NIPT: Not Inherently Patentable? An Analysis of the Patent-Eligibility of Prenatal Diagnostic Patents

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Abstract

This paper analyses the patent-eligibility of non-invasive prenatal testing ('NIPT'), an issue which was considered by the Federal Court of Australia in 2018, with judgment set to be handed down in 2019. NIPT represents an important development in prenatal healthcare and has been taken up rapidly by clinical laboratories worldwide. In the context of Australian patent law, the Court's verdict on the patentability of NIPT may have important ramifications for the patent-eligibility of methods of genetic testing more broadly. The paper begins with a discussion of the current requirements for patentable subject matter in Australia. This is followed by an analysis of these requirements in the context of the NIPT claims to be considered by the Federal Court. Included in this analysis is a discussion on whether NIPT is a 'new class of claim' and whether the 'other factors' test set out in D'Arcy v Myriad Genetics *(2015) 258 CLR 334 ('*Myriad*') precludes patentability. The paper concludes that it is likely that, based on the recent treatment of Myriad by the Federal Court in* Meat and Livestock Ltd v Cargill Inc *[2018] FCA 51 (9 February 2018), NIPT will be considered patent-eligible subject matter. However, this does not preclude the Court from finding the patent invalid on other grounds, nor does it prevent the decision from being overturned on appeal.*

1 Introduction

Recent advances in genomics have allowed scientists to develop diagnostic tools for a range of genetic disorders and diseases, providing significant benefits to the community. The issue of gene patenting has attracted attention in Australia, the High Court of Australia recently ruling naturally occurring DNA sequences non-patentable.[1] However, the High Court did not rule on the patentability of

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1 *D'Arcy v Myriad Genetics* (2015) 258 CLR 334. For commentary on the patentability of genetic materials see: M M Hopkins et al, 'DNA Patenting: The End of an Era?' (2007) 25 *Nature Biotechnology* 185–187; I Huys, G Matthijs and G Van Overwalle, 'The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods' (2012) 13 *Nature Reviews Genetics* 441–8; O A Jefferson et al, 'Transparency Tools in Gene Patenting for Informing Policy and Practice' (2013) 31 *Nature Biotechnology* 1086–1093; G D Graff et al, 'Not Quite a Myriad of Gene Patents' (2013) 31 *Nature Biotechnology*

methods for genetic diagnosis or methods involving the use of nucleic acid sequences. Before the High Court's decision, commentators were confident of the patentability of genetic diagnostic tests.[2] However, the decision has raised uncertainty as to the position in Australia.

The patentability of non-invasive prenatal testing ('NIPT') — a genetic diagnostic tool — is set to be considered in a case before the Federal Court of Australia, *Sequenom v Ariosa Diagnostics,* this year. In 2016, Sequenom commenced patent infringement proceedings, claiming that Ariosa Diagnostics and Sonic Healthcare's Harmony non-invasive prenatal test infringes its patent (Australian Standard Patent No 727919). The respondents filed cross-claims for invalidity, including on the ground of lack of patentable subject matter. The patent at the centre of the dispute claims an invention that provides a 'detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of nucleic acid of foetal origin in the sample.' The claims of the patent cover prenatal diagnoses for determination of both maternal and foetal conditions or characteristics which relate to either the foetal DNA itself or the quantity or quality of that DNA in the maternal serum or plasma. Uses include sex determination, detection of foetal abnormalities like chromosomal aneuploidies or mutations, and detection of pregnancy-associated conditions which result in higher or lower amounts of foetal DNA being present, such as pre-eclampsia. The discovery presents an important improvement in prenatal healthcare. Conventional prenatal screening methods for detecting foetal abnormalities and for sex determination use invasive techniques such as amniocentesis and chorionic villus sampling. These techniques present risks to both mother and child. The use of foetal DNA in maternal blood for non-invasive prenatal diagnoses presents an alternative that is largely free of these risks.[3]

Australia is the latest jurisdiction to consider the validity of this patent, after the US and UK came to opposite conclusions as to the inherent patentability of its subject matter.[4] The US Federal Circuit Court decided that a method for non-invasive prenatal testing was not patentable subject matter, as the method began and ended with a naturally occurring phenomenon. The US Supreme Court subsequently refused to grant certiorari to hear an appeal, and an *en banc* hearing by the Federal Court was also refused. In contrast, the High Court of Justice of

404–10; John Liddicoat, Tess Whitton and Dianne Nicol, 'Are the Gene Patent Storm Clouds Dissipating? A Global Snapshot' (2015) 33 *Nature Biotechnology* 347–52.

2 See Charles Lawson, 'Patenting Genetic Diagnostic Methods: NGS, GWAS, SNPs and Patents' (2015) 22 *Journal of Law and Medicine* 846.

3 See D Bianchi and L Wilkins-Haug, 'Integration of Noninvasive DNA Testing for Aneuploidy into Prenatal Care: What Has Happened since the Rubber Met the Road?' (2014) 60 *Clinical Chemistry* 78; Jeanne Snelling, Nikki Kerruish and Jessie Lenagh-Glue, 'Non-Invasive Prenatal Testing: The Problem with "Fast Cars"' (2016) 24 *Journal of Law and Medicine* 203.

4 *Ariosa Diagnostics Inc v Sequenom Inc*, 788 F 3d 1371 (3rd Cir, 2015) ('*Ariosa*').

the Business and Property Courts of England and Wales held that the methods for prenatal testing and diagnosis were patentable subject matter.[5] However, the patent was only partially valid, because it failed to satisfy other technical patent criteria.[6]

This paper evaluates the inherent patentability of methods for NIPT in Australia, based on the test for patentable subject matter as set out in *National Research Development Corporation v Commissioner of Patents*,[7] and re-emphasised in *D'Arcy v Myriad Genetics*.[8] The interpretation of the plurality's decision in *Myriad* by lower courts will be considered, particularly the decision of Justice Beach in *Meat and Livestock Ltd v Cargill Inc*.[9] This case is pertinent to the discussion on the patentability of NIPT in Australia for three reasons. First, it is one of the only cases that discuss the 'other factors' test set out in *Myriad*. Second, the case concerned the patentability of genetic diagnostic methods in bovines, which is conceptually similar to NIPT. Finally, Justice Beach is the presiding judge for the upcoming Federal Court hearing on the patentability of NIPT.

Part 2 of this paper gives a brief outline of the test for patentable subject matter in Australia, from the seminal case of *NRDC*, to *Myriad* and decisions that have considered *Myriad*, including *Cargill*. Part 3 outlines the claims in Sequenom's NIPT patent and applies the *NRDC* test to those claims. Part 4 considers whether the claims fall under a 'new class of claims' and applies the 'other factors' test set out by the plurality in *Myriad*. It is likely that the claims in Sequenom's patent will be considered patent-eligible subject matter. However, this does not preclude the claims from being rejected or revised on the basis of the other criteria for patentability.

2 *Patentable Subject Matter in Australia*

2.1 Manner of Manufacture

The test for patentable subject matter in Australia is set out in s 18(1)(a) of the *Patents Act 1990* (Cth). An invention must be a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies 1624,* 21 Jac 1 c 3. The leading authority on the interpretation of 'manner of manufacture' is *NRDC*, where the High Court held that 'manner of manufacture' could not be subject to a precise formula.[10] The

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5 *Illumina Inc v Premaitha Health PLC* [2017] EWHC 2930 (PAT) (*'Illumina Inc*').

6 Ibid. Claims 1, 2, 5 and 7 of patent EP (UK) 0,994,963 were invalid for lack of enabling disclosure by the Priority Document.

7 (1959) 102 CLR 252 ('*NRDC*').

8 (2015) 258 CLR 334 ('*Myriad*').

9 [2018] FCA 51 (9 February 2018) ('*Cargill*').

10 (1959) 102 CLR 252, 271: The Court held that any attempt to state the ambit of s 6 by precisely defining 'manufacture' is bound to fail.

