Lessons from *Myriad*: potential and pitfalls in determining the scope of "manner of manufacture" for nucleic acid 'inventions' under section 14(a) of the Patents Act 2013

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Part I: Patents Act 2013 (NZ) and nucleic acid 'inventions'

Part II: Judicial approaches to nucleic acid 'inventions' in the *Myriad* litigation

Part III: Recommendations for New Zealand

1. Scientific Terminology[1]

amino acid	the individual units used to build proteins.
adenine (A)	one of the four chemical nitrogenous bases in DNA that base pairs with thymine (T).
base pairing	the preferential bonding which occurs between adenine and thymine, and guanine and cytosine, nucleotides to form the higher structures of DNA and RNA.
Central dogma	the basic framework by which genetic information flows from DNA to produce a protein inside a cell.
codon	a sequence of three nucleotides which corresponds to a specific amino acid (or stop signal) during translation or protein synthesis.
chromosome	an organised package of DNA stored in the nucleus of a cell.
complementary DNA (cDNA)	a DNA molecule, usually synthesised by the action of reverse transcriptase, that is complementary to an mRNA molecule and only contains exons.
cytosine (C)	one of the four chemical nitrogenous bases in DNA that base pairs with guanine (G).
deoxyribonucleic acid (DNA)	a polymer of nucleotides whose sequence of bases encodes genetic information in all living cells.
exon	a portion of a gene that ultimately encodes for a protein and is present in both the primary and mature mRNA transcript; also referred to as a 'coding region' of DNA.
gene	the basic physical unit of inheritance, comprised of DNA.
genome	the complete set of genetic instructions in an organism; in humans, the genome is made up of 23 chromosomes which are comprised of more than 3.1 billion nucleotides.
genomic DNA (gDNA)	chromosomal DNA that encodes the genome of an organism and can be passed from one generation to the next.
guanine (G)	one of the four chemical nitrogenous bases in DNA that base pairs with cytosine (C).

[1] Terminology was directly obtained from the Glossary section of Donald Voet, Judith G Voet and Charlotte W Pratt "Fundamentals of Biochemistry: Life at the Molecular Level" (4th ed, Hoboken (NJ), John Wiley & Sons, 2015) at G-1. Some definitions have been paraphrased.

intron	a non-coding region of DNA. An intron is removed via "splicing" to produce a mature RNA molecule.
nitrogenous base	a nitrogen-containing molecule that is the determinative naming constituent of a nucleotide.
nucleotide	the small monomeric units that are the basic building blocks of nucleic acids and consists of a sugar molecule, a phosphate group and a nitrogenous base
nucleic acid	a polymer of nucleotides; the major nucleic acids are DNA and RNA.
monomer	the single, structural unit from which a polymer is built up.
mutation	a heritable alteration in an organism's genetic material, most commonly in underlying gDNA.
polymer	a molecule consisting of numerous smaller units that are linked together in an organised manner; DNA and RNA are polymers made up of long chains of nucleotides.
polymorphism	a variation in the nucleotide sequence of DNA between individuals.
polypeptide	a polymer consisting of individual amino acids units linked by linear peptide bonds.
protein	a complex molecule that consists of one or more polypeptide chains.
recombinant DNA	a DNA molecule formed by laboratory methods to bring together genetic material from multiple sources to produce a single molecule.
ribonucleic acid (RNA)	a polymer of ribonucleotides which exists in many forms, one of which is messenger RNA (mRNA).
ribonucleotides	the small, monomeric unit that is the basic building block of the nucleic acid RNA.
splicing	a form of RNA processing which transforms the primary mRNA transcript into mature mRNA whereby introns are removed and exons are joined together.
thymine (T)	one of the four chemical nitrogenous bases in DNA that base pairs with adenine (A).
transcription	the process by which RNA is synthesized under the direction of the DNA template, thereby transferring genetic information from DNA to RNA.

translation	the process by which a polypeptide (or protein) is synthesized under the direction of the sequence information contained in messenger RNA (mRNA) as specified by the genetic code.
uracil	a chemical nitrogenous base that is unique to RNA and base pairs with adenine (A).

2. Introduction

In 2013 and 2015 respectively, apex Courts in the United States of America and Australia each effectively settled the patent eligibility of genomic DNA nucleic acid sequences. Although expressed less directly by the Australian High Court, in essence, the effect of the decisions is that, of themselves, such sequences will not be 'patentable inventions'. Each Court dealt with patents of Myriad Genetics Inc. concerning BRCA1 and BRCA2, two breast cancer-related genes, but reached their conclusions for slightly different reasons, based on – essentially – different judicial approaches to the central threshold-eligibility question of what constitutes an 'invention'. One immediate consequence of these different approaches was that the Courts diverged on the patent-eligibility of nucleic acid sequences in the form of non-genomic, *complementary* DNA.

Five plus years on, biotechnological developments are presenting courts with more complex nucleic acid 'inventions'. As a result, the potential wider consequences with these divergent judicial approaches are becoming more apparent, especially from a guidance perspective. Furthermore, New Zealand's courts have not yet ruled – either way – as to the patent-eligibility of isolated nucleic acid sequences in any form.

The problem this dissertation identifies and addresses is two-fold. First, as New Zealand courts have not dealt head-on with the issue of whether patent-eligible subject matter under s 14(a) of the Patents Act 2013 may include nucleic acid-based 'inventions' – how might this proceed? Secondly, how should it proceed? The overseas decisions referred to *have* dealt with these issues, more or less directly, but analysis of the approaches suggests the courts have struggled. The aim of this dissertation is to consider a tailored judicial approach to the subject matter of nucleic acid 'inventions' that New Zealand may usefully adopt.

In order to achieve its aim, this dissertation is structured as follows:

Part I will identify the scope of the inquiry. The relevant provisions of the Patents Act 2013 will be discussed and situated in relation to legislative and judicial history in order to contextualise the fundamental concept of an 'invention' in patent law – a central

concept of this dissertation. Part I will conclude by drawing on both preceding sub-parts and secondary material to offer an account of *how* the judiciary approach the central concept of an 'invention' in the nucleic acid context. It is suggested that reasoning by proxy is employed, using what this dissertation refers to as 'Un(der)articulated tests'. These tests apply notions of difference from nature, the importance of labour and other relevant considerations to determine whether an 'invention' exists.

Part II will build on Part I by analysing the *Myriad* litigation in the Supreme Court of the United States of America and the High Court of Australia from the perspectives of the 'Un(der)articulated tests'. The focus of analysis shall be on how the tests appear to influence the salient differences in approach, most aptly highlighted in the divergence on complementary DNA patent-eligibility. It will be contended that the tests provide a useful way of understanding judicial reasoning, but in the context of nucleic acid 'inventions', that some tests are problematic and less desirable than others.

Part III will recommend a desirable judicial approach to nucleic acid 'inventions' under s 14(a) of the Patents Act 2013 based on conclusions drawn from analysis in Part II.

Part I: Patents Act 2013 (NZ) and nucleic acid 'inventions'

3. Patents – key concepts and New Zealand's Patent Act 2013

In basic terms, a patent is a defined, time-limited, legal monopoly covering, necessarily, an 'invention' – a concept which is fundamentally entwined with s 14(a) of the Patents Act 2013. Patents are granted to inventors in return for their public disclosure of technical information concerning the invention – which can be a product, or a process/method.[2] After the monopoly period, this information may be used more freely.[3] Conversely, during the monopoly, the patentee has the exclusive right to exploit the invention (e.g. create the product or utilise the process),[4] and may bring infringement proceedings to prevent others from doing so.[5] Internationally, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – of which New Zealand is a signatory – requires patent protection to be available for inventions in *all* fields of technology;[6] but it also provides for exclusions of various types of inventions, meaning significant lee-way exists for national jurisdictions to create tailored patent regimes.[7]

Section 14 of New Zealand's Patents Act 2013 sets out the necessary criteria for a "patentable invention",[8] with similar effect to the preceding 1953 Act. These criteria have similarities with requirements in other jurisdictions, particularly common law

[2] Both categories were not always recognised, see Section 4.2 below.
[3] Ian Finch "James & Wells Intellectual Property Law in New Zealand" (3rd ed, Thomas Reuters, Wellington, 2017) at 9.
[4] Patents Act 2013, s 18.
[5] Sections 140-142.
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27(1).
[7] Paul Sumpter *Intellectual Property Law: Principles in Practice* (3rd ed, CCH New Zealand, Auckland, 2017) at 273-274.
[8] See Patents Act 2013, s 13. Section 13 provides that "patents may be granted for an invention only if it is a patentable invention".

systems derived from the United Kingdom.[9] Section 14 states an invention is a patentable invention if it is:

(a) a "manner of manufacture" within the meaning of section 6 of the Statute of Monopolies;[10]

(b) novel and involves an inventive step;[11]

(c) useful;[12] and

(d) not excluded under other statutory exceptions included in other provisions.[13]

The focus of this dissertation is on the first criterion just listed, in the context of nucleic acid 'inventions'. This criterion is often treated as the threshold requirement, as it is essentially synonymous with the question: "is this an invention?". As argued below, the experience of other patent-granting jurisdictions in separating non-patentable from patentable subject matter is relevant to this issue – even when links to the wording of s 14(a) and its antecedents are weaker or even non-existent. Specifically, this dissertation considers how New Zealand courts would be likely to approach the threshold issue; and, in light of the high profile *Myriad* litigation overseas, identifies likely difficulties in this task and how they might best be navigated.

Court cases examining in detail s 14(a), or its antecedent in the 1953 Act, are not common. In part, this is because judicial consideration of a claimed invention, and whether it meets the s 14(a) requirement is not necessary for a patent to be granted. Rather, this work is largely carried out by the Intellectual Property Office of New Zealand (IPONZ). Without going into substantial detail of the process, an inventor files an application at IPONZ which describes the invention and includes claims as to the monopoly protection sought via patent. Claims must be worded carefully to ensure they accurately reflect the nature of the invention and are neither too narrow, nor too broad. If this process proceeds smoothly, the application is "examined" by an IPONZ patent examiner – focussing particularly on the claims – to ensure it complies with the Patents

[9] See generally Justine Pila "Inherent Patentability in Anglo-Australian Law: A History" (2003) 14 AIPJ 109.

[10] Patents Act 2013, s 14(a).

[11] Section 14(b)(i) and 14(b)(jj).

[12] Section 14(c).

[13] Section 14(d). The relevant statutory exclusions are ss 15 and 16.

Act 2013, including s 14, before being "accepted" (provisionally) and then granted. There is scope for the application to be opposed during the grant process, as well as for post-grant opposition to patents (e.g. re-examination, revocation).[14]

Curial intervention may occur when patents or applications are opposed or otherwise challenged and appealed, which has ramifications in that IPONZ has considerable agency in interpreting the law.[15] In essence, such disputes involve one party asserting that the patent should not be, or should not have been, granted. A major point of challenge available is to contend that the claimed invention does not exhibit the core requirements for a patent to be granted[16] – one of which is s 14(a). When a challenge is based on s 14(a), the contention is that the subject matter of the 'invention' is not a "manner of manufacture" and in effect, that there is no invention.[17] The proposition that there is no patentable subject matter for a patent to attach to requires some unpacking, as it is not entirely evident how the requirement relates to the statutory language of a "manner of manufacture" in accordance with s 14(a).[18]

[14] The specific terminology of the dispute is dependent on the stage at which it takes place: opposition (post-acceptance), re-examination (post-grant), revocation process (post-grant). Of note, s 14(a) cannot be used pre-acceptance to oppose a patent.

