined the precise phrasing of the binary 'rule'.²

2 Analysis of reasoning – D'Arcy

This Part analyses the reasoning of the three High Court judgments in order to determine the scope of D'Arcy's consequences for Australian patent law.

2.1 French CJ, Kiefel, Bell and Keane JJ

The plurality held the invention as claimed was not patentable subject matter. This case note thematically analyses the plurality judgment.

2.1.1 Informational characterisation of the DNA

The plurality held that the claims were not a manner of manufacture because the essential integer, or 'substance',³ of the invention was properly characterised as 'genetic information',⁴ namely the 'sequence of nucleotides which ... can ultimately be translated into the BRCA1 polypeptide'.⁵ The plurality held that because the substance of the claim was to genetic information the invention was therefore 'not "made" by human action'.⁶ Conversely, it was 'discerned'⁷ as the information remained the same, regardless of whether it had been isolated or not.

The plurality's conclusion in D'Arcy was therefore based upon an informational characterisation of the claims in suit. As such, the plurality repudiated the reasoning of the Full Court of the Federal Court in *Myriad*, where a chemical characterisation of the claims was made.⁸ French CJ, Kiefel, Bell and Keane JJ held that this chemical characterisation was fatal because such an '[i]dentification of the subject matter of the claims as a class of chemical compounds ... elevates form over substance'.⁹ Sherman's analysis directly accords with this line of the plurality's reasoning in D'Arcy, as Sherman argues the Full Court of the Federal Court in *Myriad* gave 'no explanation as to why the decision was made to read the claims chemically, rather than genetically'.¹⁰ As

² CCOM (1994) 51 FCR 260, 295.

³ D'Arcy [2015] HCA 35 (7 October 2015) 43 [93] (French CJ, Kiefel, Bell and Keane JJ).

⁴ Ibid.

⁵ Ibid 41 [89].

⁶ Ibid 4 [6]. See also 43 [94].

⁷ Ibid 4 [6].

⁸ *Myriad* (2014) 229 FCR 479, 517 [212]. See also *Association for Molecular Pathology v United States Patent and Trademark Office and Myriad Genetics Inc* 689 F (3d) 1303 (2012) ('*Association for Molecular Pathology*'), the United States Court of Appeals for the Federal Circuit decision which the Full Federal Court in *Myriad* cited to support a chemical characterisation.

⁹ D'Arcy [2015] HCA 35 (7 October 2015) 41 [88] (French CJ, Kiefel, Bell and Keane JJ).

¹⁰ Sherman, above n 23, 143.

noted above, the fact that the informational content in the isolated DNA was the same as the DNA 'contained in the DNA of the person from which the nucleic acid was isolated'⁴ provided the ultimate justification for the High Court plurality to read the claims genetically.

2.1.2 *The plurality's new factorial approach for subject matter at the borderline of patentability*

However the plurality's decision was not based solely on a characterisation of the isolated DNA as information. The most striking part of the plurality's judgment was that their Honours also assessed the claimed invention against a set of new factors to determine patent eligibility.⁵ This wide, factorial approach has refocused the Australian approach for patentable subject matter which 'lies at the boundaries of the concept of "manner of manufacture"'.⁶ It is submitted that this reasoning by the plurality in *D'Arcy* is a rearticulation of the broader question posited in *NRDC*, namely whether the subject matter '[i]s ... 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*?'.⁷

The factors the plurality propounded to determine whether an invention falls within the concept of manner of manufacture were:

1. whether patentability would be consistent with the purpose of the Act (including particular consideration of: any potentially negative effects on innovation; any potential of chilling effect on activities beyond those formally the subject of exclusive patent rights; and any need for the court to assess public and private interests);⁸
2. whether patentability would enhance or detract from the coherence of the law relating to inherent patentability;⁹
3. considerations of Australia's obligations under international law and the patent laws of other countries, which are relevant to Australia's place in the international community of nations;¹⁰ and
4. whether patentability would involve law-making of a kind which should be done by the legislature.¹¹

⁴ *D'Arcy* [2015] HCA 35 (7 October 2015) 41-2 [89] (French CJ, Kiefel, Bell and Keane JJ).

⁵ *Ibid* 18 [28].

⁶ *Ibid* 43 [93].

⁷ *NRDC* (1959) 102 CLR 252, 269; *D'Arcy* [2015] HCA 35 (7 October 2015) 11 [18] (French CJ, Kiefel, Bell and Keane JJ). See further Monnotti, above n 7, 464.

⁸ *D'Arcy* [2015] HCA 35 (7 October 2015) 18 [28] (French CJ, Kiefel, Bell and Keane JJ). Cf *Association for Molecular Pathology* 689 F 3d 1303 (2012), the United States Court of Appeals for the Federal Circuit decision which the Full Federal Court in *Myriad* found highly persuasive.

⁹ *Ibid* 19 [28].

¹⁰ *Ibid*.

The propounded factors accord with Sherman's analysis of the Full Court of the Federal Court's decision in *Myriad*. In his paper, Sherman explores which normative rubric Australian courts should adopt when categorising patentable subject matter.⁶ Sherman's prophetic concluding comment (made well before *D'Arcy* was heard), that it is likely '[a]t best ... that policy considerations will be indirectly taken into account as part of the doctrinal analysis'⁷ appears to directly (and correctly) predict the factorial approach propounded by the plurality.⁸

It is submitted that this is a correct prediction. This is because the new factors have refocused the approach to determining the patentability of subject matter by providing a range of purposive considerations against which patent examiners and judges may determine patentability. This purposive approach directs the decision-maker to the normative considerations prescribed by the plurality, thus mandating a policy-driven approach which the Full Federal Court in *Myriad* expressly denied as relevant on their characterisation of the claims. This is illustrated by the Full Federal Court's conclusion in *Myriad* that '[t]his case is not about the wisdom of the patent system ... it is not about whether, for policy, moral or social reasons, patents for gene sequences should be excluded from patentability'.⁹ In fact, a single Federal Court judge has now explicitly recognised the plurality's new normative approach in *D'Arcy* is underwritten by policy considerations. In obiter dictum, Jagot J in *Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC*¹⁰ stated that the plurality's rearticulation of the approach in *NRDC* 'called for consideration of a wide range of factors which would not unfairly be described as extending to questions of policy.'¹¹

The primary concern evident in the initial commentary on this '[p]urposive and consequentialist'¹² plurality reasoning is that it has introduced further uncertainty into the subject matter patentability test.¹³ The key indictments

⁶ Ibid

⁷ Sherman, above n 23, 138, 144, 145.

⁸ Ibid 144.