Court held that the requirement was satisfied where an invention included an artificially created state of affairs and had economic utility.[11] The High Court noted that the 'process must be one that offers some advantage which is material, in the sense that the process belongs to a useful art … and its value to the country is in the field of economic endeavour'.[12] *NRDC* concerned the patentability of a novel method for applying a known herbicide to crop areas. The artificially created state of affairs was the observable difference between the comparative growth of weeds and crops on sown land. This process of weed reduction was clearly of economic utility in Australia.[13]

Over time, Australian courts treated 'artificial state of affairs' and 'economic utility' as a two-limb test for satisfaction of the 'manner of manufacture' requirement.[14] The test was considered in relation to business methods in *Grant v Commissioner of Patents*,[15] where the Full Federal Court held that a mere scheme, abstract idea or information is not patentable; there must be a physical consequence, concrete effect, phenomenon, manifestation or transformation.[16] The High Court applied the test set out in *NRDC* in a medical context in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd.*[17] Four members of the Court, with Hayne J dissenting, held that a method of medical treatment was patentable subject matter where that method involved a new use of a known pharmaceutical drug. However, Crennan and Kiefel JJ in their joint judgment and Gageler J separately raised doubt over the patentability of methods of treatment more broadly; the question of whether or not 'the activities or procedures of doctors (and other medical staff) when physically treating patients' were manners of manufacture remained unresolved.[18] The decision in *Apotex* is not directly applicable to in vitro methods of diagnosis, however, because such methods do not involve the physical (in vivo) treatment of patients per se.

2.2 *D'Arcy v Myriad Genetics Inc* (2015) 258 CLR 334

The most recent applicable High Court case to the patentability of NIPT is *Myriad*, where the Court unanimously held that isolated naturally-occurring nucleic acid sequences were not patentable subject matter.[19] A joint judgment of French CJ,

11 Ibid 276.

12 Ibid 275.

13 Ibid 277.

14 See *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260, 295 ('*CCOM Pty Ltd*').

15 (2006) 69 IPR 221.

16 Ibid 228.

17 (2013) 253 CLR 284.

18 Ibid 384, 390.

19 Isolated naturally-occurring nucleic acid sequences are distinguishable from sequences that cannot be found in nature (such as sequences with mutations that are not possible without human intervention). The Court did not limit their analysis to

Kiefel, Bell and Keane JJ ('the plurality') made it clear that the concept manner of manufacture is to be developed on a case-by-case basis.[20] Their Honours reiterated the test developed from *NRDC*, stating the test as:

1. Whether the invention claimed is for a product made or a process producing an outcome as a result of human action; and

2. Whether the invention as claimed has economic utility.[21]

The plurality acknowledged that, in most cases, this two-limb test will be sufficient to establish patentability.[22] However, where the claim in substance relates to a new class involving a significant new application or extension of the principles of patentability, the Court should consider other factors.[23] These factors were listed as follows:

3. Whether patentability would be consistent with the purposes of the Act and, in particular:

    3.1. whether the invention as claimed, if patentable under s 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;

    3.2. whether the invention as claimed, if patentable under s 18(1)(a), could, because of the content of the claims, have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;

    3.3. whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.

4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability.

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genomic or native DNA, but included any nucleic acid sequences, including complementary DNA ('cDNA'). Complementary DNA includes exon sequences encoding proteins, which are generated in the laboratory to exclude introns (noncoding regions of the DNA). The plurality in *Myriad* reached the same conclusion in respect of cDNA because it 'is synthesized but replicates a naturally occurring sequence of events': at [89].

20 *Myriad* (n 8) 339.

21 Ibid 351.

22 Ibid.

23 Ibid.

5. Relevantly to Australia's place in the international community of nations:

    5.1. Australia's obligations under international law;

    5.2. the patent laws of other countries.

6. Whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by the legislature.[24]

Factors 3, 4 and 6 are of primary importance, according to the plurality, while factor 5 is of secondary significance.[25] However, Gageler and Nettle JJ in their joint judgment, and Gordon J separately did not expressly adopt this 'other factors' approach. The importance of the factors set out in *Myriad* for 'new categories' of patents has been debated. Some commentators argue that these factors constitute a new test, additional to that in *NRDC*,[26] while others argue that the decision re-emphasises the *NRDC* test and the fact that it was never intended to be rigidly applied.[27] Lawson suggests that once the High Court decided genes were not man-made according to the *NRDC* test, the factorial test might be considered non-binding dictum.[28] However, Dreyfuss, Nielsen and Nicol argue that this overlooks the fact that the plurality did not rule out the possibility that information encoded in DNA *might* be patentable.[29] In cases where a finding of patentability is possible, a finding that a new class of claim is implicated is likely, and the factorial approach would then be applied.[30] Indeed, the 'other factors'

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24 Ibid.

25 Ibid.

26 Jessica Lai, 'Gene-Related Patents in Australia and New Zealand: Taking a Step Back' (2015) 25 *Australian Intellectual Property Journal* 181, 193; Timothy Fitzgerald, Declan McKeveney and Mark Egerton, 'Developments in the Patentability of Biotechnology in Australia and the United States – Part 1' (2016) 29 *Australian Intellectual Property Law Bulletin* 222; Tanya Obranovich, 'Biotechnology and Patentability: Navigating Unchartered Waters', *Managing Intellectual Property* (15 February 2016) <http://www.managingip.com/Article/3523811/Biotechnology-and-patentability-navigating-unchartered-waters-in-Australia-and-the-US.html>.

27 William Bartlett, '*D'Arcy v Myriad Genetics Inc* [2015] HCA 35: The Plurality's New Factorial Approach to Patentability Rearticulates the Question Asked in *NRDC*' (2015) 24(1) *Journal of Law, Information and Science* 120; Jane Nielsen and Dianne Nicol, 'Patent Law and the March of Technology – Did the Productivity Commission Get It Right?' (2017) 28 *Australian Intellectual Property Journal* 4.

28 Charles Lawson, 'Patenting Nucleic Acid Sequences: More Ambiguity from the High Court?' (2018) 25 *Journal of Law and Medicine* 741, 749–50.

29 Rochelle C Dreyfuss, Jane Nielsen and Dianne Nicol, 'Patenting Nature — A Comparative Perspective' (2018) unpublished manuscript, on file with author.

30 Ibid. The plurality applied the factorial approach as well as the two-limb test, and concluded that this also indicated lack of inherent patentability.

test is a way to deal with modern technologies. It draws attention to concerns of patenting in these areas and requires the court or patent office to engage with the social and proprietary implications of either granting or denying a monopoly.

The plurality emphasised that whether a claim is patentable is a matter of substance, not form.[31] In substance, Myriad's claims were to information contained in the isolated nucleic acid sequence (the BRCA1 gene). This information was discerned rather than 'made' by human intervention.[32] The 'other factors' pointed towards a denial of patentability; the patent could have a stifling effect on innovation as the patent could be infringed without the infringer being aware they have done so.[33] Myriad's claims were broad enough to include the application of any process for isolating a patient's DNA sequence. This would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the BRCA1 protein.[34]

The judgment by Gageler and Nettle JJ has been treated with varied degrees of significance in commentary and case law.[35] Gageler and Nettle JJ identified the question of patentability as being whether the subject matter of the claim 'is sufficiently artificial' to be regarded as patentable.[36] Their Honours held that '[i]t is necessary that the inventive concept be seen to make a contribution to the essential difference between the product and nature'.[37] There must be a 'quality of inventiveness which distinguishes it from a mere discovery or observation of a law of nature'.[38] The presence or absence of the mutations and polymorphisms in the nucleic acid was the discovery and the 'antithesis of a man-made artificial state of affairs'.[39] Some commentators emphasise the distinction made by Gageler and Nettle JJ between inventiveness and mere discovery, arguing that it introduces a product of nature doctrine into Australian patent law.[40] However,

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31 *Myriad* (n 8) 371.

32 Ibid 340.

33 Ibid 372.

34 Ibid 340.

35 *Cargill* (n 9).

36 *Myriad* (n 8) 382.