[15] The agency of IPONZ is heightened in respect of s 14(a) given it cannot be used as a basis to challenge a patent pre-acceptance (above n 14). See Susy Frankel and Jessica C Lai *Patent Law and Policy* (LexisNexis, Wellington, 2016) at 1-6.

[16] The requirements in s 14 of the Act can be the basis for challenge in opposition or re-examination and revocation proceedings respectively, per ss 92(1)(a) and 114(1)(a).

[17] Susy Frankel and Jessica C Lai *Patent Law and Policy* (LexisNexis, Wellington, 2016) at 87.

[18] Patents Act 2013, s 14(a).

4. Section 14(a) of the Patents Act 2013

A cursory glance at s 14(a) does little to suggest the complexity of the history, legal rules and concepts hidden within. The threshold requirement of an 'invention' in s 14(a) is defined by reference to s 6 of the Statutes of Monopolies 1623 (the Statute), which in its entirety reads as follows:[19]

> "Provided also (and be it declared and enacted) that any declaration beforementioned [a ban on monopolies] shall not extend to any letters patents and grants of privilege for the term of fourteen years [now twenty years] or under, hereafter to be made, of the sole working or making of *any manner of new manufactures* within this realm, to the true and first inventor, and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use, so as also they be not contrary to the law, or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient".

The language is decidedly "archaic";[20] a testament to the time in which it was written. While it has "no ordinary meaning today",[21] the purpose for which s 6 of the Statute was intended is still relevant. The Statute was enacted to stop the grant of 'harmful and wide-reaching' monopolies, such as patents over basic commodities including "starch, salt and vinegar".[22] The concept of a "manner of (new) manufacture" is used by the courts to include some types of subject matter as patentable, and exclude others.[23] The question of how this process occurs, and how it should occur, are central to this dissertation.

It is useful to emphasise at this stage the closing words of s 6: "so as also they be not contrary to the law, or mischievous to the state, by raising prices of commodities at

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[19] Statute of Monopolies 1623, s 6 (emphasis added).
[20] So characterised by Lord Diplock in *Bristol-Myers Co v Beecham Group Ltd* [1974] AC 646 at 677.
[21] *Wellcome Foundation v Commissioner of Patents* [1983] NZLR 385 (CA) at [61] per O'Regan J. The lack of "ordinary meaning today" is covered in more detail in the outline of key judicial cases in Sections 4.2 and 4.3 below.
[22] Justine Pila *The Requirement for an Invention in Patent Law* (Oxford University Press, New York, 2010) at 18-21. The patents over basic commodities were harmful as they began to undermine well-established local industries and devastate the public, with the deleterious effects being compounded as patents were extended and renewed.
[23] Pila *The Requirement for an Invention in Patent Law*, above n 22, at 18-21.

home, or hurt of trade, or generally inconvenient".[24] Section 10 shall consider in more detail the effect of this proviso in interpreting the words "manner of [new] manufacture".

The Patents Act 2013 does not define a "manner of manufacture" any more than to defer to the meaning of s 6 of the Statute (which also does not define "any manner of new manufactures"). Instead, as with much of the law in this area, the task has remained with the courts.

4.1. Legislative history of the "manner of manufacture" requirement in New Zealand Patent legislation

The use of s 6 of the Statute as a touchstone for what an 'invention' is has been a constant in New Zealand's patent legislation. The Patents Act 1860 borrowed key elements from the patent system established in the United Kingdom, and was amended many times over until the Patents Act 1953 (which retained the use of s 6).[25] It was under the 1953 Act that the majority of modern jurisprudence developed,[26] heavily influenced by developments in the United Kingdom.[27] Under the 1953 Act, an "invention" was defined in s 2 to mean "any manner of new manufacture the subject of letters patent and grant privilege within section 6 of the Statute".[28]

In 1992, significant legislative reform efforts began concerning New Zealand's patent laws. Ultimately – over 20 years later – the Patents Act 2013 resulted.[29] The tradition of incorporation of s 6 was maintained,[30] however the basis of inclusion changed. By 1977,

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[24] Statute of Monopolies 1623, s 6.

[25] Intellectual Property Office New Zealand "History of Intellectual Property in New Zealand" IPONZ <https://www.iponz.govt.nz/about-iponz/history-of-ip-in-new-zealand/>.

[26] Doug Calhoun "The Patents Act 2013: a History and an Overview" *Intellectual Property Law (NZ)* (online ed, LexisNexis).

[27] The United Kingdom's patent law has limited influence in New Zealand now. In 1973, the United Kingdom joined the European common market and in response, its patent system was overhauled to reflect the principles of the European Patent Convention. The most notable change between the 1949 and 1977 Acts was the removal of reference to s 6 of the Statute. See Calhoun "The Patents Act 2013: a History and an Overview", above n 26, at 1; and Frankel and Lai *Patents Law and Policy*, above n 17, at 90.

[28] Patents Act 1953 (NZ), s 2; Statute of Monopolies 1623, s 6.

[29] Calhoun "The Patents Act 2013: a History and an Overview", above n 26.

[30] During the overhaul process, lengthy discussion centered around whether the reference to s 6 should be retained or removed in step with the United Kingdom (see 27 above). Also see Ministry of Commerce

the United Kingdom had formally dropped any reference to s 6;[31] so during drafting of what would come to be the Patents Act 2013, consideration was given to the equivalent Australian legislation – the Patents Act 1990 (Cth), which had retained reference to s 6.[32] Ultimately New Zealand also retained s 6, but no longer by reference to contemporaneous United Kingdom legislation. Instead, the 2013 Act mirrored parts of the Australian legislation (most saliently, in s 14, the list of requirements for a "patentable invention")[33] – which changed the position slightly from the 1953 Act.

Rather than having separate definitions of "invention" and "patentable invention", the 2013 Act simply sets out the requirements for an (undefined) invention to be a patentable invention.[34] However, the substance of both the 1953 Act's and the Australian Act's definitions of "invention" is contained in s 14(a).[35] Furthermore, the 2013 Act only refers to a "manner of manufacture" simpliciter (within the meaning of s 6), rather than utilising the actual words from s 6 – a "manner of *new* manufactures".[36] The likely explanation for omitting the word "new" was to avoid duplication with the similar requirement of a "novel"[37] invention.[38]

So, the United Kingdom now has diminished influence over the threshold-eligibility requirement in New Zealand – as it stands under the Patents Act 2013 – but Australia has stepped in to fill the void.

The Reform of the Patents Act 1953: Proposed Recommendations, Competition Policy and Business Law Division (1992).

[31] See above n 27.

[32] Patents Act 1990 (Cth), s 18(1). See Patents Bill 2008 (235-1), draft consultation document at 4; and the s 14 of the Patents Act 2013 where a citation explicitly references s 18(1) of the Patents Act 1990 (Cth).

[33] Patents Act 1990 (Cth), s 18(1). Section 18 contains the substantive requirements of patentability in Australia – equivalent to s 14 in New Zealand's patent legislation, see above n 10, 11, and 12. See for description of history and operation of current Australian Act.

[34] The Patents Act 1990 (Cth) does in fact still define an "invention" and "patentable invention". An invention is defined in the Dictionary to mean "any manner of new manufacture the subject of letters patent and grant of privilege within s 6 of the Statute, and includes an alleged invention". A patentable invention is defined in terms of s 18(1).

[35] Jessica C Lai "Gene-related patents in Australia and New Zealand: Taking a step back" (2015) 25 AIPJ 181 at 184-185.

[36] The retention of a near identical incorporation of s 6 of the Statute in the 2013 Act mean the substantial body of case law pre- and post-1953 Act is still relevant.

[37] Patents Act 2013, s 14(b)(i).

[38] Frankel and Lai *Patent Law and Policy*, above n 17, at 88.

4.2. Historical development of the judicial approaches to the "manner of manufacture" requirement

In jurisdictions which have included or referenced s 6 in patent regimes, the task of elaborating its contents has largely been the province of the courts rather than the legislature.[39] Two broad – but highly different – judicial approaches to s 6 have developed over time. This sub-part outlines these approaches by considering the seminal case dealing with the fundamental issue of "inherent patentability"*, Boulton and Watt v Bull* (*Boulton v Bull*),[40] and developments up until the time of *National Research Development Corporation v Commissioner of Patents* (*NRDC*)[41] – the precedent case for the s 6 inquiry in New Zealand as adopted in *Swift & Co v Commissioner of Patents*.[42] Establishing the 'lay of the land' allows *NRDC* to be considered in its proper context, which is critical to Part II's analysis of refinements made to the *NRDC* methodology in the *Myriad* litigation, as well as to Part III's assessment of these and other approaches.

In 1795, the Court of Common Pleas in *Boulton v Bull* split 2:2 over whether the 'invention' in question (a new method for using an old steam engine) was able to be patented (i.e. was it "inherently patentable"?).[43] The 2:2 split was not reflective of the competing judicial approaches adopted – as described in Section 4.2.1 below – but instead reflective of disagreement as to the delineation of where the following categories ended and began: mere principles (inherently unpatentable); vendible products (inherently patentable); and principles in practice as processes (inherently patentable)[44]. The Court did however agree that the answer involved s 6 of the Statute, but the differing methodological approaches paved the way for decades of legal theory.

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[39] The changes via legislative amendment and intervention largely being of form (i.e. structural changes) and not substance. For support of this assertion, see Frankel and Lai *Patent Law and Policy,* above n 17, at 91.

[40] *Boulton and Watt v Bull* ("*Boulton v Bull*") [1795] 126 ER 651.

[41] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

[42] *Swift & Co v Commissioner of Patents* (1960) NZLR 775 (SC).

[43] The 2:2 split did not mirror the judicial approach adopted, but instead reflected disagreement as to where vendible products (inherently patentable) ended and mere principles (inherently unpatentable) began. The invention was the former in the opinion of Eyre and Rooke CJJ, and the latter in the opinion of Heath and Buller JJ.

[44] *Boulton v* Bull, above n 40. Principles in practice in the form of inherently patentable processes was the view adopted by Eyre J (at 667-668).

4.2.1. *Boulton v Bull*

On the one hand, Heath and Buller JJ (and also to a lesser extent Eyre CJ)[45] took a textual approach and focussed on the meaning of the term "manufactures" in s 6. "Manufactures" was interpreted narrowly by Heath and Buller JJ to include only chemical and mechanical artefacts (products), based on the limited, existing understanding of how human ingenuity could benefit the public market and trade.[46] The concept of 'invention' was correspondingly limited to chemical and mechanical vendible products – such products or subject matter were inherently patentable.[47] Eyre CJ formulated a broader conception of 'invention' to include *processes* not just *products*.[48] The justification was that both produced a useful effect to benefit the market, thus 'manufacture' could ordinarily be understood in a wider sense, extending to processes.