⁹ *D'Arcy* [2015] HCA 35 (7 October 2015) 18 [28] (French CJ, Kiefel, Bell and Keane JJ).

¹⁰ *Myriad* (2014) 224 FCR 479, 516 [204]–[205] (Allsop CJ, Dowsett, Kenny, Bennett and Middleton JJ).

¹¹ [2016] FCA 169 (2 March 2013) ('*Gilead Sciences*').

¹² Ibid [658]. Jagot J considered in the same paragraph that the factorial approach was not enlivened because the principal dependent claims were to pharmaceutical compositions which, factually, differed significantly from the claims at issue in *D'Arcy*.

¹³ *D'Arcy* [2015] HCA 35 (7 October 2015) 15 [24] (French CJ, Kiefel, Bell and Keane JJ).

¹⁴ See: Fixer, above n 8; Hay, Mandelbaum and Shaheed, above n 8; Summerfield, 'Australian High Court Nukes Biotech Industry from Orbit', above n 16; Tania Obranovich, 'Patent eligibility in Australia: the winding road ahead' on Intellectual Asset Management, *IntellectualAssetManagement.com.au* (6 November 2015) <<http://intellectualassetmanagement.com.au/biotechnology/patent-eligibility-in-australia-the-winding-road>

against the application of the new test are that the reasoning and factors do not provide guidance on: how they are to be assessed,⁸ nor the weight to be afforded to individual factors,⁹ or precisely which factors must be considered in a particular case.¹⁰

Yet, despite these indictments, the common law historical roots¹¹ of subject matter patentability mean that, as argued by Sherman:

the reasons for the inclusion and exclusion of subject matter cannot be reduced to a set of 'principles' (as was suggested in *NRDC*). Instead, patentable subject matter is *determined by an array of factors*.¹²

Therefore, the plurality, by expressly rejecting the orthodox binary application¹³ of the approach laid down in *NRDC*, properly re-aligned the scope of the subject matter inquiry with the 'historically contingent concepts of patent and invention',¹⁴ both of which are determined by a range of factors. It is submitted that these two basal, historical common law requirements of 'patent and invention'¹⁵ are what the plurality in *D'Arcy* and the Court in *NRDC* determined to be the true nature of the 'manner of manufacture' subject matter inquiry in its current form as a 'general common law concept'.¹⁶

Patent and invention undoubtedly lie at the heart of the concept of the manner of manufacture inquiry. 'Patent' is the idea that the inventor makes a defined claim for the grant of a limited monopoly, an idea which is reflected in the first of the plurality's new factors. This first factor enlivens consideration of whether a monopoly will have a negative effect on innovation, thereby expressly mandating a balancing of public and private interests.¹⁷ 'Invention' underwrites the patentability inquiry, because, as argued by Sherman, it is the unfettered

[ahead.html?utm_source=rss&utm_medium=rss&utm_campaign=patent-eligibility-in-australia-the-winding-road-ahead>](#).

⁸ Fixer, above n 8.

⁹ Hay, Mandelbaum and Shaheed, above n 8.

¹⁰ Ibid. See further Part 3.3 below.

¹¹ See *Apotex* (2013) 253 CLR 294, 327 [81] (Hayne J).

¹² Sherman, above n 23, 137 (emphasis added).

¹³ It is emphasised that it is not a rejection of *NRDC* itself but a rejection of the subsequent application of the *NRDC* approach by Australian courts and patent examiners.

¹⁴ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [26] (French CJ, Kiefel, Bell and Keane JJ). On the distinction between a conceptual and textual inquiry see Greenwood, above n 7, 68–9.

¹⁵ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [26] (French CJ, Kiefel, Bell and Keane JJ).

¹⁶ Ibid. Note that s 18(1)(a) of the *Patents Act 1990* (Cth) permits a broad statutory grant of judicial discretion to develop the common law's manner of manufacture concept.

¹⁷ See *D'Arcy* [2015] HCA 35 (7 October 2015) 19 [29] (French CJ, Kiefel, Bell and Keane JJ) citing *Parkdale Custom Built Furniture Ltd v Puxu Pty Ltd* (1982) 149 191, 206 (Mason J).

'image of invention' which ensures that the 'breadth of the concept' of manner of manufacture develops the law in concert with technological developments in science. At [18] the plurality emphasised this point by acknowledging the 'widening conception' of the manner of manufacture concept which is a 'necessary feature of the development of patent law in the 20th and 21st centuries as scientific discoveries inspire new technologies'.

The plurality's propounded factors correctly realign the inquiry because they provide tangible guidance as to when these two basal requirements are not reached or exceeded. The factors thus effectuate a 'functional' rearticulation of the approach propounded in *NRDC*. To this end, it must also be noted that the word 'include' suggests the factors are non-exhaustive, and therefore it is submitted that it can be safely assumed that the plurality was endorsing the consideration of other policy factors specifically relevant in future cases.

2.1.3 Factorial approach only relevant for subject matter at the borderline of patentability: confirmation with the first post-D'Arcy appellate decision on subject matter

The plurality's new factorial approach is not, however, a wholesale revision of the *NRDC* approach. At [28], the plurality held that the propounded factors will only 'assume importance' when there arises a 'new class of claim [involving] a significant new application or extension of the concept of "manner of manufacture"'.²⁶ Thus, the plurality's reasoning at [28] in *D'Arcy* explicates that when an invention as claimed falls within the 'existing concept of manner of manufacture', 'existing principle derived from the *NRDC* decision', dictates that two primary determinates of whether the product or process is a manner of manufacture are: (i) whether the product or process claimed is for an outcome as a result of human action; and (ii) whether the invention has economic utility. It must be noted however that in light of the plurality's rearticulation of the question asked in *NRDC*,²⁷ these two considerations are ultimately subject to that question and do not displace it.