37 Ibid.

38 Ibid 383.

39 Ibid 394.

40 Peter MacFarlane and Betty Kontoleon, 'Some Legal Issues Regarding the Patenting of Human Genetic Materials' (2016) 24 *Journal of Law and Medicine* 181; Cheng Lim Saw, 'Whither Gene Patenting and the Patenting of Diagnostic Methods Post-*Mayo* and *Myriad*? The Need for Certainty in Navigating the High Seas of Policy' (2016) 8 *Law, Innovation and Technology* 207; see also Rebekah Gay and Tom Gumley 'Patents: *D'Arcy v Myriad Genetics*: What Next for Gene Patents in Australia' (2015) 18 *Law Society of NSW Journal* 70, 72.

this distinction did not form any part of the plurality or Justice Gordon's reasoning, and it has since been distinctly rejected by the Federal Court.[41] As such, the inventiveness/discovery distinction will not be discussed at length throughout this paper, only in the context of the factor 5, the applicability of international approaches.

2.3 Post-*Myriad* Decisions

After *Myriad* was handed down, the Australian Patent Office released a Practice Note and made changes to the Manual of Practice and Procedure, which now states that isolated nucleic acid sequences are not patent-eligible subject matter.[42] The Practice Note also excludes from patent-eligibility cDNA, synthetic nucleotide sequences, probes, primers and isolated interfering/inhibitory nucleotide sequences that merely replicate genetic information of naturally occurring organisms.[43] This approach is based on the plurality's holding at [89] that any full or partial sequence that replicates a naturally occurring sequence constitutes information and is not patentable.

The guidelines and the findings in *Myriad* have subsequently been applied in Patent Office decisions considering sequence information. In *Cargill Incorporated v Dow Agro Sciences LLC*,[44] a fungal sequence was held to be patent eligible because it had been codon-optimised (altered in a laboratory to contain a

41 In *Cargill* (n 9), MLA argued that Gageler and Nettle JJ in *Myriad* introduced a new threshold test of inventiveness. This argument was strongly rejected by Justice Beach. Justice Beach stated that even if Gageler and Nettle JJ had introduced a new test, there were two binding authorities against taking such an approach: *Myriad* (n 8) and *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 ('*Lockwood No 2*'). When commenting on *Microcell*, the court in *Lockwood No 2* said that [*Microcell*] does not involve a separate ground of invalidity or a discrete 'threshold' test. Beach J in *Cargill* noted that Gageler and Nettle JJ applied *Lockwood No 2*, confirming his doubts as to whether their Honours intended to introduce a threshold requirement. Justice Gordon in *Myriad* at [223] also stated that the 'distinction between discovery and invention is not precise enough to be other than misleading'. A similar sentiment was given by the High Court in *NRDC* at 264.

42 Australian Patent Office, *Manual of Practice and Procedure: 2.9.2.6 Nucleic Acids and Genetic Information* <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm>; Australian Patent Office, 'Examination Practice Following the High Court Decision in *D'Arcy v Myriad Genetics Inc*', *IP Australia* (15 December 2016) <https://www.ipaustralia.gov.au/sites/g/files/net856/f/examination_practice_following_the_high_court_decision_in_darcy_v_myriad_genetics_inc.pdf>.

43 Fitzgerald, McKeveney and Egerton discuss this guidance note, arguing that it indicates a narrow view of the exclusions set out by the High Court: Timothy Fitzgerald, Declan McKeveney and Mark Egerton, 'Developments in the Patentability of Biotechnology in Australia and the United States – Part 2' (2017) *Intellectual Property Law Bulletin* 22.

44 (2016) APO 43 (5 July 2016).

sequence of nucleotides that did not occur naturally in the fungus). The Delegate did not consider the subject matter to be near the boundaries of patentability, and therefore did not apply the other factors set out in *Myriad*.[45] In *Arrowhead Research Corporation*, interfering RNA was found to be patent-eligible, because the particular nucleotide sequences claimed were not crucial and therefore not the substance of the invention.[46] Instead, the capacity provided by the invention to identify specific target sequences was the crucial component.[47] In *Sun Pharmaceuticals v Tasmania Alkaloids*,[48] the mutagenesis of poppy seeds and screening of progeny plants to produce poppies with a higher output of codeine was patent-eligible. The Delegate found no evidence that a mutation producing levels of codeine observed in the plants had or would be naturally occurring.[49] Hence, the genetic code of the plants, and the information it contained, was not naturally occurring.

The Practice Note also sets out when the 'other factors' test set out by the plurality in *Myriad* should be applied, stating that the test should only be applied where a claim involves a 'significant new application or extension of the principles of patentability'.[50] Claims relating to technical subject matter that have not previously been rejected must be assessed according to the *NRDC* requirements.[51] The Practice Note states that subject matter that falls into established categories of patent-eligibility include recombinant or isolated proteins, pharmaceuticals and other chemical substances, methods of treatment, methods of applying herbicides and applications of computer technology.[52] Until recently, the judiciary have seemed reluctant to apply the other factors set out in *Myriad*.[53] The applicability of the *Myriad* 'other factors' test was considered in *Commissioner of Patents v RPL Central Pty Ltd*[54] and *Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC*,[55] but the other factors were not applied because the Court found that the cases did not involve new classes of claims. This reluctance of the judiciary to consider the test has led some commentators to criticise the High Court's approach in *Myriad*, arguing that it has led to uncertainty.[56] However, the 'other

45 Ibid [47].

46 [2016] APO 70 (13 October 2016) [19]–[29].

47 Ibid.

48 [2018] APO 7 (31 January 2018).

49 Ibid [69]–[71].

50 Australian Patent Office, 'Examination Practice Following the High Court Decision in *D'Arcy v Myriad Genetics Inc*' (n 42).

51 Ibid.

52 Ibid.

53 See Nielsen and Nicol (n 27).

54 (2015) 238 FCR 27, [119] (regarding an implemented business method claim).

55 (2016) 117 IPR 252 (regarding claims to chemical and pharmaceutical compounds).

56 See Lai (n 26) 193; Lawson (n 28) 749.

factors' test has since been applied by Justice Beach in *Meat & Livestock Australia v Cargill,*[57] albeit as obiter, in relation to a method patent. Indeed, Justice Beach highlighted the uncertainty surrounding the 'other factors' test in his judgment.[58] This is discussed further below.

2.4 *Meat and Livestock Ltd v Cargill Inc* [2018] FCA 51

Cargill required the Federal Court to consider the patent-eligibility of a series of method claims for identifying bovine traits from nucleic acid samples using single nucleotide polymorphisms ('SNPs'), which resulted in 'managing, selecting, breeding and cloning cattle'.[59] The SNPs were variants of specific nucleotides in the bovine genome that are linked to particular traits, such as meat tenderness, milk production and disease resistance. Livestock breeders can screen for these SNPs when deciding whether to breed particular cattle, in the hope of obtaining the desired traits in the next generation. The patent application (No 2010202253), entitled 'Compositions, Methods and Systems for Inferring Bovine Traits', was filed in 2010 by Branhaven LLC and Cargill Inc. Meat and Livestock Australia ('MLA') challenged the claims under Australia's pre-grant opposition procedure, arguing that the claims failed to satisfy the manner of manufacture test. The Delegate decided that MLA's opposition failed on all grounds, except for one ground of lack of clarity.[60] One product claim to an isolated nucleic acid also failed for lack of patentable subject matter.[61] This decision was appealed to the Federal Court and upheld by Justice Beach.

MLA claimed lack of patentable subject matter on the basis that there was nothing man-made and, therefore, no artificially created state of affairs. According to MLA, the inventors merely discovered naturally occurring bovine SNPs and the naturally occurring correlation between the SNPs and bovine traits.[62] This discovery was achieved using known standard techniques. They argued the claims did not fall within the boundaries of existing patentable subject matter, and the potential chilling effect of granting the monopoly and the desire for cohesion in patent law denied an extension of 'manner of manufacture' to include the claims.[63]

Justice Beach noted that there was some indication in the plurality's judgment in *Myriad* that, because they were not addressing method claims, by implication

57 *Cargill* (n 9) [386]–[501].

58 Ibid [391].

59 Ibid [1]–[7].

60 *Meat & Livestock Australia Limited and Dairy Australia Limited v Cargill, Inc and Branhaven LLC* [2016] APO 26.

61 Ibid.

62 *Cargill* (n 9) [386].