On the other hand, Rooke J in *Boulton v Bull* focussed on the 'spirit' of the Statute, rather than the specific words used.[49] Based on this approach, Rooke J considered the invention was a "manner of [new] manufactures" because the improvement was a sufficiently defined new thing of substantial public benefit.[50] In effect, Rooke J created an open-textured approach which transcended the specific statutory language to find the concept of 'invention' should include the improvement in order to give effect to the purpose of the Statute.[51] Rooke J's approach did not gain currency – at least explicitly – until the 1960s following the decision of the High Court of Australia in *NRDC.*[52] Until that point,

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[45] *Boulton v Bull*, above n 40, at 655 per Buller J, and at 660-661 per Heath J, and at 667-668 per Eyre CJ.
[46] Pila *Requirement for an Invention*, above n 22, at 40-41.
[47] The invention in question was neither a chemical or mechanical product, but rather a mechanical process itself which was deemed inherently unpatentable by Heath and Buller JJ.
[48] Eyre CJ extended the conception to new composition of things ("manufactures in the most ordinary sense of the word" at 666), new processes in any art producing effect useful to the public, new substances or compositions produced by such a process and new processes which use old machinery to achieve a new result (at 666).
[49] *Boulton v Bull*, above n 40, at 651 and 666 per Eyre CJ and Rooke J respectively.
[50] At 658 per Rooke J.
[51] The purpose of the Statute, one heavily steeped in policy, shall be described in more detail in Section 6.2.3. below.
[52] *NRDC,* above n 41. See Pila "Inherent Patentability in Anglo-Australian Law: A History", above n 9, for further discussion as to the development of inherently patentable and unpatentable classes of subject matter prior to *NRDC* under the textual approach.

the predominant judicial approach followed the outlines of the other Judges' approaches: a methodology which used 'strictures inherent in the term "manufactures" to identify and categorise patentable subject matter in a rigid way'.[53]

4.2.2. Post *Boulton v Bull,* pre *NRDC*

As an ostensibly textual approach with a focus on the term "manufactures" was applied, it created a positive conception of an 'invention' (e.g. a tangible, vendible product) – albeit a very nebulous and hopelessly broad criterion. Over time, application of the strict methodology slowly expanded the categories of 'inherently patentable' subject matter recognised in *Boulton v Bull* (e.g. mechanical or chemical products), reflecting changing understandings of benefits to public market and trade.[54] However, the requirement that a product or process produce a vendible artefact continued to be a restrictive, limiting criterion.[55]

Application of the methodology also formed various negative conceptions of what an 'invention' was *not*, which led to the threshold exclusion of various "manifestly non-inventive" categories of subject matter, as "inherently unpatentable". Relatively non-contentious categories included "discoveries"[56], "ideas"[57] and, as recognised early on in *Boulton v Bull*, "principles of nature".[58] However, these categories gave rise to more specific, secondary categories such as 'surgical and therapeutic methods of medical

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[53] William van Caenegem *Intellectual and Industrial Property in Australia* (LexisNexis Buttersworth, Australia, 2009) at 165.
[54] Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 165.
[55] Stephen Hubicki and Brad Sherman "We have never been modern: the High Court's decision in *National Research Development Corporation v Commissioner of Patents*" in Andrew T Kenyon, Megan Richardson and Sam Ricketson (eds) *Landmarks in Australian Intellectual Property Law* (Cambridge University Press, New York, 2009) 73 at 87.
[56] *Ralston v Smith* (1865) 114 ER 1013 (Comm Pleas) explained the distinction between inherently patentable 'inventions' and inherently unpatentable "discoveries".
[57] *Young v Rosenthal* (1884) 1 RPC 29 (QB) acknowledged "ideas" as being a version of 'mere abstract discovery' incapable of being the subject matter that constitutes a "manner of manufacture".
[58] *Boulton v Bull*, above n 40. In the words of Buller J, "[t]he very statement of what a principle is proves it not to be a ground for a patent. It is the first ground and rule for arts and science, or in other words the elements and rudiments of them". While there was dissonance in the overall judgment, Eyre CJ, Rooke J, Heath J and Buller J all converged on the viewpoint that "abstract" principles (at 668) and "mere unorganised principles of science" (at 655) were inherently unpatentable.

treatment for humans[59], agricultural, horticultural and other biotechnological subject matter, and presentations of information'.[60] Most exclusions were based on the subject matter not falling within the words "manner of [new] manufactures" as understood by the courts – rather than relying on the latter half of s 6,[61] which was seldom used as a basis for inherent unpatentability.[62]

A fixation with the words "manner of [new] manufactures", in other words the textual approach,[63] created various separate conceptions of what an 'invention' inherently *was* or *was not*. However, in some cases the line between what was 'inherently patentable' and 'inherently unpatentable' was difficult to discern. This difficulty was present in *Boulton v Bull* itself, as Eyre CJ noted:[64]

> "I have dwelt the more largely upon this part of the case [that being whether the invention was for an inherently-unpatentable-mere-principle or an inherently-patentable-principle-put-into-application] because, in my apprehension, this is the foundation upon which the whole argument will be found to rest."

More substantially, Rooke J problematised the distinction between inherently-unpatentable-mere-principle; and inherently-patentable-principle-in-practice because:[65]

> "The term principle is equivocal; it may denote either the radical elementary truths of a science, or those consequential axioms which are founded on radical truths, but

[59] *C & W's Application* (1914) 31 RPC 235 (SG). The ratio that methods of medical treatment for humans were unpatentable was endorsed in *Maeder v Busch* (1938) 59 CLR 684 (HCA).
[60] The listed categories derive from in-depth discussions of subject matter exclusions to patentability and development of the said classes over time in: Pila "Inherent Patentability in Anglo-Australian Law: A History" above n 9; and Pila *Requirement for an Invention*, above n 22, at 90.
[61] The latter half of s 6 being: "so as also they be not contrary to the law, or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient", see above n 19.
[62] See Pila *Requirement for an Invention*, above n 22, at 72-81 for the justification of each inherently unpatentable category based on interpretation of 'manufactures' instead of reliance on the specific statutory exclusions.
[63] The textual approach adopted by Eyre, Heath and Buller CJJ as opposed to the 'spirit' approach propounded by Rooke J in *Boulton v Bull* above n 40.
[64] *Boulton and Watt v Bull*, above n 40, at 667-668 per Eyre CJ.
[65] At 659 per Rooke J.

> which are used as fundamental truths by those who do not find it expedient to have recourse to first principles."

The challenge with the term "inherently" is it encourages courts to draw delineations, with little reasoned justification. The term also suggests some intrinsic feature mandates classification in a particular way, which can create an overly static, immutable conception of an 'invention', which is unable to respond to technological developments.[66] As such, the textual approach unhelpfully tethered the developing conception of an 'invention' to the limited, traditional conception of an 'invention' or 'manufacture' as understood in 1623.

4.3. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252

The invention in *NRDC* was for a process which used known chemicals for a previously unknown purpose – selective weed eradication. The question of law was whether the method invention could constitute a "manner of manufacture" as the Patents Act 1952 (Cth) required.[67] The problem was that the claimed invention appeared to fall into a previously carved out, inherently unpatentable category of subject matter (agricultural and horticultural processes), and also did not satisfy the positive requirement of producing a vendible product.[68] *NRDC* has attained a "sacrosanct" position in New Zealand (and Australian) patent law as it fundamentally redirected the nature of the s 6 inquiry.[69]

First, the Court rejected the textual approach which had been determinative in assigning meaning to s 6:[70]

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[66] Ann L Monotti "The Scope of 'Manner of Manufacture' Under the Patents Act 1990 (Cth) after *Grant v Commissioner of Patents*" (2006) 34(3) FedLawRw 135 at 136.
[67] *NRDC*, above n 41, at 268.
[68] Pila *Requirement for an Invention*, above n 22, at 90-91. The selective weed eradication, the Commissioner claimed, was also for the 'mere use of a known substance' – another apparent area where the invention failed to satisfy what the term a "manner of manufacture" meant.
[69] Brad Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia" (2015) 37 Syd LR 135 at 136.
[70] *NRDC*, above n 41, at 271.

> "The truth is that any attempt to state the ambit of s 6 of the Statute of Monopolies by precisely defining "manufacture" is bound to fail."

The conception of 'invention' was explicitly approached based *not* on the "direct explication and in the language of its own day, nor yet by carrying forward the usage of the period in which the Statute was passed, but with reference to the established ambit of s 6 of the Statute".[71] Instead, the Court found the "right" approach was to pose the question:[72]

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

To determine "proper" subject matter, the Court found it must look to the 'scope of permissible subject matter'.[73] The correct approach thus invites a *conceptual* inquiry into the term a "manner of manufacture", rather than an interpretative inquiry into its "exact etymological meaning" – an approach highly reminiscent of the 'spirit' approach propounded by Rooke J many years earlier.[74] In keeping with the widening conception of the notion of a "manner of manufacture", the Court widened the traditional understanding of a "vendible product",[75] to encompass:[76]

> "[a] "product" [consisting of] an artificially created state of affairs… [when] the significance of the product is economic".

The selective weed eradicator in *NRDC* satisfied these two requirements, and the Court also found no basis to continue exclusion of agricultural and horticultural processes by

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[71] *NRDC*, above n 41, at 269.
[72] At 269 (emphasis added).
[73] At 269.
[74] *Boulton v Bull*, above n 40. See Section 4.2.1 above for detailed discussion of the 'spirit' approach.
[75] Hubicki and Sherman "We have never been modern: the High Court's decision in *National Research Development Corporation v Commissioner of Patents*", above n 55, at 88. The traditional understanding was limited to chemical and mechanical vendible products. The origins of this understanding could be traced back to *Bolton v Bull,* as was noted by the Court in *NRDC*. For explanation of the decision of *Boulton v Bull,* see Section 4.2.1 above.
[76] *NRDC*, above n 41, at 277.

reason of their nature; thus the selective weed eradicator was found to fall within the concept of a "manner of manufacture", and was therefore an 'invention'.[77]

While seemingly straight-forward, this decision radically redirected the "manner of manufacture" inquiry.[78] The redirection addressed difficulties created by rigid application of the historical categories, not by doing away with the methodology of identifying and categorising subject matter, but instead by requesting the methodology be applied in a more liberal fashion.[79] It also preserved the judicial arm's flexibility in light of inevitable scientific and technological developments.[80] In this respect, the redirection can almost be viewed as necessary: a necessary progression to ensure patent law developed in step with modernising technological and societal conditions.[81]

4.4. Interpreting claims: the primacy of substance over form

Finally, a brief but important point of law which requires description is how the courts interpret claims. The subject matter of an invention as claimed in a claim is:[82]

> "…To be understood as a manner of substance and not merely as a matter of form."

Thus, in instances where craftily-drafted claims may in fact be attempting to obtain a monopoly over a previously established unpatentable subject matter, the primacy of substance over form gives the courts the ability to transcend specifics and look to the essence of what is being claimed. "Products of nature", an inherently unpatentable category of subject matter, are particularly vulnerable to such drafting techniques. One such "product of nature", nucleic acids, are central to this dissertation and shall now be discussed in Section 5.