Commissioner of Patents v RPL Central ('RPL'),²⁸ handed down on 11 December 2015 and discussed further below in Part 3.3, was the first appellate decision to

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- ²⁶ Sherman, above n 23, 137. See further Alain Pottage and Brad Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, 2010).
 - ²⁷ *NRDC* (1959) 102 CLR 252, 269 (Dixon CJ, Kitto and Windeyer JJ).
 - ²⁸ *D'Arcy* [2015] HCA 35 (7 October 2015) 11 [18] (French CJ, Kiefel, Bell and Keane JJ).
 - ²⁹ Greenwood, above n 7, 58.
 - ³⁰ *D'Arcy* [2015] HCA 35 (7 October 2015) 18 [28] (French CJ, Kiefel, Bell and Keane JJ).
 - ³¹ *Ibid.*
 - ³² See above nn 5, 7, 64–66 and accompanying text.
 - ³³ [2015] FCAFC 177 (15 December 2015). See further Patrick Gunning, 'Computer implemented business methods – routine patent cases for Australian courts?' on King & Wood Mallesons, *IP Whiteboard* (21 December 2015) <<http://ipwhiteboard.com.au/computer-implemented-business-methods-routine-patent-cases-for-the-australian-courts/>>.

consider subject matter at the borderline of patentability post-*D'Arcy*. In *RPL*, Kenny, Bennett and Nicholas JJ unanimously found that the computer-implemented business method claim in suit did not reach *D'Arcy*'s threshold requirement of 'a new class of claim involving a significant extension of the concept of manner of manufacture'.⁷⁵ As such, the Court correctly held that it was not necessary to consider the new factors propounded by the plurality. The Court's reasoning, in essence, was that the claimed 'method does not include any steps that are outside the normal use of a computer',⁷⁶ a conclusion reached 'by applying the established principles as they relate to a computer-implemented business method'.⁷⁷ As submitted in the paragraph above, these 'established principles' are the extant reasoning derived from *NRDC* jurisprudence, which can ultimately be expressed by the two factors stated at [28] in *D'Arcy*.

Subject to Part 3.3 below, it is therefore submitted that the decision in *RPL* supports the plurality's reasoning in *D'Arcy*. This is because Kenny, Bennett and Nicholas JJ made a qualitative decision on whether the claim to a computer-implemented business method reached the threshold requirement. In their Honours' determination that the claim did reach the threshold, they correctly applied the reasoning of the plurality in *D'Arcy* as to when the factorial approach is properly engaged. Although the Court in *RPL* correctly applied *D'Arcy*, the author submits below in Part 3.3 that an obiter dicta statement in *RPL* may be interpreted to mean that Kenney, Bennett and Nicholas JJ perhaps consider the plurality's new factorial approach introduces a slight degree of uncertainty into the law.

2.1.4 The plurality changing trajectory on legislative exclusions from patentability – a *sui generis* inversion?

A striking feature of the plurality's reasoning is what may potentially be characterised as an inversion regarding the role of legislative exclusion from patentability. The Act contains⁷⁸ what has been described as 'minimal'⁷⁹ specific subject matter exclusions from patentability. For example, 'human beings and, the biological processes for their generation' cannot be the subject of a patent monopoly.⁸⁰ *Myriad* had argued in the High Court that the legislature had 'expressly denied to enact any such exclusion [of gene patents] on more than one occasion' which 'sets this area apart from mere silence by the legislature'.⁸¹

⁷⁵ [2015] FCAFC 177 (15 December 2015) 36 [119].

⁷⁶ *Ibid* 34 [112].

⁷⁷ *Ibid* 34–5 [115].

⁷⁸ *Patents Act 1990* (Cth) ss 18(2), 50(1).

⁷⁹ Monnotti, above n 7, 462.

⁸⁰ *Patents Act 1990* (Cth) s 18(2). See also s 18(3) for the express exclusions of plants and animals for the purposes of innovation patents. Section 18(4) operates to limit the extent of the s 18(3) express exclusion.

⁸¹ *Myriad Genetics Inc*, 'Respondent's Written Submissions', Submission in *D'Arcy v Myriad Genetics Inc*, S28/2015, 24 March 2015, 13 [68].

Myriad submitted that it follows from this proposition that, if there is no such express or implied exclusion, isolated DNA sequences are patentable subject matter.

It is instructive to set out the plurality's direct answer to this issue of legislative exclusion:

[t]his Court is not concerned in this appeal with "gene patenting" generally, but with whether the invention as claimed in Claims 1 to 3 falls within established applications of the concept of manner of manufacture. *If it does not, then the question is one of inclusion not exclusion.* The legislative history cannot be read as impliedly mandating the patentability of claims for inventions relating to isolated nucleic acids coding for particular polypeptides.^a

This approach has been criticised by Summerfield on the basis that it places upon Parliament an 'incumbent' duty to legislate in favour of exclusion, despite the minimal positive restrictions on patentability in the Act. The plurality met this argument by confining its reasoning to the level of generality at which the legislative history considered gene patents.^a

It is submitted that there is potential for the plurality's reasoning to be characterised as an 'inversion', because it is seemingly *sui generis*, enlivened specifically on the facts of *D'Arcy*. The relevant facts appear to be what was referred to, by both the plurality and Myriad, as the litigation's 'legislative history'.^a This legislative history includes: (i) Australian Law Reform Commission Report No 99;^a (ii) the Senate's rejection of amendments to the Patents Bill 1990 (Cth);^a and (iii) the Legal and Constitutional Affairs Legislation Committee of the Senate's rejection of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Cth).^a Myriad relied on all three facts to submit that the legislature had expressly declined to exclude gene patents from patentability.^a

The crux of the *sui generis* reasoning turns on the plurality's finding that, if the claims did not fall within an established application of the manner of manufacture concept, it was then a necessary question of legislative 'inclusion

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- ^a *D'Arcy* [2015] HCA 35 (7 October 2015) 24 [37] (French CJ, Kiefel, Bell and Keane JJ) (emphasis added).
 - ^a Summerfield, 'Australian High Court Nukes Biotech Industry from Orbit', above n 16.
 - ^a *D'Arcy* [2015] HCA 35 (7 October 2015) 24 [37] (French CJ, Kiefel, Bell and Keane JJ).
 - ^a *Ibid* 23 [36].
 - ^a Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004), 130–1 [6.53].
 - ^a Commonwealth, *Parliamentary Debates*, Senate, 17 September 1990, 2478–2482.
 - ^a Senate Legal and Constitutional Affairs Legislation Committee, Commonwealth, *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (2011) 64 [5.25]–[5.26].
 - ^a Myriad Genetics Inc, 'Respondent's Written Submissions', Submission in *D'Arcy v Myriad Genetics Inc*, S28/2015, 24 March 2015, 13 [68].

not exclusion⁸ from patentability. It may be argued this requirement for the legislature to include new classes of claims adds another barrier to patentability for subject matter at the borderline of patentability and is therefore an 'inversion' of the regime prescribed by the Act. In addition, it is submitted that this reasoning is discordant with Crennan and Kiefel JJ's (with Gageler J agreeing) reasoning in *Apotex*. Their Honours' reasoning was that the absence of any express or implied exclusion of the subject matter at issue in that case was a strong reason in favour of according patentability.⁹ Regardless of whether the plurality's reasoning on legislative inclusion was sui generis, it is submitted that such reasoning is a necessary integer in the plurality's broader finding that it was discharging its judicial function according to the common law method (see further Part 3.2 below).