63 Ibid.

such claims might be more readily viewed as being within the existing boundaries of patentable subject matter.[64] In regard to Cargill's method claims, Justice Beach distinguished *Myriad* because the claims in *Cargill* were not entirely directed to naturally occurring genetic information.[65] The case did not just involve looking at a claim to a nucleic acid molecule and considering whether the invention should be characterised as a chemical structure or as genetic information. Nor did the case just deal with claims that involved the discovery of an objectively observed correlation between genotype and phenotype. This was only the starting point for the analysis of the claims.[66] His Honour held that the claims in issue involved the practical application of the genetic information to a particular use. The claims gave rise to an artificially created state of affairs because they involved the taking of a sample and analysing that sample to identify SNPs associated with particular traits of interest.[67] Thus, the claims were 'within the plain vanilla concept of manner of manufacture as outlined in *NRDC* and *Myriad*' and were not at the boundaries of patentable subject matter.[68]

When commenting on the 'other factors' test, Justice Beach raised a number of questions that remain unanswered as to how the test should be applied:[69]

- Is this a policy-driven approach to the assessment of patentability for cases on or beyond the existing boundaries?
- Is this approach properly characterised as purposive or consequentialist or both?
- Is there a clear threshold to justify moving into such a space, and if so, what? In some cases, reasonable minds might differ as to whether a case is within or outside of existing boundaries.
- Has the plurality just been more transparent about the considerations to be taken into account when assessing whether new or difficult subject matter is proper?
- How are factors 3.1 and 3.2 to be ranked and weighted with factor 3.3?
- What is the scope of factor 3.3?
- How are factors 3, 4 and 6 ranked and weighted as between themselves?

64 Ibid [409].

65 Ibid [426].

66 Ibid [13].

67 Ibid [455].

68 Ibid [428].

69 Ibid [391].

- How is factor 5 to be weighted with the other factors?
- Is a judge obliged to consider each and all of the factors or only some?

Justice Beach considered that it was not necessary for him to answer any of these questions, because the claims did not constitute a new class of claim involving a significant new application of or extension of the concept of manner of manufacture.[70] Nevertheless, Beach J went on to consider the other factors, without answering the questions above. In his Honour's view, all of the factors pointed towards patentability.[71] His Honour rejected MLA's argument that upholding patentability would lead to inconsistency with *Myriad*, as the claims were not directed to genetic information per se but rather its use.[72] When considering coherency with foreign law, Beach J noted that he was unable to undertake such an assessment by considering only 'cherry-picked jurisprudence from one jurisdiction'.[73] Finally, Beach J held that the breadth of the claims would not likely have a substantial chilling effect on innovation.[74]

Although the claims were deemed patentable subject matter, Beach J found aspects of them to be lacking clarity and poorly defined.[75] The parties were instructed to amend the application on that basis. Given the litigious activity of the parties in other jurisdictions, it is likely that the decision will be appealed. Possible grounds for appeal regarding subject matter include whether the claims were appropriately dealt with as method claims in substance, and whether they involve more than the discovery of associations with naturally occurring traits.

3 Application of NRDC *and* Myriad

3.1 Construction of the Claims

Before considering how the *NRDC* test and the additional *Myriad* factors might apply in the context of the NIPT case, it is important to set out the claims in Sequenom's NIPT patent (Australian Patent No 727919).[76] When determining patentability, the court will consider each claim separately and independently.[77] The claims can broadly be separated into two types:

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70 Ibid.

71 Ibid.

72 Ibid [487].

73 Ibid [490].

74 Ibid [496].

75 Ibid [947].

76 *AU Standard Patent Serial No 727919*, filed on 4 March 1998 (Expired on 4 March 2018).

77 See *Cargill* (n 9) [262].

a) claims to a detection method for detecting the presence of foetal nucleic acids; and

b) claims to a method of prenatal diagnosis.

Together, the claims constitute a general concept of detection of foetal DNA in maternal serum or plasma, which includes its application in a method of performing prenatal diagnosis. An example of type (a) is claim 1, which provides for '[a] detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample'. Claims 2–5 narrow claim 1, claiming methods that: amplify the foetal nucleic acid; amplify by polymerase chain reaction; amplify using a specific oligonucleotide primer; and detect nucleic acids by means of a sequence specific probe. Claims 6–11 narrow the method based on the type of nucleic acids detected. These include where the nucleic acid sequence is detected from: the Y chromosome; the DYS14 locus (on the Y chromosome) and the SRY gene (located on the Y chromosome); a paternally-inherited non-Y chromosome; a paternally-inherited non-Y sequence that is a blood antigen gene (eg Rhesus D gene); and a paternally-inherited non-Y sequence that is a gene which confers a disease phenotype in the foetus. Claims 13–19 claim the use of the methods stated in the claims above when used for specific purposes, including: for sex-determination, to detect pre-eclampsia; and to detect foetal chromosomal aneuploidy.

Claims 22–6 are examples of type (b), methods of prenatal diagnosis. Claim 22 encompasses:

A method of performing a prenatal diagnosis, which method comprises steps of:

i) providing a maternal blood sample;

ii) separating the sample into a cellular and a non-cellular fraction;

iii) detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction according to the method of any one of claims 1 to 21;

iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid.

Further, claim 25 provides for '[a] method of performing a prenatal diagnosis on a maternal blood sample, which method comprises removing all or substantially all nucleated and anucleated cell populations from the blood sample and subjecting the remaining fluid to a test for foetal nucleic acid indicative of a maternal or foetal condition or characteristic'. The final claim, claim 26, broadly claims '[a] method of performing a prenatal diagnosis on a maternal blood sample, which method comprises obtaining a non-cellular fraction of the blood sample and performing nucleic acid analysis on the fraction.'

The patent specification provides that the invention comprises of a detection method for the presence of nucleic acids of foetal origin in a maternal serum or plasma sample. The invention 'thus provides a method for prenatal diagnosis'.[78] The specification highlights that the claims are methods of detecting any type of nucleic acid, not just DNA. Further, the claims are not limited to specific nucleic acid extraction processes. Standard amplification techniques, such as polymerase chain reaction (PCR), can be used to amplify the foetal DNA sequences. Examples given of the application of the method to the detection of paternally-inherited sequences which are not possessed by the mother include: foetal rhesus D status determination in rhesus negative mothers, haemoglobinopathies, and paternally-inherited DNA polymorphisms or mutations.

The plurality in *Myriad* emphasised the requirement to identify the substance of the claims.[79] On its face, there is no attempt in the NIPT patent to claim rights over the foetal nucleotide sequences or the genetic information that the sequences encode. As highlighted above, the claims are formally method claims for the detection and use of nucleic acids. A possible argument is that the claims are, in substance, to the genetic information found in the cell-free foetal nucleotide sequences. Indeed, the genetic information stored in the cell-free foetal DNA detected in the method is important to the ultimate outcome — the diagnosis. However, particularly for the type (a) claims, it is clear that the particular nucleotide sequences detected are not critical to the invention.[80] Rather, the capacity provided by the method to identify sequences is the substance of the invention. A more plausible argument relates to the type (b) claims — that in substance, these claims are to the naturally-occurring correlation between the quantity or quality of foetal nucleic acid sequences and the foetal or maternal trait. However, given Justice Beach's construction of the method claims in *Cargill*,[81] it is unlikely that the Federal Court would conclude that the NIPT patent claims are, in substance, product claims to genetic information or merely claims to the discovery of a natural correlation. Justice Beach stated that diagnostic method claims are not directed purely to genetic information; they are directed to methods involving the practical application of the identification of the foetal nucleic acids and their association with a trait or condition.[82] Beach J also highlighted in *Cargill* that the claim must be considered as a whole, not as its individual elements. It is inappropriate to focus on an individual element of the claim, such as the foetal nucleic acids:

> It is impermissible to disregard the wording of the claims and diminish their formal content under the guise of having regard to the substance of what is claimed. There is no suggestion in Myriad that claims to methods involving the practical

78 Lo and Wainscoat (n 76).

79 *Myriad* (n 8) 371.

80 See *Arrowhead Research Corporation* (2016) APO 43 (5 July 2016).

81 *Cargill* (n 9).