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[77] *NRDC*, above n 41, at 277.
[78] Hubicki and Sherman "We have never been modern: the High Court's decision in *National Research Development Corporation v Commissioner of Patents*", above n 55, at 94-96.
[79] At 94.
[80] Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 166.
[81] Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35, at 183.
[82] *Research Affiliates LLC v Commissioner of Patents* (2014) FCR 378 at 401.

5. Nucleic acids as the subject matter of an 'invention'

The following provides a primer on important scientific knowledge which must be understood in order to properly consider legal approaches to nucleic acid 'inventions'.[83]

5.1. Properties of nucleic acids

Nucleic acids are deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), both of which are complex biomolecules. Chemically, nucleic acids are highly similar. Nucleic acids are comprised of individual units, called nucleotides, that come in various forms: adenine (A), guanine (G), cytosine (C), thymine (T) and uracil (U). DNA contains all nucleotides except *U*, and RNA contains all except *T*. Nucleotides are linked end-to-end to form long strands, colloquially know as DNA and RNA. Structurally, both nucleic acids are quite different. DNA is comprised of two strands which are intertwined to form a stable double-helix structure. RNA is single-stranded and less stable, and because of this, can form a wide variety of dynamic structures. Of importance, RNA can be present in the human body as pre-messenger RNA (pre-mRNA) and mature messenger RNA (mature mRNA, or simply mRNA).

At the chemical and structural level, nucleic acids are unremarkable. And yet, this unremarkable arrangement of nucleotides gives rise to remarkable biological functions. DNA and RNA house invaluable genetic information that encodes how to build, maintain and reproduce biological systems, such as the human body. Nucleic acids are not generally functionally active, nor do they participate in biochemical reactions within the human body, but rather the genetic information contained within flows from and through them to proteins – the functionally active, effector molecules. Proteins are manifestations of the genetic information contained within nucleic acids. The Central Dogma of molecular biology summarises how the processes of *transcription* and *translation* allow information to flow through biological systems. DNA is *transcribed* into pre-mRNA. The information is only *transcribed* from one format to another as the

[83] The following discussion, unless noted otherwise, is based on Donald Voet, Judith G Voet and Charlotte W Pratt "Fundamentals of Biochemistry: Life at the Molecular Level" (4th ed, Hoboken (NJ), John Wiley & Sons, 2015). In particular Chapter 3: Nucleotides, Nucleic Acids and Genetic Information.

biochemical "languages" are highly similar.[84] The pre-mRNA is further modified via a process called 'splicing' to produce mature mRNA; mature mRNA is then *translated* to produce a protein. RNA and proteins are expressed in different biochemical "languages" thus the information is *translated*.[85] DNA is made up of both coding (exonic) sections and non-coding (intronic) sections. During splicing, non-coding regions are removed from the pre-mRNA as they are not needed to produce the mature mRNA or the protein. So, DNA and (mature messenger) RNA contain similar, but not identical, genetic information.

The basal importance of nucleic acids is most succinctly illustrated when something goes *wrong*. A section of DNA that is made up of coding, exonic sections is called a gene. The human body has approximately 22,000 genes, which encode for proteins that carry out all the functions that make us human. A normal, functional gene is coined a 'wild-type'.[86] A gene which differs from the 'wild type' by virtue of the nucleotide sequence is a 'mutant'. Mutants contain mutations which are simply a change in the underlying nucleotide sequence.[87] In the context of the Central Dogma, mutations *change* the underlying DNA and/or RNA, and can lead to the resultant protein being unable to carry out its integral cellular function which in turn can cause genetic disorders or a predisposition to the development of certain diseases. Given the pervasive nature of nucleic acid mutations – in contrast to other biomolecules – significant time, resources and expertise has been invested in identifying and understanding the relationship between specific nucleic acid mutations on the one hand, and disease and disorder on the other.

[84] Brief of James D. Watson, Ph.D as Amicus Curiae in Support of Neither Party *Association for Molecular Pathology v Myriad Genetics Inc,* 133 S. Ct. 2107 (2013) (No. 12-398) at 5.
[85] Brief of Watson, above n 2, at 5.
[86] A 'wild type' is the most commonly, occurring functional version of the gene. It is possible to have a gene sequence which *differs* from the 'wild type' gene sequence but is not a mutant i.e. contains a silent mutation.
[87] Mutations can be as simple as a change in a single nucleotide (called single nucleotide polymorphisms (SNPs)), say where an A becomes a T, or more complex additions, deletions or rearrangements of entire genes (which contain hundreds if not thousands of nucleotides).

5.2. Application of nucleic acids within the biotechnology industry

In a wide sense, biotechnology is the science of utilising biological resources to achieve desired outcomes.[88] Often, and certainly in the biotechnology considered in the court cases this dissertation analyses, the desired outcome is to understand, treat and potentially cure or prevent diseases and disorders that are based on nucleic acids.[89]

To achieve this desired outcome, three common scientific techniques are implemented in tandem: 'isolation'[90], 'cloning'[91] and 'sequencing'[92]. Such techniques are used to produce isolated nucleic acid gene sequences,[93] which allow for direct comparison between the sequence of nucleotides in an isolated sequence and a wild-type sequence in order to identify differences, i.e. mutations.[94]

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[88] Amanda Warren-Jones *Patenting rDNA: Human and Animal Biotechnology in the United Kingdom and Europe* (Lawtext, Witney (Oxfordshire), 2001) at 1.

[89] Jeanne Snelling, Nikki Kerruish and Jessie Lenagh-Glue *Judging Genes & Choosing Children*: Revisiting Law, Ethics and Policy in the Genomic Era (University of Otago, Dunedin, 2017) at 29.

[90] 'Isolation' is the process of removing nucleic acid fragments from the *in vivo* environment to enable *in vitro* studies: the DNA is extracted from the cell and separated from other associated cellular components to purify the DNA and enable cloning and sequencing. This is required as genes do not exist in the cell as discrete entities but instead as a small segment of a much larger DNA molecule. Restriction nucleases – enzymes that 'cut' the DNA at specific sites defined by the local nucleotide sequence – facilitate the initial separation of the gene before secondary methods are used to further purify the targeted nucleic acid sequence.

[91] 'Cloning' is the process of making multiple copies of an isolated DNA fragment. This is important as it simply provides a greater amount of the specific DNA – or 'start' material' – for sequencing purposes.

[92] 'Sequencing' is the process of 'reading' the underlying order of nucleotides in the isolated, cloned gene fragment.

[93] 'Isolated gene sequences' are sections of DNA that have been removed from the natural DNA of a person. The DNA is extracted from cells in the human body, and is therefore derived from natural DNA.

[94] While progress in developing methods of nucleotide 'isolation' and 'cloning' were important, developments in sequencing technology facilitated the 'boom' in the biotechnology sector. Initially, only short isolated fragments of ~100 bases could be "read" during sequencing. But most genes are significantly longer. The average length of a gene in the human body is 54,000 nitrogenous bases long, the shortest being a few 100 nitrogenous bases and the longest 2,400,000 nitrogenous bases. For example, the BRCA1 and BRCA2 genes – which will be central to later discussions in relation to the *Myriad* litigation – are comprised of 81,000 and 85,000 nitrogenous bases long, respectively. The task of "reading" shorter fragments and re-compiling them in the 'right order' used to be laborious and error-prone. In time, with technological advances in large-scale sequencing techniques and computational abilities, longer sequences of nucleotides could be 'read'. See generally Warren-Jones *Patenting rDNA: Human and Animal Biotechnology in the United Kingdom and Europe*, above n 88.

Two types of isolated gene sequences are central to this dissertation: genomic DNA (gDNA) and complementary DNA (cDNA) isolated gene sequences. An isolate in the form of gDNA is derived from DNA and contains coding *and* non-coding regions. The resultant gDNA molecule contains the same genetic information as in DNA, and consists of A, G, C and T nucleotides. An isolate in the form of cDNA is derived from RNA and thus *only* contains coding regions. The formation of cDNA isolates is more laborious than gDNA isolates, reflective of the inherent chemical instability of RNA.[95] To create cDNA, mRNA is isolated by the lab technician from a cell in the human body; *before* cloning and sequencing, the mRNA is reverse transcribed[96] to produce a double-stranded mRNA:cDNA hybrid; the strand of mRNA is then degraded and replaced by a newly synthesised strand of cDNA. The outcome is a double-stranded cDNA molecule. Chemically, it contains A, G, T and C nucleotides – like DNA – and does not contain U as found in mRNA. Genetically, the information is derived from mRNA and contains only coding regions. The result is a DNA-analogous chemical and structural compound which houses RNA-analogous genetic information.

In order to make comparisons between an isolate and a wild-type sequence, the wild-type sequence must first be known. In the 1990s, as the biotechnology "boom" was beginning, so too was a race to identify the location and wild-type sequence of genes associated with breast and ovarian cancer – this race is central to the legal case this dissertation analyses in Section 8.[97] Myriad Genetics, Inc (Myriad) won the race, identifying the precise location of two such genes, BRCA1[98] and BRCA2[99], amongst the ~3 billion nucleotides that comprise the human genome.[100] BRCA1 and BRCA2 are

[95] See generally Bruce Alberts and others *Molecular Biology of the Cell* (4th ed, Garland Science, New York, 2002) at "Isolating, Cloning and Sequencing" for discussion as to the challenges posed by RNA.
[96] Reverse transcription is the opposite of transcription and facilitated by an enzyme called reverse transcriptase. Until the discovery in 1970 of the reverse transcriptase family of enzymes, RNA was unable to be 'read' and the genetic information contained within was unobtainable.
[97] This dissertation shall focus only on the race to discover BRCA1 and BRCA2, but note other different genes associated with breast cancer had been identified and were at the centre of the race too.
[98] Y Miki and others "A strong candidate for the breast and ovarian cancer susceptibility gene *BRCA1*" (1994) 226 Science 66.
[99] SV Tavtigian and others "The complete BRCA2 gene and mutations in chromosome 13q-linked kindreds" (1996) 12(3) Nat Genet. 333.
[100] Myriad was deemed to have won the race for BRCA1 and BRCA2, however this was somewhat contentious as other research groups asserted it was in fact them; for example a US research team led by Marie Claire King at the University of California at Berkley, who later formed OncorMed, was first to

tumour suppressors,[101] and mutations in either gene prevent the human body from producing the tumour suppressor protein, which in turn increases an individual's risk of developing breast or ovarian cancer.[102] Myriad employed the common scientific techniques of 'isolation', 'cloning' and 'sequencing' to first discover BRCA1 and BRCA2, and then to identify many common mutations in both genes. With both of these pieces of knowledge, Myriad developed diagnostic tests for early detection of predisposition and susceptibility to breast and ovarian cancer.[103]

identify the presence of BRCA1 somewhere in chromosome 17. Patent infringement proceedings were filed by both parties against one another; the matter was settled when Myriad acquired OncorMed (JM Hall and others "Linkage of early-onset familial breast cancer to chromosome 17q21" (1990) 250 Science 1648.).

[101] The location, function and wider cellular implications of both genes is discussed in JA Duncan, JR Reeves and TG Cooke "BRCA 1 and BRCA2 proteins: roles in health and disease" (1998) 51(5) Mol Pathol 237, which was published four years after the initial 'discovery' of BRCA1 in chromosome 17.