2.2 Gageler and Nettle JJ

Gageler and Nettle JJ held that the patent claims were 'lacking in the necessary quality of inventiveness'¹⁰ and were therefore not a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*.

2.2.1 Parity between Australian artifice and the US product of nature doctrine?

Gageler and Nettle JJ's judgment turns on what their Honours cast as an analogue of the US product of nature doctrine, namely the threshold concept of inventiveness. This threshold concept is conceptually distinct from the Act's s 18(1)(b)(ii) 'inventive step' requirement for patentability.¹¹

Sherman raises the point that the Full Court's reasoning in *Myriad* relies on a taxonomical exercise in categorisation, to obscure the 'conceptually very similar (if not identical)'¹² nature of the Australian and US tests of subject matter patentability. On this point, Gageler and Nettle JJ directly cite Sherman's article in their holding that Australian patent law's threshold requirement of inventiveness is effectively synonymous with the US product of nature doctrine.¹³ Sherman neatly encapsulates the overt similarity between these two doctrinal approaches in his comment that

nature and artifice are flip sides of the same coin. While the product of nature doctrine may not exist in name, there is little doubt that it exists conceptually in Australian law.¹⁴

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- ⁸ *D'Arcy* [2015] HCA 35 (7 October 2015) 24 [37] (French CJ, Kiefel, Bell and Keane JJ).
 - ⁹ *Apotex* (2013) 253 CLR 284, 382 [279]–[280] (Crennan and Kiefel JJ), 390 [314] (Gageler J).
 - ¹⁰ *D'Arcy* [2015] HCA 35 (7 October 2015) 56 [136] (French CJ, Kiefel, Bell and Keane JJ).
 - ¹¹ See further Mary Padbury, 'Inventiveness apart from Novelty and Inventive Step – The High Court's Decisions on Manner of Manufacture in *Philips* and *Ramset*' (1998) 9 *Australian Intellectual Property Journal* 161.
 - ¹² Sherman, above n 23, 141.
 - ¹³ *D'Arcy* [2015] HCA 35 (7 October 2015) 53–4 [128], 57 [136] (Gageler and Nettle JJ).
 - ¹⁴ Sherman, above n 23, 141.

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Therefore, their Honours' reasoning is predicated on what is, in essence, a de facto product of nature doctrine, which is framed in the terms of 'whether the subject matter of the claim is sufficiently artificial, or in other words different from nature, to be regarded as patentable'."

This reasoning is markedly similar to the considerations raised by the US Supreme Court in *Mayo Collaborative Services v Prometheus Laboratories, Inc.** In this decision, Breyer J (delivering the opinion of the Court) held that:

to transform an unpatentable law of nature in a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it'."

Gageler and Nettle JJ's requirement of a threshold concept of inventiveness is a corollary of Breyer J's proposition that laws of nature simpliciter are not patentable. The doctrinal similarity is further illustrated by Gageler and Nettle JJ's finding that the 'inventive concept be seen to make a contribution to the essential difference between the product and nature'."

2.2.2 Introducing a slight degree of uncertainty into the Australian requirements for patentability

The primary ramification of Gageler and Nettle JJ's reasoning with respect to this doctrinal similarity on inventiveness is that it creates a slight degree of uncertainty in Australian patent law. As such it is submitted that their Honours' reasoning on doctrinal similarity is excluded from forming part of *D'Arcy's* ratio for three reasons. First, it is because the critical question arises as to whether Gageler and Nettle JJ's judgment (which was ultimately unanimous with the plurality and Gordon J on the result) has imported a separate threshold requirement of inventiveness into Australian patent law. Whilst a threshold test of inventiveness is not an intrinsically uncertain test, a separate requirement of inventiveness outside cases concerning analogous use has not previously formed part of the Anglo-Australian manner of manufacture jurisprudence. If followed in future decisions, it is submitted, with the greatest respect, that Gageler and Nettle JJ's line of reasoning on the threshold requirement of inventiveness introduces a slight degree of undesirable uncertainty into Australian patent law.

The second reason is that it is submitted the state of the law on the separate threshold requirement of inventiveness is sufficiently settled to the extent that it does not provide jurisprudential support for Gageler and Nettle JJ's threshold test of a 'requirement on inventiveness'." Gageler and Nettle JJ's reasoning

- * *D'Arcy* [2015] HCA 35 (7 October 2015) 53 [127] (Gageler and Nettle JJ).
- * 132 S Ct 1289 (2012) ('*Mayo*'). Gageler and Nettle JJ did not reference the decision of *Mayo* in their judgment.
- * Ibid 1294 (emphasis in original).
- * *D'Arcy* [2015] HCA 35 (7 October 2015) 54 [128].
- * Separate from the statutory 'inventive' step under s 18(1)(b)(ii).
- * *D'Arcy* [2015] HCA 35 (7 October 2015) 55 [131].

relied on a unanimous High Court in *Commissioner of Patents v Microcell*¹⁰⁹ which held an invention could be denied patentability on the basis the face the specification did not disclose the a sufficient degree of inventiveness to constitute 'manner of manufacture'.¹¹⁰ Gageler and Nettle JJ further relied on *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd*,¹¹¹ where Brennan, Deane and Toohey JJ held there is a 'necessary quality of inventiveness'¹¹² required before an invention will be a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*.

Yet in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]*¹¹³ Gummow, Hayne, Callinan, Heydon and Crennan JJ held that the 'decision in *Microcell* has not always been properly understood; it does not involve a separate ground of invalidity or discrete 'threshold' test'.¹¹⁴ Gageler and Nettle JJ cited this obiter dicta statement yet proceeded to expound the threshold requirement of inventiveness 'notwithstanding' this recent statement of a majority of the High Court. It is submitted that while the Court in *Lockwood* did not overrule *Microcell*, it was explicitly cautioning against, and judicially disapproving of, the introduction of the type of test expounded by Gageler and Nettle JJ.¹¹⁵ In addition, the *Microcell/Philips* lineage of jurisprudence has been criticised.¹¹⁶ In particular, Brennan and Christie observed that in *Philips* the 'majority's suggested application of s 18(1)(a) is inconsistent with its own judgment'.¹¹⁷ They argue this is because Brennan CJ, Deane and Toohey JJ characterised s 18(1)(a) as operating in two mutually exclusive ways. Their Honours' first characterisation of s 18(1)(a) that it required consideration of the 'pure' question of whether the invention was a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*. The second characterisation was that s 18(1)(a) operates to exclude claims for analogous use where this is not apparent on the face of the specification.¹¹⁸

¹⁰⁹ (1959) 102 CLR 232 ('*Microcell*').