82 Ibid [453].

> application of nucleic acids could be dismissed as being in substance just directed to genetic information.[83]

3.2 Application of *Myriad*

It is unlikely that the decision by the High Court in *Myriad* on the patentability of genetic information can be directly applied to the NIPT claims. Like in *Cargill*,[84] it is possible to distinguish the NIPT claims from those in *Myriad*. As discussed above, the claims are limited to methods of detecting foetal nucleotide sequences in maternal serum or plasma samples and to methods of performing prenatal diagnoses using the detected nucleotide sequences. The NIPT claims are not product claims to the foetal nucleotide sequences or the genetic information that the sequences encode. Justice Beach noted in *Cargill*, the distinction between claiming the medium in which information is embedded (nucleic acids) and claiming a concrete application of that information.[85]

Passages throughout all three judgments in *Myriad* may in fact support a finding of patent-eligibility for NIPT methods. Justice Beach in *Cargill* emphasised that the judges in *Myriad* not only explained they were not addressing method claims using nucleic acids, but perhaps implied that such claims on their face may be more readily seen as within the existing boundaries of manner of manufacture.[86] The plurality in *Myriad* emphasised that the claims relating to methods using nucleic acids and for preparation of chemically synthesised nucleic acids were not in issue.[87] Their Honours also stated that there was no 'question about the utility of the applications of isolated nucleic acids reflected in those undisputed claims'.[88] Further, the plurality observed: 'If a process which does not product a new substance but nevertheless results in a "new and useful effect" so that the new result is an artificially created state of affairs providing utility, it may be considered a manner of new manufacture.'[89] Justices Gageler and Nettle also distinguished the product claims from process claims:

> the application of a naturally occurring phenomenon to a particular use may be a manner of manufacture if it amounts to a new process or method of bringing about an artificially created state of affairs of economic significance. Even so, the inventor cannot claim to have invented the naturally occurring product as opposed to the process of application. … In so far as the invention consists in the application of a naturally occurring phenomenon to a particular use, the inventor cannot claim to

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83 Ibid [454].

84 Ibid [424]–[433].

85 Ibid [455].

86 Ibid [409].

87 *Myriad* (n 8) 365.

88 Ibid.

89 Ibid 346, citing Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 19.

> have invented the naturally occurring phenomenon as opposed to the method of use and has no claim to a monopoly over the naturally occurring phenomenon as opposed to the method of use.[90]

Their Honours stated at [168]:

> It is not disputed that a process or method of detecting the increased likelihood of certain kinds of malignancy by isolating the BRCA1 gene and examining it for the presence of any of the specified mutations and polymorphisms may be patentable subject matter as a process (subject to considerations of novelty and inventive step). But, to repeat, claim 1 is not a claim for any such process.

Justice Beach in *Cargill* noted that the words 'subject to considerations of novelty and inventive step' are not to be overlooked.[91] Their Honours implicitly recognised that a method involving the use of naturally occurring sequences for a particular purpose may be within the established concept of a manner of manufacture and may be patentable *if* it satisfies the other requirements for patentability.[92] Finally, Gordon J observed that claim 4 of the patent in *Myriad* was an invention.[93] Claim 4 was directed to a probe containing a fragment of the isolated nucleic acid which was usually constructed artificially, had a radioactive label attached and could be used to identify mutations that might suggest a predisposition to cancer. Although claim 4 was not in dispute, and thus the comments are obiter, the passage suggests that her Honour did not intend for methods of detection or diagnosis to be considered non-patentable subject matter.[94]

3.3 *NRDC* Test: Artificial State of Affairs and Economic Utility

3.3.1 Methods of Detection

If claim 1 is construed to be in substance a method of detection, it is likely that the *NRDC* criteria are satisfied. Prior to the work of James Wainscoat and Yuk-Ming Lo (the inventors named in Sequenom's patent) it had not been suspected that cell-free foetal DNA ('cffDNA') was present in maternal blood. On the contrary, maternal serum was typically discarded as biological waste.[95] The inventors were thus the first to discover that a useful result could be attained by detecting the presence of a nucleic acid of foetal origin in a maternal serum or

[90] *Myriad* (n 8) 385.

[91] *Cargill* (n 9) [429].

[92] Ibid, citing *Myriad* (n 8) 385.

[93] *Myriad* (n 8) 414.

[94] See *Cargill* (n 9) [431].

[95] See Lo and Wainscoat (n 76).

plasma sample, as is claimed.[96] The artificial state of affairs could be described as the isolation of the foetal nucleic acids, which could be of economic utility in providing insight into foetal and maternal conditions.[97] Indeed, the fast rate at which the technology was taken up by clinical laboratories worldwide is indicative of the invention's economic utility and the important progression in prenatal testing it represents.[98]

3.3.2 Methods of Diagnosis

As discussed above, the claims to a method of diagnosis could in substance be claims to information embodied in the natural correlation that exists between the foetal nucleic acid sequences and the disease trait. If this were the court's interpretation of the claims, it is arguable that there is no artificially created state of affairs because no product is 'made', and there is no process producing an artificial outcome as a result of human action. The identification of the disease trait from the information obtained from the sample is not information made by human action; it is discerned.[99] The propensity of the foetus or mother for the disease or condition is not changed by the researcher who identifies that propensity. It is merely a discovery and the only added knowledge is about the inherent nature of the foetus or mother.[100]

Even if the court considers that the claims are to more than a mere correlation, a diagnosis may be considered 'at best an abstract, intangible situation', only involving 'intellectual information'.[101] Nothing concrete or tangible is created. However, if the approach in *Cargill* is adopted for the NIPT claims, this argument is unlikely to succeed. Like in *Cargill*, the diagnostic claims involve the practical application of a naturally occurring phenomenon to a particular use. The method involves human interaction, which generates an artificially created state of affairs of economic significance.[102] Beach J referred to the procedure through which the nucleic acid sample must be taken in the bovine diagnostic method, and the requirement to identify the SNPs through practical scientific methods.[103] In a

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96 See Ylva Strandberg Lutzow, 'Patent Eligibility of Diagnostic Methods in Australia Versus the United States' (2015) *Intellectual Property Law Bulletin* 246; Bianchi and Wilkins-Haug (n 3).

97 *NRDC* (n 7) 275.

98 See Bianchi and Wilkins-Haug (n 3).

99 See *Myriad* (n 8) 340.

100 See the arguments made by MLA in *Cargill*: *Cargill* (n 9) [439].

101 *Grant v Commissioner of Patents* (2006) 154 FCR 62, 228.

102 Indeed, a method of physically isolating a serum sample, measuring expression levels of foetal nucleotides and determining whether the foetus or mother has a specific disease seem to satisfy the requirement of a man-made process producing a useful and concrete result: see Strandberg Lutzow (n 96); Lawson (n 2).

103 In reference to claim 8 of *Cargill*'s patent, Beach J noted that the inclusion of additional features relating to the technical process of hybridising the nucleic acid sample (in

similar vein, the human interaction required for the diagnosis in NIPT is set out in claim 22, which includes separating the maternal blood sample into cellular and non-cellular fractions, detecting the presence of foetal nucleic acids in the non-cellular fraction, and then providing a diagnosis based on the presence, quantity or sequence of the nucleic acid. Described in this manner, it is clear that the claim is more than drawing an inference about the potential for the trait or condition to exist; it is more than an intellectual exercise.

It is also clear that the NIPT diagnostic method is of economic significance. In *Myriad*, isolation of the nucleic acid per se did not lead to an economically useful result. The plurality stated that 'economic significance is not demonstrated by stating that the artificially created state of affairs is a step along the way to a process or method itself claimed as an artificially created state of affairs of economic significance'.[104] Likewise, Gageler and Nettle JJ stated:

> it is not the isolation of nucleic acid … which leads to the 'economically useful result' of treating breast cancers. It is rather the discovery of a naturally occurring correlation between the presence of the mutations … and an increased probability of actual or potential malignancy.[105]

These statements support a finding that methods *using* nucleic acid sequences to obtain a prenatal diagnosis would constitute an economically useful result.