[102] The increased cumulative lifetime risk is from 12.7% to ~40-85% and 1.4% to ~16-40%; for breast and ovarian cancer, respectively: Richard Gold and Julia Carbone "Myriad Genetics: In the eye of the policy storm" (2010) 12(4) Genet Med. 39 at 42.

[103] Breast Cancer Foundation NZ "Breast awareness: Genetic counselling & testing" Breast Cancer Foundation <https://www.breastcancerfoundation.org.nz/>.

6. Unpacking the patent eligibility inquiry: the difficult concept of an 'invention' and un(der)articulated tests

6.1. The difficult concept of an 'invention'

The existence of an 'invention' is central to s 14(a) of the Patents Act 2013, however, it is a particularly challenging concept. Through application of the common law methodology, a "manner of manufacture" has both embraced and excluded various categories of inherently patentable and unpatentable subject matter. The status of such taxonomical categories of subject matter (e.g. agricultural and horticultural processes[104]) has also changed over time, to further exacerbate challenges posed by the flexible, vague concept of an 'invention'. Ultimately, the result was a morass of different and potentially conflicting ideas about what qualified as an 'invention'.

6.2. Un(der)articulated tests

Whether an 'invention' exists is a challenging and perhaps even unanswerable question. So, rather than approach this tough question head on, courts often rely on other distinctions as proxies for this type of reasoning. The proxies, herein known as 'Un(der)articulated tests' or simply 'the tests', are selected according to how suitable they appear to be for the claims before the court.[105] The opportunity to select between tests raises the possibility that some may not work very well in particular contexts – a possibility which this dissertation suggests, is realised in the context of nucleic acid 'inventions'.[106]

[104] The category of subject matter went from being inherently unpatentable to a subject matter which *could* be included within the concept of a "manner of manufacture" (as per *NRDC*, above n 41).
[105] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1195.
[106] 'Un(der)articulated' tests that do not bode well in the context of nucleic acid 'inventions' are described in Section 8, specifically Sections 8.4.3 and 8.5.

For the purposes of this dissertation, only a selection of 'Un(der)articulated tests' shall be described in order to facilitate analysis of the *Myriad* litigation.[107] The tests focussed on are:

1. Judging Difference (from "nature")
2. Labour-centric
3. Policy-centric

The first two tests are attributable to the article "*What Does It Mean to Invent Nature*" by Brad Sherman, in which a third test is also described – the test being an 'Inventive Concept'.[108] This test shall not be discussed in this dissertation as it was not implemented by the majority of the High Court of Australia in *Myriad*, the majority judgment being the central point of analysis in Section 8.[109] Moreover, the test has also been criticised as highly duplicative of the requirement for "an inventive step".[110] The 'Policy-centric' test has not been explicitly noted, but instead broadly described and endorsed by various academics.[111]

The 'Un(der)articulated tests' act as proxies in attempt to answer the elusive question as to whether an 'invention' exists. The proxies operate by building implicitly upon the inventive process used to produce the 'invention' – in this context, the BRCA1/2 isolates – but each test focusses on different aspects of the process.[112] The courts do not attempt

[107] The analysis of the *Myriad* litigation takes place in Section 8 below.
[108] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1203. The 'Inventive Concept' test requires the inventive process to be scanned in search of an element, or combination of elements, that can be seen as sufficient to ensure the patent in practice amounts to an extension of a patent upon the (inherently unpatentable) natural nucleic acid itself. This test is sometimes implemented with a secondary requirement contingent upon the first: once an 'inventive concept' is identified, the concept must then be seen to make a contribution to the difference between the raw nucleic acids and the product as claimed in the claims i.e. contribute to the essential element or substance of the 'invention'.
[109] The minority judgment of Gageler and Nettle JJ in *Myriad* can be seen to rely on the 'Inventive Concept' test. However such reliance has been criticised as it imported an element of 'inventiveness' which is seen to be highly duplicative of the requirement for "an inventive step" in section 18(1)(b)(ii) of the Patents Act 1990 (Cth). See 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) JLIS 120 at 133-135 for a post-*Myriad* critique of this un(der)articulated test.
[110] Patents Act 2013, s 14(b)(jj).
[111] Rochelle Dreyfuss, Jane Nielsen and Dianne Nicol "Patenting nature – a comparative perspective" (2018) 5(3) JLB 550 at 571; Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35.
[112] Brad Sherman "What Does It Mean to Invent Nature?" (2015) 5 UC Irvine L Rev 1193 at 1202.

to strictly recreate the process – the inquiry is legal rather than scientific[113] – but instead marry the notion of the inventive process with particular policy ends.[114] An end common to all the tests is the inherent risk that the 'invention' may mirror the underlying natural nucleic acids too closely, which in turn would mean (if granted), the patent would essentially monopolise 'part of the storehouse of knowledge of all men which should be free to all and reserved exclusively to none'[115] – like the harmful early patents over "starch, sugar and salt".[116] This policy end undergirds *all* the 'Un(der)articulated tests' and, in this sense, judicial approaches *always* involve policy considerations.[117]

6.2.1. Judging Difference (from "nature")

'Judging Difference' focusses on the beginning and end of the inventive process: the "raw materials" (i.e. natural nucleic acids), and the product as claimed in the claims. Judgement is passed by carrying out two or sometimes three steps.[118]

First, the court must determine how the natural nucleic acids and the product(s) are to be characterised – characterisation is often determined by looking to the claims, and interpreting them as a manner of substance and not form to identify the essential element of the 'invention'.[119] Secondly, the "raw materials" and the products are compared in search of "differences"; and thirdly, if required, identified "differences" may be qualitatively assessed to determine whether they are salient enough to attain the threshold required.[120] Nucleic acids are not visible to the human eye, thus determination of "difference" must be engaged with in an abstract, conceptualised manner. Moreover, the line between salient differences or otherwise is often slim, as the act of isolation does not significantly alter the "raw materials" – a point which is variably contentious and

[113] Dan L Burk "Edifying Thoughts of a Patent Watcher: The Nature of DNA" (2013) 60 UCLA L. Rev. Disc. 92 at 95.
[114] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1203.
[115] *Funk Bros Seed Co v Kalo Inoculant Co*, 333 U.S. 127, 132 (1948) (SC).
[116] Pila *The Requirement for an Invention in Patent* Law, above n 22, at 18-21.
[117] It should be noted that the policy-ends are given greater deference, in a more transparent manner, with the 'Policy-centric' test (per Section 6.2.3 below).
[118] The two- or three-step test was outlined Sherman in "What Does It Mean to Invent Nature?", above n 112, at 1211.
[119] See 'Interpreting claims: the primacy of substance over form' (Section 4.4).
[120] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1211.

highly dependent upon the first step of characterisation to determine what feature is being compared (i.e. chemical, structural, functional differences).

6.2.2. Labour-centric

The 'Labour-centric' test takes a figurative step back from the inventive process and instead assesses the process indirectly through the role of the inventor.[121] The premise of this test is that natural nucleic acids are "naturally occurring" and, almost by definition, "unaltered by the human hand",[122] and are thus inherently unpatentable. But alteration of nature through work done by the human hand, *can* create something "new".[123] The caveat "*can*" requires emphasis as it gives rise to two variations of the 'Labour-centric' test.[124] First, an almost non-existent, low-threshold level of work is imposed 'whereby – within certain parameters – the mere exercise of labour, skill and work is enough to render the subject matter patentable'.[125] Secondly, a higher-threshold is imposed whereby quantitative and qualitative limits are placed upon the work which can be said to have transformed the unpatentable natural nucleic acids into an 'invention'.[126] Overall, the court looks to whether those orchestrating the inventive process have 'displayed the requisite level of skill to "individualise nature".[127]

The work used to produce an isolated nucleic acid is highly technical and complex: to a person or body outside the scientific community, the work can easily be characterised as meeting the low- or high-threshold. Yet the façade of complexity is stripped away within the biotechnological industry as the work is common-place and practiced in

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[121] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1206.
[122] At 1206 (citing *In re Roslin Institute* (Edinburgh), 750 F.3d 1333, 1336 (Fed Cir 2014)).
[123] "The distinction is between products of nature, whether living or not, and human-made inventions" (per *J.E.M. Ag Supply Inc v. Pioneer Hi-Bred International, Inc.*, 534 US 124, 130 (2001) (SC) (citing *Diamond v Chakrabarty,* 447 U.S. 303, 313 (1980) (SC)).
[124] See Brad Sherman and Lionel Bentley *The Making of Modern Intellectual Property Law: The British Experience 1760-1911* (Cambridge University Press, Cambridge, 1999) at 46, for a detailed description of the two forms of the 'Labour-centric' approach.
[125] Sherman "What Does It Mean to Invent Nature?", above n 112, at 1207.
[126] At 1207-1208.
[127] At 1205.

laboratories all around the world.[128] The disconnect between the courts and those involved in the industry shall be unpacked further in Section 8.4.2 below.

6.2.3. Policy-centric

While policy-centric considerations are implicitly folded into the other 'Un(der)articulated tests', the 'Policy-centric' test exists in a standalone form – the court strictly focusses on the consequences of monopolisation of the 'invention' and uses such consideration to determine whether the subject matter is patentable.

Monopolies granted through the patent system represent State supported curtailment of competition as by nature they are anti-competitive.[129] While anti-competitive manoeuvres are prima facie undesirable,[130] patents are justified on the basis they incentivise the act of 'invention' and *eventually* lead to long-term economic growth and increased range, supply, quality and efficiency of goods and services available to the community.[131] Incentivisation is seen as necessary, but for the time-limited monopoly which can be exploited, less innovation would take place and society as a whole would not reap the rewards of such innovation.[132] Justification of patents is thus dependent upon the competing rights, of the inventor and society as a whole,[133] being in rough balance i.e. the benefit *eventually* reaped by society should be significant enough to justify the anti-competitive manoeuvre.[134] After all, "the patent system is a *public* instrument of economic and social policy and the rights it confers must advance overall public welfare, not undermine it".[135]

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[128] See generally Warren-Jones *Patenting rDNA,* above n 88, for discussion of biotechnological processes (beyond isolation, cloning and sequencing) implemented to nucleic acids 'inventions' and how such processes are prevalent, commonly used and well-understood within the industry.
[129] John Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies" in Graeme Austin and Charles Rickett (eds) *International Intellectual Property and the Common Law World* (Hart Publishing, Oxford, 2000) at 215.
[130] At 215.
[131] At 215.
[132] At 215.
[133] Patents Act 2013, s 3(a)(ii).
[134] Harmful monopolies, such as those granted over "starch, salt and vinegar" (above n 22) clearly result in an imbalance of rights based on the 'Policy-centric' test.
[135] Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies", above n 129, at 215.

6.3. Abandonment approach

The above discussion of 'Un(der)articulated tests' has dealt with one response to the challenge posed by the difficult concept of an 'invention' – applying flexible case-by-case reasoning, based on interrelated conceptions of what amounts to an 'invention', in an implicit (rather than explicit) manner.