¹¹⁰ *D'Arcy* [2015] HCA 35 (7 October 2015) 54 [130]. See *ibid* at 246.

¹¹¹ (1995) 183 CLR 655 ('*Philips*').

¹¹² *Ibid* 664.

¹¹³ (2007) 235 CLR 173 ('*Lockwood*').

¹¹⁴ *Ibid* 211 [106].

¹¹⁵ *D'Arcy* [2015] HCA 35 (7 October 2015) 55 [131].

¹¹⁶ Cf Mark Summerfield, 'Inventiveness – It's Just Not Obvious!' on Mark Summerfield, *Patentology.com.au* (4 March 2013) <<http://blog.patentology.com.au/2013/03/inventiveness-its-just-not-obvious.html>>. Summerfield argues that Gummow, Hayne, Callinan, Heydon and Crennan JJ in *Lockwood* did in fact overrule *Microcell*. See also Duncan Bucknell, 'Australia's Highest Court Just Made it Harder to Invalidate Patents' on Duncan Bucknell, *DuncanBucknell.com* (23 May 2007) <<http://duncanbucknell.com/2007/05/23/australias-highest-court-just-made-it-harder-to-invalidate-patents/>>.

¹¹⁷ *Ibid*; Brennan and Christie, above n 26, 259. Padbury, above n 93, 170.

¹¹⁸ Brennan and Christie, above n 26, 259.

¹¹⁹ *Ibid*.

The third reason is that it is submitted that the plurality in *D'Arcy* only made a cursory reference to *Philips*, citing it for a proposition much narrower in scope than suggested by Gageler and Nettle JJ. The plurality's proposition was that 'invention', for the purposes of s 18, means 'anything which is not, on the face of the specification, a proper subject of letters patent according to traditional principles'.¹¹⁴ It is therefore submitted that this narrow construction of *Philips* by the plurality, in concert with the enactment of the separate s 18(1)(b)(ii) inventive step since *Microcell* was decided,¹¹⁵ renders the line of jurisprudence relied upon by Gageler and Nettle JJ unsuitable for importing a new threshold requirement of inventiveness.

2.3 Gordon J

Gordon J's decision was relatively straightforward, with her Honour's reasoning being conceptually similar to the plurality's reasoning on the 'informational'¹¹⁶ content of the isolated DNA sequences. Gordon J elucidated the steps Myriad Genetics Inc undertook to separate the DNA, and ultimately found that 'Myriad did not create, make or alter any of the nucleic acid sequence in the BRCA1 gene'.¹¹⁷ This was because the fact the mutations in the BRCA1 gene are indicative of breast cancer was a 'fact existed before Myriad worked it out'.¹¹⁸ As such it was not a manner of manufacture under the *NRDC* approach.¹¹⁹

Being the decision of only a single Justice, Gordon J's judgment inherently carries less weight than either of the other two judgments. Yet Gordon J reasoned in similar terms to the plurality on the genetic information and was united on the ultimate ratio of *D'Arcy*. This means on the somewhat narrower question of isolated DNA and cDNA in future cases and patent examinations, her Honour's judgment should be considered as highly concomitant with the plurality's decision.

3 Consequences of D'Arcy

This Part examines three of the most pressing consequences of *D'Arcy* for Australian patent law. The selection of these consequences is not intended to be exhaustive.

¹¹⁴ *D'Arcy* [2015] HCA 35 (7 October 2015) 7 [12] (French CJ, Kiefel, Bell and Keane JJ).

¹¹⁵ See Brennan and Christie, above n 26, 260. See Dawson and McHugh JJ at 676 in *Philips* who formed the minority: '[i]f the decision in *Microcell* upon the question of invention were to be made today, it would be made under the 1990 Act by reference to s 18(1)(b)(ii) and not by reference to the phrase "manner of manufacture" in s 18(1)(a).

¹¹⁶ *D'Arcy* [2015] HCA 35 (7 October 2015) 43 [92] (French CJ, Kiefel, Bell and Keane JJ).

¹¹⁷ *Ibid* 86 [248].

¹¹⁸ *Ibid* 71 [173].

¹¹⁹ *Ibid* 87 [249].

3.1 Immediate consequences for patents of isolated and synthesised gene sequences – DNA, RNA and cDNA

D'Arcy has created a degree of uncertainty as to the patentability of isolated gene sequences, with particular industry concern directed towards the eligibility of synthesised cDNA. Immediately following the judgment, some commentators read the plurality judgment very narrowly and confined *D'Arcy* to its facts,¹²⁸ and others interpreted it much more broadly, holding concerns for the patentability of all isolated gene sequences.¹²⁹

The Australian Patent Office initially interpreted *D'Arcy* very narrowly.¹³⁰ What followed was a public consultation on its examination practice in light of the decision.¹³¹ The Australian Patent Office received 22 non-confidential submissions in this public consultation.¹³² The tenor of the submissions ranged from very supportive of the proposed examination practice¹³³ to extremely critical of the proposed interpretation.¹³⁴ In December 2015 the Australian Patent Office made an official change to its examination practice.¹³⁵ While slightly broader than its initial construction, the revised examination practice is still relatively narrow in scope. This confined construction interprets *D'Arcy* as standing for the proposition that the following are ineligible subject matter: (i) isolated naturally occurring nucleic acid sequences molecules; and (ii) cDNA, synthetic nucleic acid, probes, primers and interfering/inhibitory nucleic acids which merely replicate the genetic information of a naturally occurring organism. IP Australia's approach is starkly contrasted with the US Patent and Trademark Office, which broadly interpreted the 2013 Supreme Court decision (*AMP*), rendering a large number of claims directed to natural products

¹²⁸ Grant Shoebridge, *Will the Australian High Court Myriad 'gene patent' decision impact the patenting of all isolated biological material?* (16 October 2015) LinkedIn.com <<https://www.linkedin.com/pulse/australian-high-court-myriad-gene-patent-decision-all-shoebridge>>.

¹²⁹ Obranovich, above n 56.

¹³⁰ Australian Patent Office, *Consultation On Our Proposed Examination Practice Following The High Court Decision D'Arcy v Myriad Genetics Inc* (23 October 2015) IP Australia <<http://www.ipaustralia.gov.au/about-us/public-consultations/Consultation-on-our-proposedexamination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>>.

¹³¹ Australian Patent Office, above n 11.

¹³² Available at: <<http://www.ipaustralia.gov.au/about-us/public-consultations/Revised-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>>.

¹³³ See, eg, the submissions of: Baldwins Intellectual Property, the Law Council of Australia and the Institute of Patent and Trade Mark Attorneys.