4 New Class of Claim? The 'Other Factors' Test

4.1 A New Class?

The other factors considered by the plurality in *Myriad* do not arise unless the claims in question require an extension of the existing concept of manner of manufacture to a new class of claim or if the claims are on the border.[106] The Australian Patent Office states that regard should be had to patents that have already been granted when determining this.[107] However, as highlighted by Justice Beach in *Cargill,* it is likely that minds would differ as to when something was on the border or was an extension of the concept, and the plurality's discussion in *Myriad* provides little guidance.[108] The plurality simply held that gene patents fell within a new class of claim involving 'unimagined technologies

addition to the method in claim 1) confirmed that it was patentable subject matter: at [473].

104 *Myriad* (n 8) 370.

105 Ibid 394–5.

106 Ibid.

107 Australian Patent Office, 'Examination Practice Following the High Court Decision in *D'Arcy v Myriad Genetics Inc*' (n 42).

108 *Cargill* (n 9) [391].

with unimagined characteristics and implications'.[109] It is arguable, however, that many new inventions involve unimagined technologies, otherwise they would not satisfy the requirement of novelty.[110] Considerable uncertainty remains as to exactly what is at the boundaries of patentability.

In relation to the claims for methods of detection, such as claim 1, an analogy can be drawn with patentable methods of detection for biological molecules other than nucleic acids. Examples include the detection of proteins and viruses in human samples. Given that these methods of detection have received patent-eligibility previously,[111] it is unlikely that the NIPT detection claims would be considered a new class of claim. In relation to methods of diagnosis, Justice Beach in *Cargill* found that the methods for identifying a bovine trait from identified SNPs were not an extension of the manner of manufacture.[112] As noted earlier, the claims, directed to novel and inventive methods and processes, were within the 'plain vanilla concept of manner of manufacture'.[113] It is likely that a similar approach will be taken to the NIPT patents. Justice Beach's decision on this could, however, be appealed in the near future, so a discussion of the 'other factors' remains relevant.[114]

4.2 Consistency with the Act's purposes

The plurality in *Myriad* emphasised three primary considerations in relation to the Act's purpose: Whether the invention could give rise to a large new field of monopoly protection with potentially negative effects on innovation (factor 3.1); whether the invention could have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee (factor 3.2); and whether according patentability would involve the court assessing important and conflicting public and private interests and purposes (factor 3.3).[115] As indicated earlier, it is unclear whether all three of these factors must be considered, and whether they should be afforded equal weight. Indeed, it seems

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109 *Myriad* (n 8) 348.

110 Indeed, this sentiment was recognised by the Court in *NRDC* when it emphasised that the meaning of manner of manufacture would change over time: 'To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound': *NRDC* (n 7) 271.

111 See, eg, *AU Standard Patent Serial No 706440*, filed on 28 February 1997 (Ceased on 30 September 2004).

112 *Cargill* (n 9) [391].

113 Ibid [428].

114 Indeed, Justice Beach considered the factors himself on the basis that he could be wrong.

115 *Myriad* (n 8).

that Justice Beach in *Cargill* primarily considered whether a chilling effect would be felt on future research.[116]

4.2.1 Public and private interests and purposes

Policy arguments for and against patenting genetic diagnostic tests have been surveyed by commentators previously. Nicol and Liddicoat identify potential problems with patenting gene sequences and, by extension, genetic diagnostic methods, including diagnostic labs being denied access to tests, difficulties in obtaining second opinions, and delays in the development of adjunct or additional tests or the increase in accuracy of current diagnoses.[117] Similarly, Saw emphasises the issues that patentability may have on the access and affordability of genetic tests.[118] However, these authors highlight the fact that patent infringement is rarely instituted for research use of patented technology in Australia.[119] There is little empirical research supporting a correlation between gene patents and price inflation for diagnostic services, and recent research suggests that the unique structure of the Australian system protects public laboratories (a significant proportion of the market for genetic diagnostic tests in Australia) from patent enforcement action.[120] This point is supported by research that reports minimal differences to accessibility to diagnostic tests post-*Myriad*.[121] Further, the purpose of the *Patents Act* more generally should not be forgotten: to

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116 A potential chilling effect was also a key point to the reasoning of the plurality in *Myriad*, as discussed earlier.

117 Dianne Nicol and John Liddicoat, 'Do Patents Impede the Provision of Genetic Tests in Australia?' (2013) 34(3) *Australian Health Review* 281; Dianne Nicol and John Liddicoat, 'Legislating to Exclude Gene Patents: Difficult and Unhelpful, or Useful and Feasible?' (2012) 22 *Journal of Law, Information and Science* 1.

118 Saw (n 40).

119 While Sequenom's diagnostic claims may not have a research use per se, the claims to methods for detection may interfere directly with research. Research use may also be excluded from infringement due to the 'experimental use' and 'Crown use' exceptions in the *Patents Act 1990* (Cth). See ibid; Dianne Nicol et al, 'The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation' (Occasional Paper No 8, Centre for Law and Genetics, 2014) 86–7 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2503314>; Dianne Nicol, 'Implications of DNA Patenting: Reviewing the Evidence' (2011) 21(1) *Journal of Law, Information and Science* 7.

120 Dianne Nicol, Jane Nielsen and Verity Dawkins, 'The Impact of the High Court's Decision in *D'Arcy v Myriad Genetics Inc* on the Cost of Genetic Testing in Australia' (2017) unpublished manuscript, on file with author. See also Dreyfuss, Nielsen and Nicol (n 29).

121 Nielsen and Nicol (n 27). It has been predicted, however, that method claims may have more of a pronounced impact on the availability of genetic testing than claims over nucleotide sequences: Isabelle Huys et al, 'Legal Uncertainty in the Area of Genetic Diagnostic Testing' (2009) 27 *Nature Biotechnology* 903.

encourage innovation by means which do not stifle it.[122] Exclusive rights give a monetary incentive for invention and investment in biotechnology, and the granting of patents leads to more publicly-available information. [123] If patentability of genetic diagnostic methods is denied, this may lead to more information being kept as trade secrets.[124] In this way, a chilling effect may be felt if patentability is denied. The current uncertainty in the biotechnology sphere post-*Myriad* may also contribute to this chilling effect.

4.2.2 Large new field of monopoly

Emphasis was placed by the plurality and Justice Gordon in *Myriad* on the breadth of Myriad's claims.[125] It is arguable that, absent limitations on the type of foetal nucleic acid detected, the purpose of detection and the technical means employed, claim 1 of the NIPT patent is as broad as Myriad's claims. The monopoly is over any foetal nucleic acid 'detected' in maternal serum or plasma. However, in *Cargill*, Justice Beach commented that the breadth of claims per se is not indicative of a lack of patentable subject matter.[126] The breadth of the claims is a legally and conceptually distinct ground of invalidity, which may suggest that the boundaries of the monopoly are elusive.[127] When considering manner of manufacture, Justice Beach emphasised that the court must focus on the nature of the subject matter to which claims are directed, rather than the breadth of the claims. Thus, it seems that Justice Beach placed emphasis on the 'with potentially negative effects on innovation' part of factor 3.1.

4.2.3 Chilling effect on research

In *Myriad*, the plurality held that granting the patent would cause a chilling effect on research, primarily because the patent could be infringed without the infringer being aware.[128] This was because the claims were to any isolated nucleic acids (of unidentified length) that contained the BRCA1 sequence. A researcher could isolate a piece of DNA and, after sequencing, later realise that it included a DNA sequence that was covered by the patent. Thus, the chilling effect would be felt on activities *beyond those formally the subject of the patent,* such as research in non-

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122 *Myriad* (n 8) 352; see also *Lockwood No 2* (n 41) 194.

123 Christopher M Holman, 'The Critical Role of Patents in the Development, Commercialization and Utilization of Innovative Genetic Diagnostic Test and Personalized Medicine' (2015) 21 *Boston University Journal of Science and Technology Law* 297; Nicol (n 119).

124 Saw (n 40).

125 *Myriad* (n 8) 352, 414–15; the plurality's focus on the breadth of Myriad's claims and the broad monopoly afforded to Myriad has been emphasised by commentators, including Saw (n 40).

126 *Cargill* (n 9) [500].