An alternative response, the 'Abandonment approach', sees little utility in engaging deeply with the concept of an 'invention' in this context. Instead, it simply does not engage, or only engages to a small extent, with the concept. An illustrative example is provided in the European Directive on the Legal Protection of Biotechnological Inventions (the Biotech Directive).[136] The Biotech Directive states that "[a]n element isolated from the human body or otherwise produced by means of technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".[137] It is made clear that the act of "isolation" is sufficient to produce an invention. In the context of the Patents Act 2013, a functionally similar equivalent would be for the courts to simply skip s 14(a). This would have the effect of side-stepping the role of the threshold-eligibility requirement and pushing to the fore other requirements such as novelty,[138] inventive step[139] and usefulness[140]. The abandonment of the concept of an 'invention' can be instituted by many, for example the legislature, courts or other bodies involved in the regulation of patents, but what typifies this approach is that a clear line exists as to what amounts to an 'invention'.[141]

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[136] Biotech Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213). The Biotech Directive regulates how nucleic acid-related inventions are patented in accordance with the European Patent Convention ("EPC") by the European Patent Organisation and its organ, the European Patent Office ("EPO").

[137] Biotech Directive, above n 136, art. 5.2; Implementing Regulations to the Convention on the Grant of European Patents (last amended December 2017), r. 29(2). The use of "may" is not to express doubt as the patentability of isolated nucleic acids, but rather making it clear that further requirements must also be satisfied for the invention to be a patentable invention.

[138] Patents Act 2013, s 14(b)(i).

[139] Section 14(b)(ii).

[140] Section 14(c).

[141] Jessica C Lai "Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision" (2015) 5(5) UC Irvine L Rev 1014 at 1047.

Part II: Judicial approaches to nucleic acid 'inventions' in the *Myriad* litigation

The current judicial approach to s 14(a) of the Patents Act 2013 was established in *NRDC.* However, beyond the broad, judicial approach propounded, New Zealand has no curial guidance as to whether isolated nucleic acids constitute patentable subject matter, are a "manner of manufacture" in accordance with s 14(a), and thus an 'invention' which can receive patent protection.[142]

As it stands, an inferred presumption from the non-curial practice of IPONZ to grant nucleic acid-related patents is that such subject matter is included within the current concept of a "manner of manufacture".[143] Yet overseas developments suggest this presumption may be unstable – demonstrated in analysis of the *Myriad* litigation in the remainder of Part II – and should curial proceedings ensue in New Zealand, may be displaced.[144]

7. Overseas judicial approaches to nucleic acid 'inventions'

7.1. Factual overview of the litigation in Australia and the United States

In 2013 and 2015 respectively, apex Courts in the United States and Australia each settled the patent eligibility of Myriad's BRCA-related product patents that were the

[142] See Frankel and Lai *Patent Law and Policy*, above n 17, at 376-377.
[143] Sumpter *Intellectual Property Law: Principles in Practice*, above n 7, at 301.
[144] In New Zealand, while the presumption in favour of inclusion to allow the patentability of nucleic acid inventions has remained free from legal challenge, it has not remained free from social controversy. Genetic Technologies Limited (GTG) was the exclusive licensee in New Zealand and Australia of Myriad Genetics BRCA patents equivalent to those challenged in the Australian courts. In 2003, GTG approached a number of New Zealand organisations including District Health Boards and Crown Research Institutes, seeking to enforce the BRCA patents and receive significant licensing fees in return. Despite fears that legal enforcement might have resulted, no such proceedings materialised and the patents remained unenforced but valid in New Zealand until their expiration midway through 2015: see generally Alison Heath "Preparing for the genetic revolution – the effect of gene patents on healthcare and research and the need for reform" (2005) 11 CanterLawRw 59.

subject of revocation proceedings.[145] The patents in suit were not exactly equivalent,[146] nor were the laws upon which the challenges were based,[147] and the apex Courts reached opposite conclusions as to the patent eligibility of cDNA.[148] Nonetheless, as this dissertation identifies, the relevant similarities on both counts – and the explicit consideration of United States law in both Australian appellate decisions – provide a wide scope for useful comparative consideration.

7.1.1. The patents in issue

Based on its 1990s work on the BRCA genes,[149] Myriad filed and obtained – in jurisdictions including New Zealand[150], Australia[151] and the United States[152] – two broad types of patents. First, over an isolated wild-type sequence and an array of associated mutations of BRCA1 and BRCA2 (product patents); and second, associated diagnostic tests (process patents). The product patents are those which are in issue in the litigation. In Australia, the product patents in suit were for 'isolated nucleic acids coding for mutant or polymorphic BRCA1 polypeptides in the form of gDNA, RNA and cDNA'.[153] In the

[145] In 2013, proceedings began in the Federal Court of Australia (FCA) before Nicholas J who found in favour of Myriad and deemed the isolated BRCA gene sequences in the form of gDNA, RNA and cDNA patent eligible. Approximately four months later, the Supreme Court of the United States of America (SCOTUS) declared the opposite (save for cDNA). In 2014, the decision of the FCA was unsuccessfully appealed to the Full Court of the Federal Court of Australia (FCAFC). Finally, an expected appeal to the High Court of Australia (HCA) in 2015 achieved an unexpected result: the decisions of both lower courts were unanimously overturned and reversed. Thus SCOTUS and the HCA were in agreement but for the patent eligibility of cDNA.

[146] See Frankel and Lai *Patent Law and Polic*y, above n 17, at 383 for further discussion of the salient differences between the patents in suit in the litigation.

[147] The Australia litigation is based on s 18(1) of the Patents Act 1990 and the "manner of manufacture" inquiry discussed in Part 1. The United States litigation is based on 35 USC § 101 which excludes an otherwise patentable invention if it falls within the implicit exception for a 'product of nature'.

[148] The Supreme Court of the United States found cDNA patent eligible, while the High Court of Australia found cDNA patent ineligible.

[149] See Section 5.2 above.

[150] New Zealand Patent Nos 291330, 291621, 291624 and 326525 for patents covering both BRCA1 and BRCA2.

[151] Australian Patent Nos 686004, 691331, 691958 and 773601. The patents are equivalent to the listed New Zealand Patent Nos, above n 10.

[152] United States Patent Nos 28922194, 57377995.

[153] See *D'Arcy v Myriad Genetics Inc* (HCA), below n 174, at [3] for precise wording of the claims of the challenged patents. It is important to note what the patents did not cover: BRCA1 or BRCA2 per se, nor an isolated BRCA1 or BRCA2 gene sequence. In Australia, the challenged patents were directed towards an isolated BRCA1 *with required mutations or polymorphisms.*

United States, a single patent – deemed determinative of the point of law – was in issue;[154] the product patent covered 'an isolated BRCA1 polypeptide with a prescribed amino acid sequence'.[155] The claims covered an isolate in the form of gDNA and cDNA.[156] So, the Australian litigation covered gDNA, cDNA and RNA, whilst the United States was solely concerned with gDNA and cDNA.[157] The breadth of the Australian patents was also limited to the mutated or polymorphic gene, whilst the United States patents covered the wild-type gene.[158] Overall, while the differences are worth being aware of,[159] they are not of great consequence to the broad central issue that both proceedings dealt with; the central issue being are isolated nucleic acid sequences (in the form of various derivatives, e.g. gDNA, RNA, cDNA) something that can properly be the subject of a valid letters patent.[160]

7.1.2. The legal challenges to the patents in Australia and the United States

The Australian litigation challenged the validity of Myriad's product patents on the basis that they were not proper subject matter for the grant of a patent. In short, that they were not a qualifying "manner of manufacture" under s 6 of the Statute. The United States litigation challenged Myriad's product patents on an analogous ground – that they did not meet the requirement in 35 U.S.C. § 101 for inventions patentable.[161] Under § 101, an inventor may obtain a patent for a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof…" *unless* the invention falls into one of the implicit, judicially-created categories of *excluded*

[154] The SCOTUS were in actuality considering patents which over both BRCA1 and BRCA2: *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2113.
[155] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2113.
[156] At 2113.
[157] Frankel and Lai *Patent Law and Policy*, above n 17, at 383.
[158] At 383.
[159] See Jessica Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?" (2016) 47 IIC 537 at 544-545 for detailed descriptions of the differences between the patents in suit in the Australian and the United States *Myriad* litigation.
[160] Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc:* Patenting Genes in Australia", above n 69, at 141.
[161] 35 U.S.C. § 101 (Supp 1952).

subject matter read into the provision.[162] Categories include "laws of nature",[163] "products of nature",[164] "natural phenomena"[165] and "abstract ideas [or principles]".[166] The United States imported the judicial exceptions entirely from the English common law.[167] "Products of nature" shall be returned to in Section 8.1 below as this is the category which isolated nucleic acids arguably fall into.

The relevant legal principles governing the enquiry in Australia were materially the same as the New Zealand position (recalling that New Zealand adopted the Australian leading case of *NRDC*).[168] Based on these key similarities, the Australian line of cases is the focus of this dissertation. In *Myriad,* the High Court of Australia (HCA) delivered three separate judgments which agreed on the overall result, albeit with some differences in the reasoning.[169] Nonetheless, a majority of four justices subscribed to the plurality opinion authored by French CJ, Kiefel, Bell and Keane JJ, and accordingly the joint judgment is the focus of this dissertation.[170] The majority engaged with the legal analysis in the United States, apparently accepting its potential relevance to the "manner of manufacture" inquiry. Therefore, while the Australian litigation remains the core focus, the relevance of the United States litigation cannot be overlooked and thus shall supplement analysis where appropriate.

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[162] The threshold-eligibility requirement contains implicitly excluded categories of subject matter which are 'read into' the language of § 101. While § 101 is not synonymous with s 6, it has a similar operative effect in that it provides an opportunity for the judiciary to exclude various subject matter which would otherwise be deemed an 'invention' and thus have the capacity to be a 'patentable invention'.

[163] *Bilski v Kappos,* 561 U.S. 593 (2010) (SC).

[164] *Diamond v Chakrabarty,* 447 U.S. 303 (1980) (SC). See *Diamond v Chakrabarty* at 307-310 for discussion of 'product of nature' exclusion.

[165] *Mayo Collaborative Services v Prometheus Laboratories Inc.,* 566 U.S. 66 (2012) (SC).

[166] *Alice v CLS Bank International,* 134 S. Ct. 2347 (2014) (SC).

[167] H Jared Doster "The English Origins of the Judicial Exceptions to 35 U.S.C. § 101" (2019) 11(4) Landslide (online ed, American Bar Association). See Section 4.2.1 for the categories of inherently unpatentable subject matter as established in accordance with English common law.

[168] For summary of the leading case of *NRDC,* see Section 4.3.

[169] For an exhaustive detailed comparison of the three judgments, see 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) JLIS 120.

[170] The decision to focus on the plurality judgment was based on the fact it formed the opinion of the majority and also because aspects of both minority judgments have been the subject of criticism. For example, see *Meat & Livestock Australia Ltd v Cargill Inc* [2018] FCA 51 at [446]-[460] per Beach J in regard to the importation of a concept of 'inventiveness' via reliance on the 'Inventive Concept' test by Gageler and Nettle JJ.