¹³⁴ See, eg, the submissions of: Professor Luigi Palombi, Alphapharm Australia and the Cancer Council of Australia.

¹³⁵ Australian Patent Office, above n 11.

susceptible of ineligibility.¹²⁸ The reason for this disparity may be attributed to the difference between the ratios of *D'Arcy* and *AMP*.

It is the inclusion by the Australian Patent Office of cDNA as being patent-ineligible (where it merely replicates the genetic information of naturally occurring organism) that is perhaps the most controversial immediate consequence of the decision. The basis for this inclusion is [89] of the plurality judgment, where their Honours held that the genetic information was the essential element of the invention as claimed, and '[t]hat characteristic also attaches to cDNA, covered by the claims'.¹²⁹

Two commentators have interpreted this finding narrowly. First, Summerfield has argued that it goes no 'further than to establish that cDNA is ineligible for patenting in circumstances where a corresponding claim to isolated DNA would not be patent-eligible'.¹³⁰ Second, Shoebridge confines the ratio of *D'Arcy* on cDNA even more strictly, such that the only patent-ineligible cDNA would be that 'used for genetic diagnostic testing ... that rely on a review of the relevant nucleic acid sequence information'.¹³¹ Such a narrow application by the courts and patent examiners would significantly quarantine the ratio of *D'Arcy*, thereby limiting its immediate implications in the field of genetic testing, but only time will tell if this narrow approach is applied in subsequent decisions; at least one commentator appears to think a broader approach is likely.¹³²

3.2 The common law methodology revitalised? A strong approach by the French CJ Court

It is submitted that the plurality's reasoning can be characterised by a strong re-assertion of the constitutional role of the courts in propounding judge-made law where:

Parliament has left it ... to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy.¹³³

This line of reasoning permeates throughout the plurality's judgment.¹³⁴ The

¹²⁸ See: Mark Summerfield, 'Proposed Australian Examination Practice Gives Narrow Interpretation to High Court's Myriad Ruling' on Mark Summerfield, *Patentology.com.au* (18 October 2015) <<http://blog.patentology.com.au/2015/10/proposed-australian-examination.html>>; cf Gene Quinn, USPTO Releases Patent Eligibility Guidance (15 December 2014) IPWatchdog.com <<http://www.ipwatchdog.com/2014/12/15/uspto-releases-patent-eligibility-guidance/id=52663/>>.

¹²⁹ *D'Arcy* [2015] HCA 35 (7 October 2015) 42 [89] (French CJ, Kiefel, Bell and Keane JJ).

¹³⁰ Summerfield, 'Proposed Australian Examination Practice', above n 118.

¹³¹ Shoebridge, above n 112.

¹³² Obranovich, above n 56.

¹³³ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [25] (French CJ, Kiefel, Bell and Keane JJ).

curial genesis of the language (but not the practice)¹²⁴ of 'common law methodology' is in French CJ's judgment in *Apotex*. The relevant section of French CJ's judgment is titled 'Patentability of medical treatments – A "common law" question?'.¹²⁵ In *Apotex*, French CJ ultimately found that methods of medical treatment of human beings were patentable subject matter as it was not logically and normatively coherent to exclude such treatments when applying the manner of manufacture common law methodology.¹²⁶

In support of why the courts should engage in such common law methodological reasoning, French CJ in *Apotex* reasoned that a 'process characteristic' of the common law is case-by-case decision making.¹²⁷ French CJ held that this process:

...is also a characteristic of the application by courts of broadly stated statutory provisions, the interpretation, fleshing out, and application of which the legislature has left to the courts.¹²⁸

This analysis is mirrored by French CJ's holding in *D'Arcy* that s 18(1)(a) of the Act prescribes 'broad textual parameters within which principles of law are to be ascertained, applied and developed'.¹²⁹ Thus *D'Arcy* is authority for the proposition that this justification of the common law method lies in the inherently complex application of these legal principles regarding patentability, which are 'pregnant with rules and applications awaiting discovery'.¹³⁰ It follows that '[c]ase-by-case decision-making' is the best legal mechanism to properly effectuate the finely-balanced 'political compromise'¹³¹ imbued within the 1623 concept of 'manner of manufacture'.¹³² This means that when determining what is patent-eligible subject matter, the deliberately ambulatory nature of the common law concept of manner of manufacture enables Australian courts to

¹²⁴ Ibid 3 [5], 4 [7], 11 [18], 16 [25], 17 [26].

¹²⁵ See ibid 3 [5], where French CJ, Kiefel, Bell and Keane JJ found that the 'case-by-case' development of the concept of 'manner of manufacture' owes its provenance to the reasoning of Dixon CJ, Kitto and Windeyer JJ at 269 in *NRDC* (1959) 102 CLR 252.

¹²⁶ *Apotex* (2013) 253 CLR 284, 296 [8].

¹²⁷ *Apotex* (2013) 253 CLR 284, 319 [50]. The point of distinction between *D'Arcy* and *Apotex* is that in the latter case, French CJ held at [50] that the exclusion of medical treatment was an 'anomaly' as today's use of pharmaceutical drugs for treatment was not essentially non-economic, whereas no such logical or normative anomaly was present on the facts of *D'Arcy*.

¹²⁸ Ibid 302 [18].

¹²⁹ Ibid.

¹³⁰ Ibid.

¹³¹ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [26] (French CJ, Kiefel, Bell and Keane JJ).

¹³² Ibid.

¹³³ Ibid, citing Chris Dent, "Generally Inconvenient": The 1624 *Statute of Monopolies* as Political Compromise' (2009) 33 *Melbourne University Law Review* 415, 451–3.

¹³⁴ The Court in *NRDC* implicitly recognised this in the crucial passages that form part of its ratio decidendi at 269.

maintain the necessary political compromise between private monopoly and public benefit.¹⁶

As such it is submitted that French CJ in *Apotex*, and consequently the plurality in *D'Arcy*, reasoned within the rubric of a 'common law methodology' in order to clearly demarcate the differing functions (and inherent limitations) of both judge-made law and legislation. Such a stark demarcation was necessary in order for the High Court to propound an acceptable methodological, legal framework within which it could legitimately either include or exclude from patentability controversial subject matter, without being the subject of criticism that its reasoning had impermissibly transgressed into the province of the legislature. In support of this proposition, in *D'Arcy*, the plurality strongly emphasised that at issue were claims 1-3, meaning the Court was 'not concerned in this appeal with "gene patenting" generally'.¹⁷

However, as recognised by French CJ in *Apotex*, '[c]hoosing between or balancing competing objectives may overlap with the legislative function'.¹⁸ *D'Arcy* is one such instance of this legitimate zone of overlap. Critique has already been levelled at the Court on this point. In response to *D'Arcy*, Summerfield has submitted that the High Court 'wants [us] to understand that, despite superficial appearances, it is not, in fact, making policy!'.¹⁹ Yet running contrary to Summerfield's line of argument are the factors propounded by the plurality, and their Honours' express approval of '[p]urposive and consequentialist' ²⁰ considerations when reasoning using the common law methodology. These both suggest, in fact, the Court is properly demarcating its role and function in concert with the statutory framework prescribed by the *Patents Act 1990* (Cth).