127 See *CCOM Pty Ltd* (n 14) 294, 295.

128 *Myriad* (n 8) 372.

breast cancer areas. Regarding the NIPT claims to methods of detection, researchers would only infringe the claims if they were to detect foetal nucleic acid sequences in maternal plasma and serum. This may cause a similar issue to that discussed in *Myriad*, depending on the meaning of 'detect'. If 'detect' is limited to intentional isolation of the foetal nucleic acid sequences from the plasma or serum sample, then it is unlikely that researchers would unknowingly be liable for infringement. If detect is interpreted more broadly, then it may cause researchers to be wary of conducting any research on maternal plasma or serum samples.[129]

A chilling effect may occur on up-stream scientific research if the methods for detection were granted, as isolating DNA sequences can be the first step to scientific work regarding genes.[130] Indeed, if researchers sought to study cell-free foetal DNA in maternal serum or plasma, it is likely that any detection of the DNA would infringe claim 1 of the NIPT patent. In regards to the claims limited to paternally-inherited foetal DNA, a researcher may be unable to determine whether the foetal DNA is inherited from the mother or father without further research (unless it concerns a sequence on the y chromosome). Infringement would not be ascertainable until the genetic code was detected, raising a similar issue to that discussed in *Myriad*. However, this would not be a chilling effect on research *beyond* the formal substance of the patent; the method for detecting foetal DNA in maternal plasma or serum *is* the very substance of the patent. The fact that the patent may include any method of detection is not a matter to be considered under subject matter, but clarity.

Similarly, it is arguable that a claim for a method of diagnosis would not have a chilling effect on activities beyond those formally the subject of the patent. The claims to methods for diagnosis in the NIPT patent involve isolating the nucleic acid and using it for a particular purpose.[131] The breadth of the patent is narrowed by the fact that it would not be infringed unless a person uses the method for that particular purpose (to give a diagnosis). This is similar to the patent in *Cargill*, where claim 1 involved a 'method for identifying a trait'. Justice Beach held that the word 'for' placed a limit on what was claimed, 'such that the method claimed must result in being able to identify … a trait. It is clear in context that claim 1 stipulates a purpose constraint'.[132] Therefore, a product that is merely suitable for that purpose will not infringe the claim. The use of such a product for a different

[129] Indeed, the UK patent was interpreted by the Court to include indirect detection: *Illumina Inc* (n 5) [220].

[130] Tiana Leia Russell, 'Unlocking the Genome: The Legal Case against Genetic Diagnostic Patents' (2012) 16 *Marquette Intellectual Property Law Review* 81, 112.

[131] Claims 18 and 19 claim the methods described in the claims above for the detection of pre-eclampsia and foetal chromosomal aneuploidy. In *Cargill*, Beach J noted that the word 'for' places a limit on what is claimed. Thus, the method claimed must result in being able to detect pre-eclampsia or foetal chromosomal aneuploidy.

[132] *Cargill* (n 9) [282].

purpose will also not infringe. This is dissimilar to *Myriad*, where any isolation of DNA containing the patented sequence would lead to infringement.

In *Cargill*, Justice Beach took a practical approach to finding that the claims will not have or may not have had a chilling effect on future research in the livestock industry in Australia.[133] Justice Beach found that there was no evidence to support a chilling effect, particularly after the claims were narrowed, based on his Honour's interpretation of the claims' terms. Justice Beach used examples of other patents granted in the area to demonstrate that MLA's assertion of a chilling effect was unwarranted. The first example was patent no 2007335195 titled 'Artificial selection patent method and reagents', granted in 2017. Claim 1 covers both plants and animals and is of great breadth. It refers to 'informative markers', but Justice Beach highlighted that it is not clear what is meant. It may include DNA polymorphisms, SNPs, indels, short tandem repeats, microsatellites, mini-satellites, restriction fragment length polymorphisms and amplified fragment length polymorphisms.[134] There is also little information in the patent on how to get an informative marker. Justice Beach commented that '[o]ne can make the jury point that if MLA's chilling effect point was good, then this patent would be an example par excellence'.[135] The second example was patent no 2002229406 titled 'DNA markers for meat tenderness' granted on 5 March 2007. Claim 1 provides a method for assessing the tenderness of meat from an animal, comprising testing of the animal for the presence or absence of a particular genetic marker. Beach J noted a number of features of this claim including that the type of animal and the type of genetic marker is not constrained.[136] Noting that this patent is granted to MLA, Justice Beach commented that MLA's argument 'hardly sits well with its own patent and its effect'.[137] Justice Beach's practical approach raises a number of questions: Are these patents raised to demonstrate that research was not curtailed since the patent application in 2010? Or are the patents raised to demonstrate that there are much broader patents that have been granted in the area? Is this approach problematic given that these patents have not faced opposition and have not been scrutinised by the Court for patent-eligibility post-*Myriad*? How many references to patents are required to

133 Ibid [497]–[498]. In *Cargill*, MLA argued that the claims will have or may have had a chilling effect on future research in the livestock industry in Australia. This was contrary to public interest and would be generally inconvenient, contrary to s 6 of the Statute of Monopolies. If researchers investigated the effects of a particular SNP that was not one of the SNPs specified in the claim, they could not determine if Cargill's patent had been infringed without conducting significant research to determine if any one of the SNPs used is within 500,000 nucleotides of a specified SNP.

134 Ibid [497].

135 Ibid.

136 Ibid [498].

137 Ibid.

demonstrate that a chilling effect has not been or will not be felt? These questions remain unresolved in the NIPT space.

4.3 Coherency with Australian law

The plurality in *Myriad* noted that a key factor to consider was whether affording patentability would enhance or detract from the coherence of the law. Referring to *Apotex*,[138] their Honours explained:

> Having regard to the established patentability of pharmaceutical products, the exclusion of treatments using such products was anomalous and had no stable logical or normative basis. … Their inclusion was consistent with the existing application of the law and served to enhance its coherence.[139]

It may be argued that this statement in *Myriad* supports the converse argument; if the product is inherently non-patentable subject matter, consistency requires any method using that product to also be non-patentable. Indeed, this was argued (unsuccessfully) by MLA in *Cargill*.[140] However, as noted by Beach J in *Cargill*, this argument conflicts with holdings in previous cases, including the seminal case of *NRDC*.[141] In *NRDC*, the chemicals used in the method claim were known and hence non-patentable. This did not preclude the Court from finding that the novel use of the chemical constituted an invention.[142] A distinction could be made between genetic diagnostic methods and cases like *NRDC.* In *NRDC*, the product was not inherently non-patentable subject matter; it was not patentable because the chemical was already known and therefore not novel. However, this does not explain the more fundamental issue that, in some way or another, almost all method claims will involve the use or application of non-patentable subject matter, such as a 'law of nature'. This point was emphasised by Justice Beach when rejecting MLA's argument that, because product claims to genetic information were non-patentable, so too should claims to methods using that genetic information.[143] Justice Beach stated that 'it is well accepted that method claims can use known products and apply natural laws to their working',[144] regardless of whether the natural laws themselves are patentable. Therefore, it is likely that affording patentability to NIPT methods of detection and diagnosis would be consistent with Australian law.

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138 (2013) 253 CLR 284.

139 *Myriad* (n 8) 351.

140 *Cargill* (n 9) [487].

141 Ibid [413], citing Gageler and Nettle JJ in *Myriad* (n 8) 385.

142 See also *Shell Oil Co v Commissioner of Patents* [1982] 2 SCR 536, where the patentee could not claim to have invented the known compounds which were applied as part of the patentable process to a new use of plant growth regulation.

143 *Cargill* (n 9) [492].