8. Analysis of *D'Arcy v Myriad Genetics* [2015] HCA 35

In *Myriad*, the HCA found the BRCA1/2 isolates in the form of gDNA *and* cDNA were not a "manner of manufacture". In the United States, the Supreme Court of the United States (SCOTUS) found gDNA isolates unpatentable, but instead deemed cDNA isolates patentable inventions. Section 8 references decisions of both lower courts in Australia, the Federal Court of Australia[171] (FCA) and the Full Court of the Federal Court of Australia[172] (FCAFC), and also the SCOTUS[173] where appropriate, to analyse the following critical point of the HCA in *Myriad*[174]:

1. Rejection of the 'product of nature' doctrine
2. Augmentation of *NRDC*: a multi-factorial, policy-laden approach
3. Rejection of the substance of the subject matter: "chemical compound" *or* "genetic information"
4. The multitude of un(der)articulated tests applicable to determine patentability of complementary DNA (cDNA)
5. Post-*Myriad* developments

8.1. Rejection of 'product of nature' doctrine

A cursory reading of Section 7.1.2, the legal basis for challenge in Australia and the United States, shows how the jurisdictions are doctrinally quite different despite sharing a common origin.[175] In fact, the HCA in *NRDC*[176] explicitly rejected the presence of, or reliance on in Australian patent law, the "product of nature" doctrine to exclude subject

[171] *Cancer Voice Australia and Yvonne D'Arcy v Myriad Genetics Inc* [2013] FCA 65.
[172] *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115.
[173] *Association for Medical Pathology v Myriad Genetics Inc.,* 133 S Ct 2107 (2013) (SC).
[174] *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.
[175] See Doster "The English Origins of the Judicial Exceptions to 35 U.S.C. § 101", above n 167 for a detailed, chronological history of the importation of judicial exceptions from the English common law into the United States.
[176] Although, the rejection was endorsed in *D'Arcy v Myriad Genetics Inc* (FCAFC), above n 172, at [144] stating "there is no statutory or jurisprudential limitation of patentability to exclude 'products of nature'. To the contrary, the High Court has specifically rejected such an approach". The HCA in *Myriad* did not comment – either way – but more importantly, did not overrule the FCAFC on this point, nor the previous finding by the HCA in *NRDC*.

matter which would otherwise be a "manner of manufacture".[177] Dixon CJ, Kitto and Windeyer JJ in *NRDC* were critical of the United States approach as "laws of nature", "products of nature" and alike are "vague and malleable terms infected with too much ambiguity and equivocation"[178] – a statement which echoed the words of Rooke J on the topic of an inherently-unpatentable-mere-principle vs an inherently-patentable-principle-in-practice (Section 4.2.2).[179] Instead, the focus on the inherent character of the subject matter, through the lens of "artifice" brought about by human action, was considered to be a better determinant.[180] Therefore, generally the United States is fixated by nature, and Australia (and New Zealand) with artifice. Yet when the specific statutory language is put to one side and a spotlight placed on the operation of both tests, similarities become apparent.

Brad Sherman proposed in his article 'Before the High Court: *D'Arcy v Myriad Genetics Inc:* Patenting Genes in Australia' that:[181]

> "The US product of nature doctrine and the Australian test of artificially created state of affairs are the same question asked from different perspectives. In both cases, they build on an (implicit) image of what it means to invent something; albeit asked from different perspectives: *nature and artifice are flip sides of the same coin*."

Using the implicit image of what it means to invent something, both jurisdictions draw on the premise that the basic building blocks of nature are inherently unpatentable: the United States requires a *distancing* from nature to avoid exclusion, while Australia

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[177] The "product of nature" doctrine implements the 'Judging Difference (from "nature")' test as it allows the court to exclude subject matter which is found in nature where no "differences" or "marked" differences are exist after Step One, Two and Three are carried out (Section 6.2.1).

[178] *NRDC,* above n 41, at 263-264 (citing *Funk Brothers Seed Co v Kalo Inoculant Co,* 333 U.S. 127, 134-135 (1948) (SC) per Frankfurter J).

[179] Dixon CJ, Kitto and Windeyer JJ suggested 'arguments drawn from such terms (i.e. vague and malleable terms) for ascertaining patentability could fairly be employed to challenge almost any patent as everything that happens may be deemed 'the work of nature''. Yet, it is suggest by commentators, for example Sherman below n 181, that a requirement for "artifice" is also vague and malleable insofar as it could also be employed to uphold almost any patent: what can truly be said to be unaltered by the human hand?

[180] Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35, at 183.

[181] Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc:* Patenting Genes in Australia", above n 69, at 141, as cited in the minority judgment in *D'Arcy v Myriad Genetics Inc,* above n 174, at [136] per Gageler and Nettle JJ (emphasis added).

requires an *attainment* of artifice to reach inclusion. The legal question is therefore whether an isolated nucleic acid, in various forms, is *excluded* or *included* due to the various similarities and differences between the product in nature and the 'invention' as claimed in the claims.

Implementation of 'Judging Difference' in Australia through *NRDC*, and the United States through the "product of nature" doctrine, are logically equivalent: it is a distinction without substantial difference.[182] However, as shall become apparent throughout Part II, the HCA in *Myriad* de-emphasised the importance of, and placed less reliance on, the somewhat flawed 'Judging Difference' test. So while the "product of nature" doctrine may be alive and well in all but name in Australian patent law,[183] it is in a limited fashion of less significance.

8.2. Augmentation of *NRDC*: a multi-factorial, policy-laden approach

The majority judgment propounded a multi-factorial, policy-laden approach that augmented the approach taken in *NRDC.*[184] Since *NRDC*, the language of an "artificially created state of affairs" of "economic utility" had come to be applied almost as though it was a statutory test for what constituted a "manner of manufacture",[185] as subsequent courts overlooked the point that the terms had only been employed to address the claims at hand.[186] The HCA in *Myriad* rejected this rigid, modern orthodox application of *NRDC* in order to give effect to the intentions of the HCA in *NRDC.*[187] By way of explanation, the majority noted:[188]

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[182] Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia", above n 69, at 142.

[183] The de-emphasis of the "product of nature" / "artifice test (Judging Difference) in Australian patent law is apparent in Sections 8.2 and 8.5 below.

[184] The question being: "[i]s this a proper subject for a letters patent according to the principles which have developed for the application of s 6 of the Statute of Monopolies 1623?" (*NRDC* at 269).

[185] The FCA and FCAFC in *Myriad* applied the language of *NRDC* in a strict, formulaic manner: see FCA at [88] and FCAFC at [218]. "Manner of manufacture" was seen as synonymous with an 'artificially created state of affairs' of 'economic utility'.

[186] The rigid understanding of *NRDC* was rejected by the HCA in *Myriad* as "[e]ngaging with that criterion in this case places the question of patentability in too narrow a frame" (at [91]).

[187] 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) JLIS 120.

[188] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [5].

> "*NRDC* held that terminology of "manner of manufacture" taken from s 6 of the Statute of Monopolies was to be treated as a concept for case-by-case development. It thereby mandated a common law methodology for its application. It did not confine that methodology to the use of any verbal formula in lieu of "manner of manufacture."

To provide guidance on how to apply the common law methodology, the majority set forth a broad, open-textured framework of a list of non-exhaustive factors to consider when determining whether the concept of a "manner of manufacture" could rightly be extended, by judicial decision, to encompass the claimed invention:[189]

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action;
2. Whether the invention as claimed has economic utility;
3. Whether patentability would be consistent with the purposes of the Act (considering in particular: any potential negative effects on innovation; any potential chilling effects on activities beyond the scope of the patent; any need to consider important and conflicting public and private interests);
4. whether patentability would enhance or detract from the coherence of the law relating to inherent patentability;
5. considerations of Australia's obligations under international law and the patent law of other countries, which are relevant to Australia's place in the international community of nations; and
6. whether patentability would involve law-making of a kind which should be done by the legislature.

The first two factors – which bear significant similarities to the terms used in *NRDC* – are "necessary" to characterise an invention as a "manner of manufacture",[190] and ordinarily will be 'necessary *and* sufficient'.[191] However, when a 'new class of claim involves a significant new application or extension of the concept of "manner of manufacture", the HCA found other factors – including Factors 3-6 above – assume importance' and are to

[189] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [28].
[190] The language used to depict the first two factors is clearly derived from the terms used in a case-specific manner *NRDC* (at 277).
[191] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [28].

be considered when determining the patent-eligibility of the subject matter.[192] Factor 3 serves as a reminder that the patent system is a "public instrument".[193] Factor 4 affirms the notion that a "manner of manufacture" is a *concept,* expanded and contracted through judicial consideration of what has come before.[194] The importance of Factor 5 is less obvious – a point which shall be returned to in Section 8.5 below. Factor 6 identifies an inherent conflict in this area of law: the role of the judiciary and the legislature. While the courts can interpret the concept of a "manner of manufacture", they cannot go beyond this and write the law themselves.[195]

The 'Judging Difference' test is clearly evident in Factor 1, as is the 'Policy-centric' test in Factors 3-6 in the framework constructed by the HCA.[196] From *NRDC* to *Myriad,* little change in the language or requirements of the 'Judging Difference' is apparent; however, this is not so for the 'Policy-centric' test. This test has been pushed to the fore and is explicitly considered: once un(der)articulated in *NRDC*,[197] the test has been articulated by *Myriad.*[198] The act of bringing policy factors to the fore decreased uncertainty and increased transparency as it directly acknowledged considerations which, it would seem, are illogical to exclude: the patent system is undergirded by policy and is purposed to balance the rights of the few against the wider interests of society .[199]

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[192] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [28]

[193] Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies", above n 129, at 215.

[194] See Section 4.2 to understand how the concept of a "manner of manufacture" has created classes of inherently patentable and unpatentable 'inventions'.

[195] Frankel and Lai *Patents Law and Policy*, above n 17, at 389. In the present case, French CJ and others found Factor 6 of significant relevance and ultimately found 'to include isolated nucleic acids within the scope of a "manner of manufacture" involved an extension of the concept" not appropriate for judicial determination" (at [94]).

[196] For further explanation of the 'Un(der)articulated tests', see Section 6.2 above.

[197] In *NRDC,* the HCA considered policy factors under the guise of whether the subject matter was "proper" (at 277) – proper being the key word which imported such considerations. *NRDC* did not, to the same extent as the HCA in *Myriad,* openly discuss the relevance of such policy factors. See above Section 4.3 and Pila *Requirement for an Invention*, above n 22, at 90-95 for further comment in support of this proposition.

[198] The articulation by the HCA is in distinction to the FCAFC in *D'Arcy v Myriad Genetics Inc,* above n 172, where policy-centric factors were explicitly rejected as being of any relevance: "[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' (at [204]-[205] per Allsop CJ, Dowsett, Kenny, Bennett and Middleton JJ).

[199] Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies", above n 129, at 215.

The majority applied the framework without resort to the "generally inconvenient" proviso of s 6,[200] and determined that the BRCA1/2 isolates in the form of gDNA, RNA and cDNA had not produced an outcome as a result of human action (Factor 1).[201] Moreover, the subject matter also lay on the bounds of the concept of a "manner of manufacture", and considerations flowing from Factors 3-6 militated against characterisation as such.[202] The finding by the HCA that the 'invention' failed to satisfy Factor 1 was based on an antecedent determination as to the substance of the subject matter.[203]

8.3. Rejection of the substance of the subject matter: "chemical compound" *or* "genetic information"?

The antecedent finding as to the substance of the subject matter was the determinative point upon which the outcome of the 'Judging Difference' test and the outcome of the case for that matter, turned on.