The key issue in contention is the identification of the point at which the Court is overtly and impermissibly exercising a legislative function, in contrast to the legitimate discharge of its judicial law-making function informed by policy factors. In *Apotex*, French CJ addressed this issue by delineating at least one indicator of when this point has been transgressed, namely when the justiciable matter involves 'large questions of public policy and reconciliation of interests in tension'.²¹ It is submitted that the plurality in *D'Arcy* did not transgress too far and correctly discharged its judicial function according to the common law methodology because it identified the precise point of transgression. It did so by expanding on French CJ's reasoning in *Apotex* and enumerating three further indicators. These indicators of the point of transgression into legislative function are when the claim involves: (i) the creation of important rights as against the world; (ii) far-reaching questions of public policy; and (iii) affects

¹⁶ See further Dent, above n 143, 444–5.

¹⁷ *D'Arcy* [2015] HCA 35 (7 October 2015) 24 [37] (French CJ, Kiefel, Bell and Keane JJ).

¹⁸ *Apotex* (2013) 253 CLR 284, 317 [45].

¹⁹ Summerfield, 'Australian High Court Nukes Biotech Industry from Orbit', above n 16.

²⁰ *D'Arcy* [2015] HCA 35 (7 October 2015) 15 [24] (French CJ, Kiefel, Bell and Keane JJ).

²¹ *Apotex* (2013) 253 CLR 284, 316 [44].

the balance of important conflicting interests.¹⁸¹ The plurality's first and fourth new factors explicitly incorporate these considerations; both direct lower courts and patent examiners to consider whether the grant of a patent monopoly appropriately resides in the province of the legislature for claims at the borderline.¹⁸² On this point, Lai articulates a theme evident from the plurality's common law methodological reasoning in *D'Arcy*,¹⁸³ namely that Australia's 'higher courts need to set clearer precedents'¹⁸⁴ in order to perform their function of making judge-made law by interpreting statute.¹⁸⁵

As such it is submitted that the plurality's strong demarcation of the role of the courts and legislature in Australian patent law clarifies the conceptual framework within which decision-makers must now operate when determining patent-eligibility for borderline subject matter. As such, the plurality's use of the common law methodology, under the rubric of manner of manufacture, is apt and appropriate legal reasoning which provides judicial guidance to lower courts and patent examiners. Future cases will ultimately judge the efficacy of this conceptual framework.

3.3 The purposive factorial approach: Introduction of uncertainty into the law with respect to other types of borderline subject matter?

Commentary following *D'Arcy* appears somewhat united on the point that it introduces a degree of uncertainty into Australian patent law for other types of subject matter at the borderline of patentability.¹⁸⁶ The most prominent example is a computer-implemented business method. Whether such an invention is patentable subject matter has been recently considered by two Full Federal Court decisions. First, *Research Affiliates LLC v Commissioner of Patents*¹⁸⁷ and second, *RPL*¹⁸⁸ (as discussed above in Part 2.1.3).

In *Research Affiliates* the Full Federal Court held that an investment index that was computer implemented was not patentable because it was an 'abstract idea', a scheme 'merely implemented in a computer' but not directed to the

¹⁸¹ *D'Arcy* [2015] HCA 35 (7 October 2015) 4 [7] (French CJ, Kiefel, Bell and Keane JJ).

¹⁸² *Ibid* 18 [28].

¹⁸³ *Ibid*.

¹⁸⁴ Dr Jessica Lai, 'Gene-related patents in Australia and New Zealand: Taking a step back' (2015) 25 *Australian Intellectual Property Journal* 181, 193

¹⁸⁵ *Ibid*.

¹⁸⁶ See above nn 8 and 56. See also Clayton Utz, *High Court goes cold on patentability of isolated nucleic acid* (8 October 2015) ClaytonUtz.com <http://www.claytonutz.com/publications/news/201510/08/high_court_of_australia_goes_cold_on_patentability_of_isolated_nucleic_acid.page>; Trevor Davies and Linda Govenlock, 'High Court unanimously finds isolated genetic material not patentable' on Allens Linklaters, *Scintillia: Intellectual Property at Allens* (8 October 2015) <<http://allensip.blogspot.com.au/2015/10/high-court-unanimously-finds-isolated.html>>.

¹⁸⁷ (2014) 227 FCR 378 ('*Research Affiliates*').

¹⁸⁸ [2015] FCAFC 177 (15 December 2015).

improvement of 'what might broadly be called "computer technology"'.¹⁵⁹ In so finding, and applying the manner of manufacture jurisprudence, Kenny, Bennett and Nicholas JJ reasoned in terms somewhat similar to the plurality in D'Arcy. Most similarly the Full Court held that the subject matter of the invention was to be considered as a 'matter of substance and not merely as a matter of form'.¹⁶⁰

However, critical to the reasoning of the Full Court was a hitherto orthodox interpretation of NRDC, as evident in the statement that patentability was to be determined in accordance with the 'principles that have been developed and explained so well in NRDC'.¹⁶¹ An antecedent step in the Full Court's reasoning¹⁶² was that their Honours' determined that the investment index was a method which did not have an 'artificial effect falling squarely within the true concept of what must be produced by a process'.¹⁶³ As such it could not be the proper subject of letters patent. This antecedent step correctly applied NRDC orthodoxy and did not consider purposive factors. The Full Federal Court's decision in Research Affiliates informs the reasoning of RPL which fell for determination post-D'Arcy.