144 Ibid [487].

4.4 Coherency with other jurisdictions

The plurality in *Myriad* listed Australia's obligations under international law and the patent laws of other countries as relevant considerations in the 'other factors' test. In *Cargill*, MLA argued that the claims should not be directed to patentable subject matter having regard to decisions in the US which have rejected claims to methods of diagnosis based on discoveries or principles of nature.[145] The cases raised by MLA were *Mayo Collaborative Services v Prometheus Laboratories Inc*[146] and *Ariosa Diagnostics Inc v Sequenom Inc*[147] (a decision on the US equivalent to Sequenom's NIPT patent). However, Justice Beach found himself unable to undertake the consideration enunciated by the plurality in *Myriad*, stating:

> I cannot determine coherency with foreign law generally by only considering cherry-picked jurisprudence from one jurisdiction. Consistency with one foreign jurisdiction might produce inconsistency with another foreign jurisdiction. I have not had the benefit of any comprehensive international survey.[148]

Justice Beach also highlighted that the plurality pronounced this as a factor of secondary importance, commenting that his primary role as a trial judge is to apply 'an evolving conception from the Statute of Monopolies in the context of Australian legislation and Australian conditions, not any foreign law approach'.[149]

The concerns of Justice Beach are exemplified by reference to NIPT. In the US, the Federal Circuit Court found that Sequenom's method claims in patent no 6,258,540 for detecting paternally-inherited cffDNA in maternal plasma or serum were invalid.[150] In contrast, in the UK, Illumina's method for prenatal diagnosis was found to be patentable subject matter.[151] The patent had similar wording to the patents registered in the US and Australia.

4.4.1 The UK Approach

In the UK, patentability was questioned on the basis of the breadth of claim 1,[152] arguing that, in substance, the claim was to the mere discovery that foetal DNA is detectable in maternal serum or plasma. The respondents argued that the claim was to any method involving this discovery and no technical limits were placed on the method of detection. The method itself did not result in or enable any

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145 Ibid [488].

146 566 US 66 (2012) ('*Mayo*').

147 *Ariosa* (n 4).

148 *Cargill* (n 9) [490].

149 Ibid [491].

150 *Ariosa* (n 4).

151 *Illumina Inc* (n 5).

152 Claim 1 is of similar wording to claim 1 of the Australian patent.

meaningful or technical effect.[153] However, Justice Carr did not accept that claim 1 was to a mere discovery. It was not directed to information about the natural world, but to a practical process — a detection method which uses information about the natural world.[154] The sample of plasma or serum used was artificially created, and the claimed method of detection was also an artificial process. Thus, the method was a practical process of implementing a discovery, for practical applications.[155] These sentiments are similar to those of Justice Beach in relation to Cargill's method patents, indicating that a similar approach may be taken in relation to NIPT in Australia.

4.4.2 The US Approach

In the US, the Federal Circuit Court applied the Supreme Court case of *Mayo* to Sequenom's NIPT patent.[156] In *Mayo*, the Supreme Court held that a method of comparing and analysing rates of drug metabolism in the human body with reference data failed to satisfy the patentable subject matter requirement on the basis that it amounted to patenting a law of nature. The Court devised a two-step test.[157] The first step is for the court to determine whether the claims at issue are directed to a patent ineligible concept, such as a natural phenomenon. If yes, the court must consider the elements of each claim, both individually and as an ordered combination to determine whether the additional elements recited in each claim transform the nature of the claim into a patent eligible application. To be patent eligible, another inventive concept would have to be added, amounting to something 'significantly more than a patent upon the natural law itself'.[158] The conclusion of the Court in *Mayo* was that the relevant claims included no other elements or combination of elements sufficient to ensure that the patent in practice amounted to significantly more than a patent upon the natural law itself.[159] In *Ariosa*, the Full Federal Circuit Court held that the NIPT method claims began and ended with a natural phenomenon, and the additional elements in the method steps individually and as ordered in combination were not enough to

153 *Illumina Inc* (n 5) [187].

154 Ibid [189].

155 Ibid.

156 *Ariosa* (n 4).

157 *Mayo* (n 146).

158 Ibid.

159 *Ariosa* (n 4); see United States Patent and Trademark Office, 'Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection' (4 May 2016) <https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf>; *Alice Corporation v CLS Bank International*, 573 US 208 (2014); see also Dreyfuss, Nielsen and Nicol (n 29) for an overview of US decisions post-*Mayo* and a discussion of the profound effect that *Mayo* has had on the US patent landscape.

supply an inventive concept.[160] The existence of cffDNA in maternal blood was a natural phenomenon and the method ended with paternally inherited cffDNA, which was also a natural phenomenon. Appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, was not enough to supply an inventive concept.[161]

The importance of the US case law to the Australian patent system is contested. Saw draws a similarity between the discovery/invention distinction discussed in US case law (*Mayo* and *Ariosa*) and the judgment of Gageler and Nettle JJ in *Myriad*.[162] However, arguably too much emphasis is placed on this part of Justices Gageler and Nettle's judgment, to the detriment of Saw's analysis. The author fails to discuss the plurality judgment in great detail, which departs significantly from the US approach. As discussed earlier, the introduction of an inventiveness threshold into Australian patent law has already been rejected by the Federal Court post-*Myriad*.[163] Arguably, the discovery/invention distinction conflates the patentable subject matter and inventive step requirements in Australian patent law. The question of whether an application is new and useful or has inventive concept belongs in a consideration of novelty. Lawson also discusses US case law in the context of patenting genetic diagnostic methods, relying heavily on the US case of *Mayo* to decide if diagnostic methods are patentable in Australia.[164] Lawson mentions art 17.9.14 of the *Australia–United States Free Trade Agreement* and the requirement that 'each Party shall endeavour to reduce differences in law and practice between their respective systems'.[165] He suggests that this makes US law relevant in determining the application of the Australian patent scheme.[166] However, the likelihood of the US approach being followed in Australia is diminished on consideration of Justice Beach's comments in *Cargill*. When discussing the US approach, Justice Beach stated:

> The US approach accepts that a method involving the application of a law of nature may be patentable. … What workable method in its application is ever free of a law

[160] *Ariosa* (n 4).

[161] Ibid.

[162] Saw (n 40) 234.

[163] See *Cargill* (n 9) [502]–[516].

[164] Lawson (n 2).

[165] United States–Australia, signed 18 May 2004, [2005] ATS 1 (entered into force 1 January 2005) art 17.9.14.

[166] Lawson also argues that the US solution to the reproducibility problems of genetic diagnostic methods is to make the subject matter patent-ineligible. However, this seems to be converging two different issues: reproducibility problems have nothing to with US or Australian tests on patentable subject matter, and problems with reproducibility should be dealt with in the utility assessment: Lawson (n 2).

> of nature? The US debate turns more on the question of what it takes to transform an unpatentable law of nature into a patent-eligible application of such a law.[167]

His Honour distinctly rejected application of the test in *Mayo*, stating that '[t]he exposition of the test (particularly the second stage) in *Mayo* is too sweeping for me to work out whether I am acting consistently or inconsistently with its spirit'.[168] These comments suggest that, like the UK, Australia will not adopt the US discovery/invention distinction or law of nature test in the near future, and that the US NIPT decision will play little part in deciding the patentability of NIPT in Australia.

5 Conclusion

The above analysis supports a conclusion that NIPT is inherently patentable subject matter in Australia. However, the outcome largely depends on the construction of the patent's claims. If construed to be, in substance, methods of detection and diagnosis, rather than claims to genetic information, patent-eligibility is a likely outcome. Methods for detecting cffDNA in maternal plasma or serum and methods for using that cffDNA to perform a diagnosis for a foetal/maternal condition seem to satisfy the *NRDC* requirements of artificial state of affairs and economic utility. Based on the Federal Court's recent application of the plurality's decision in *Myriad*, it is unlikely that NIPT constitutes a new class of claim and, if it did, the other factors in *Myriad* largely point towards patent-eligibility. However, a conclusion that NIPT is patent-eligible subject matter does not necessarily suggest that the Federal Court will decide that Sequenom's patent is valid. The patent may be rejected or revised on other grounds of patentability. These include novelty, inventiveness, utility and sufficiency. As suggested by Justice Beach in *Cargill*, deploying other grounds of patentability may be a more refined mechanism for dealing with broad claims, as opposed to using the blunt instrument of patent eligibility.

Although Sequenom's NIPT patent has now expired, the Court's verdict on the patentability of NIPT may have important ramifications for the patent-eligibility of methods of genetic testing more broadly. If the NIPT methods and, by extension, genetic testing methods generally were found to be patentable subject matter, this could present an effective balance between promoting innovation and ensuring accessible healthcare. This is particularly so given that naturally-occurring nucleic acid sequences are not patentable subject matter in Australia. Such a balance could ensure that the uncertainty felt by the US biotechnology industry as a result of *Mayo* is not replicated in Australia.

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167 *Cargill* (n 9) [492].

168 Ibid.