As discussed further above in Part 2.1.3, the Full Federal Court's appellate decision in RPL,¹⁶⁴ handed down on 11 December 2015, was a case that considered the subject matter at the borderline of patentability post-D'Arcy. In RPL, Kenny, Bennett and Nicholas JJ unanimously held that the computer-implemented business method claim in suit did not 'involve a new class of claim involving a significant extension of the concept of manner of manufacture'.¹⁶⁵ Therefore it was held that the factors enumerated by the plurality in D'Arcy were not engaged, meaning the factors' 'wide-ranging considerations'¹⁶⁶ did not have to be addressed by the Court in RPL. However, the key point is that Kenny, Bennett and Nicholas JJ, in the next sentence, stated in a piece of obiter dicta that it was 'fortunate'¹⁶⁷ the factors did not have to be addressed 'because the Court does not have the bases for analyses of this kind'.¹⁶⁸

It is submitted that one reading of this obiter dicta is simply that the Full Federal Court did not have 'any evidence'¹⁶⁹ before it to adequately assess the claim against all of the plurality's factors, had it been required to do so. Yet this

¹⁵⁹ *Research Affiliates* (2014) 227 FCR 378, 403 [119].

¹⁶⁰ *Ibid* 401 [107]. See also *D'Arcy* [2015] HCA 35 (7 October 2015) 41 [88] (French CJ, Kiefel, Bell and Keane JJ).

¹⁶¹ *Research Affiliates* (2014) 227 FCR 378, 403 [117].

¹⁶² *Ibid* 403 [116].

¹⁶³ *Ibid*.

¹⁶⁴ [2015] FCAFC 177 (15 December 2015).

¹⁶⁵ *Ibid* [119].

¹⁶⁶ *Ibid*.

¹⁶⁷ *Ibid*.

¹⁶⁸ *Ibid*.

¹⁶⁹ *Ibid*.

author further submits that, by employing a degree of divination to read 'judicial tea leaves',¹⁷⁰ this obiter dicta suggests that the Full Federal Court may also be interpreted as implying the plurality's factorial approach is too wide and introduces a degree of uncertainty into the law. Such an argument would be based on the proposition that it is unclear how much weight is then to be accorded to one factor over another.

A direct counter to this argument is an explicit recognition by the plurality in *D'Arcy* that factors '3, 4 and 6 are of primary importance.'¹⁷¹ However given there are only four new factors, such differentiation by the plurality does not resolve the issue. Regardless of what the Full Federal Court in *RPL* meant by its statement that it did not have the requisite 'bases for analysis', we are still waiting to see an application of the plurality's factors for a new class of claim at the borderline of patentability. In January 2016 *RPL* Central filed in the High Court requesting special leave to appeal the Full Federal Court's decision.¹⁷²

The fact that the Full Federal Court in *RPL* did not apply the new factors may give rise to a legitimate concern regarding uncertainty in the law. This is that lower courts may adopt an extended and strained interpretation of *D'Arcy* in order to avoid invoking and subsequently applying the new factors. That is, courts may expand the meaning and operation of the 'existing principle'¹⁷³ that the plurality held must be considered before the new factors are enlivened for consideration. This could lead to the new factors being rendered of lesser importance than the significance accorded to them by the plurality. Therefore the threshold of what constitutes a 'significant new application or extension'¹⁷⁴ of the manner of manufacture concept, that is capable of enlivening the factorial approach, may be an issue for the High Court if it grants *RPL* Central special leave to appeal.

4 Conclusion

D'Arcy has provided long-awaited guidance on the patentability of human genes in Australia, and in doing so, has propounded a new approach to determining whether subject matter is patentable. The plurality's approval of the approach laid down in *NRDC* has confirmed that the inquiry is one not subject to the 'fetters of an exact verbal formula'¹⁷⁵ but is rather directed to the

¹⁷⁰ Anthony Gray, 'Good faith in Australian Contract Law after *Barker*' (2015) 43 *ABLR* 358, 360.

¹⁷¹ *D'Arcy* [2015] HCA 35 (7 October 2015) 15 [24], 19 [28] (French CJ, Kiefel, Bell and Keane JJ).

¹⁷² See <http://www.fedcourt.gov.au/publications/judgments/hca-special-leave>. See further Mark Summerfield, 'RPL Central Requests Leave to Appeal Software Patent Eligibility Ruling to High Court of Australia' on Mark Summerfield, *Patentology.com.au* (31 January 2016) <<http://blog.patentology.com.au/2016/01/rpl-central-requests-leave-to-appeal.html>>.

¹⁷³ *D'Arcy* [2015] HCA 35 (7 October 2015) 18 [28] (French CJ, Kiefel, Bell and Keane JJ).

¹⁷⁴ *Ibid.* See also *RPL* [2015] FCAFC 177 (15 December 2015) 36 [119].

¹⁷⁵ *NRDC* (1959) 102 CLR 252, 271 (Dixon CJ, Kitto and Windeyer JJ).

true nature of 'manner of manufacture'.¹⁶ This true nature has twin arms – the concepts of 'patent and invention'¹⁷ which lie at the heart of the plurality's reasoning. This approach is a rearticulation of the approach laid down by the Court in *NRDC*, illustrating the durability and longevity of the reasoning of that decision. French CJ, Kiefel, Bell and Keane JJ went further than a rejection simpliciter however, rising to Sherman's call for the 'High Court to reflect on what is meant by 'invention', and to consider the criteria that we might use to decide whether something is patent-eligible'.¹⁸ Their Honours did so by propounding a set of factors for use when subject matter is at the borderline of patentability. As part of a methodological, legal framework for determining patentability, these factors are a welcome exercise of the Court's law-making function. Despite initial criticism (and perhaps subject to the appeal in *RPL*) the factors are likely to enable decision-makers to fully give effect to the purposes of the Act outside the rigid binary dichotomy of 'artificially created state of affairs' of 'economic significance'.

It is further submitted that Gageler and Nettle JJ's reasoning on a threshold requirement of inventiveness does not form part of *D'Arcy*'s ratio. To incorporate this reasoning into *D'Arcy*'s ratio may introduce a slight degree of uncertainty into the requirements of Australian patent law, as the High Court in *Lockwood* seemingly disapproved of any ongoing role for a separate threshold concept of inventiveness. Gageler and Nettle JJ's reasoning on the similarity between the Australian concept of artifice and the US product of nature doctrine does not provide adequate judicial guidance for Australian courts and patent examiners.

Finally, it is submitted that outside of the immediate effect of the decision on the patentability of isolated gene sequences, the two most important consequences of *D'Arcy* are for other types of subject matter at the borderline of patentability and the effect of the plurality's reasoning under the rubric of a common law methodology. Both require further judicial exposition to fully determine their effects. Perhaps the High Court may take the opportunity presented by *RPL* Central's special leave application to further expound how the factorial approach to patentability applies, and the precise point at which the new factors are enlivened.

¹⁶ *Patents Act 1990* (Cth) s 18(1)(a).

¹⁷ *D'Arcy* [2015] HCA 35 (7 October 2015) 17 [26] (French CJ, Kiefel, Bell and Keane JJ).

¹⁸ Sherman, above n 23, 144.