Two competing conceptions of the substance were submitted: "chemical compound" (per Myriad) or "genetic information" (per D'Arcy). The FCA and the FCAFC found it was a "chemical compound", which in turn, it is argued, made it easier to identify obvious differences – in Step 2 of 'Judging Difference' (Section 6.2.1) – between the isolated BRCA1/2 gene sequences and the natural gene sequences.[204] Chemical, structural and functional differences were found to be of "critical importance" and sufficient to reach the threshold requirement for an "artificially created state of affairs".[205] However, on appeal the HCA took issue with the lower courts' characterisation of the substance of the subject matter, stating:[206]

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[200] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [23].
[201] It was not contentious that the invention as claimed had economic utility: see the judgment of French CJ and others at [84].
[202] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [93]-[94].
[203] The claims, it must be noted again, are to be interpreted as a manner of substance and not form: *Research Affiliates LLC v Commissioner of Patents*, above n 82, at 401.
[204] *D'Arcy v Myriad Genetics Inc* (FCAFC), above n 172, at [191] and [194] identified chemical, structural and functional differences.
[205] At [215].
[206] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [88].

> "Identification of the subject matter of the claims as a class of chemical compounds is the premise upon which the [FCAFC's] conclusion is based. It is a premise which, with respect, elevates form over substance to the detriment of the developmental function entrusted to the Court…".

Instead, when "properly construed",[207] the substance was deemed to be "genetic information".[208] In turn, comparison during Step 2 of the 'Judging Difference' test between the "genetic information", as it exists in the isolated BRCA1/2 gene sequences and the natural gene sequences, yielded no identifiable, "marked" differences.[209] In essence, the act of isolation – with all the resultant chemical, structural and functional differences – was deemed irrelevant, and the threshold level of "artifice" was not attained.[210]

'Judging Difference' was implemented by the HCA to establish a chemical compound/genetic information dichotomy not reflective of the true nature of nucleic acids. Nucleic acids present the court with a unique problem insofar as the biomolecules can correctly be construed in *both* chemical and genetic terms: DNA and RNA are chemical structures which house invaluable genetic information.[211] The true nature of nucleic acids as hybrid biomolecules was indirectly acknowledged by the HCA: 'the invention of an isolated nucleic acid *in a formal sense* embodies a product, namely a chemical compound, that is brought about by human action'.[212] So, the lower courts were

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[207] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [27]. "Properly" is most likely in reference to the FCAFC judgment at [194] which rejected the "genetic information" characterisation as this elevated the "language" of the claim over the substance – a clear misapplication of the approach to claim construction, see Section 4.4 above.

[208] "Genetic information" was identified as the substance because its 'existence [was] an essential element of the invention' (at [89] per French CJ and others).

[209] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [89].

[210] At [90]-[91]. It is unclear, however, from the judgment as to whether the BRCA1/2 isolates were ultimately found *not* to be a "manner of manufacture" because of the failure to produce the threshold level of "artifice" or because consideration of Factors 3-6 militated against the characterisation. This point is explored further in Section 8.5 below.

[211] Classification of the substance is also not limited to "chemical compounds" or "genetic information" – these were simply the two submitted by Myriad Genetics Inc and D'Arcy respectively. An example of an alternative classification is: a pharmaceutical composition (*Arrowhead Research Corporation* [2016] APO 79).

[212] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [94].

not incorrect in their chemical-centric characterisation, the HCA just preferred another. Yet in preferring the "genetic information" reading, the HCA adopted essentialist reasoning and did not provide guidance as to *why* one characterisation trumped the other: it just did.[213] As such, the final characterisation of the substance of the 'invention' was infallible.

Infallibility and the mere fact that logic did not compel the conclusion is not, in of itself, a fault; neither is essentialist reasoning – both are commonly implemented by courts. However, in the context of nucleic acids, the reasoning adopted by the HCA had the effect of robbing future courts[214] of much needed guidance. What swayed the HCA to favour one characterisation over the other – was it properties of the nucleic acid isolates themselves, the wording of the claims,[215] or something else entirely? When assessed from the perspective of guidance, the chemical compound/genetic information dichotomy is problematic as it was plagued by a lack of clear, principled reasoning used to reach transparent conclusions.

Also, the dichotomy does not lend itself to application to more complex nucleic acid 'inventions'. What if an 'invention' is predicated on "genetic information" (inherently unpatentable) *and* chemical, structural and functional differences – what degree of difference from nature would be required then?[216] This conundrum shall be discussed further below, in the context of cDNA BRCA1/2 isolates, to demonstrate the limited utility of the dichotomy.[217]

Science informs – but cannot answer – the legal question to whether the BRCA1/2 isolates constitute a "manner of manufacture" and ultimately, whether an 'invention'

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[213] A reason (of sorts) could be gleaned from the HCA assertion that the FCAFC did not 'properly construe' (at [27]), the substance whereby implying the lower court applied an *im*proper approach (at [88]). But it does not follow logically that the conclusion reached is also incorrect, whereby the HCA is again in the uncomfortable position of needing to explain *why* it favoured one substance over the other at first instance.

[214] A party that may wish to appeal the decision is also robbed of guidance as to what grounds to appeal on. The process of reasoning to reach the conclusion is not known, so it is challenging to formulate an appeal with little to go on. Obviously, this concern was not realised with the judgment of the HCA as this is Australia's highest appellate court.

[215] The wording of the claims was one reason, but not determinative, as to why the substance was "genetic information", above n 213.

[216] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [89]-[90].

[217] See Section 8.4 below.

exists.[218] Science is important, and it provided the HCA with the fundamental building blocks upon which to base its decision; but science cannot and should not be determinative. It was up the court to explain why some pre-existing scientific realities can become "made"[219] (i.e. chemical compounds), while others "discerned"[220] (i.e. genetic information) and the HCA fell short in providing much needed substantive guidance on this point. However, an inability to explain *why* is not necessarily reflective of deficiencies in the HCA's approach, but rather reflective of inherent challenges posed by nucleic acids and the 'Judging Difference' test.

8.4. The multitude of un(der)articulated tests applicable to determine patentability of complementary DNA (cDNA)

Complementary DNA, also known as 'cDNA', is a synthetic nucleic acid created *in vitro.*[221] A cDNA molecule is chemically similar to DNA, but the genetic information in cDNA is derived from RNA. If nucleic acids are hybrids then cDNA is the hybrid of hybrids: a true mixture of the properties of DNA and RNA.[222] This section shall compare the 'Un(der)articulated tests' used to determine the patentability of BRCA1/2 isolates in the form of cDNA. The judgment of the SCOTUS in the United States *Myriad* litigation now assumes importance because first, it reached a contrasting result to the HCA on question of cDNA patent-eligibility; and secondly, because the SCOTUS provided an example of the 'Labour-centric' test. For both reasons, jurisdictional comparison of the *Myriad* cases highlights the implications and consequences of the different tests.

8.4.1. Judging Difference (from "nature")

The HCA again used 'Judging Difference' to quickly establish that a BRCA1/2 isolate in the form of cDNA was not an 'invention' because the essential element of "genetic information" in cDNA was merely replicative of "naturally occurring sequence of coding

[218] Dan L Burk "Edifying Thoughts of a Patent Watcher: The Nature of DNA" (2013) 60 UCLA L. Rev. Disc. 92 at 95.
[219] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [6].
[220] At [6].
[221] See 'Application of nucleic acids within the biotechnology industry' (Section 5.2).
[222] Refer to Section 5.2 for the process of creation of cDNA.

regions of DNA".[223] In contrast, the SCOTUS used 'Judging Difference' as part of its reasoning[224] in finding that the BRCA1/2 isolates in the form of cDNA[225] were *patent-eligible* as:[226]

> "…[C]reation of a cDNA sequence from mRNA results in an exons-only molecule that is *not naturally occurring*… cDNA retains the naturally occurring exons of DNA, but is *distinct from the DNA from which it was derived*."

The SCOTUS first "chemically" compared cDNA and mRNA,[227] then compared the "genetic information" of cDNA and gDNA. The application of 'Judging Difference' by the SCOTUS requires some unpacking as it is not immediately apparent how Steps One, Two and Three (Section 6.2.1) are being applied. First, (clearly shown in the former part of the above excerpt) the unreasoned conclusion that cDNA is "not naturally occurring" – and thus patent-eligible – can only be founded on "chemical" differences.[228] The reliance on "chemical" properties is at odds with the Court's previous, specific rejection of this property as being a solid foundation upon which to base analysis. When discussing gDNA, the SCOTUS noted as much because 'Myriad's claims do not rely in any way on the chemical changes or specific chemical composition of a particular molecule'.[229] Reliance now for cDNA seems inconsistent, when it was not permitted before for gDNA.

The second application of 'Judging Difference', upon which the SCOTUS decision on cDNA-patentability rests, was between the "genetic information" of cDNA and natural,

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[223] *D'Arcy v Myriad Genetics* (HCA), above n 174, at [89].
[224] The SCOTUS also used the 'Labour-centric' un(der)articulated tests in respect of cDNA, see Section 8.4.2 below.
[225] The SCOTUS only found cDNA patent-eligible, and not gDNA. 'Judging difference' was used to find "isolated gDNA coding for a BRCA1 polypeptide" ineligible as 'it contained a naturally-occurring segment of DNA, of which the genetic information was not created nor altered by Myriad' (at 2111 and 2115).
[226] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2119.
[227] At 2119.
[228] Section 5.1 above outlines the properties of nucleic acids. The "chemical differences" were most likely disparate sugar groups and/or the specific composition of nucleotides. But this is an educated guess – based on scientific knowledge – as the SCOTUS did not itself make the reasons known. Previously, at 2112, Thomas J in delivering the opinion of the Court established the identicality of the "genetic information" contained within cDNA and mRNA – thus this property of nucleic acids could not form the basis of comparison in the excerpt – which lends further support to the proposition that "chemical differences" were being relied on.
[229] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2118.

unisolated DNA. The comparison can be observed in the latter part of the above excerpt and is substantiated by the previous assertion that cDNA is "derived" from DNA.[230] While technically true that cDNA is derived from DNA (the pre-existing, antecedent nucleic acid), this comparison fails to accord deference to the fact that cDNA is derived from *mRNA* when it is made *in vitro.*[231] The conflicting statements as to the origin of cDNA reflect the challenging nature of cDNA as the hybrid of all hybrids: chemical structure derived from DNA, genetic information derived from RNA.[232]

The limited utility of the chemical compound/genetic information dichotomy is highlighted by the challenge the SCOTUS had with applying 'Judging Difference' to cDNA. At Step One, Two and Three, the Court has not one but *two* correct properties which could form the basis of a comparison. As a chemical compound, the BRCA1/2 cDNA could be compared to DNA or mRNA. As genetic information, the BRCA1/2 cDNA could be compared to DNA or mRNA. Thus instead of two characterisations correct in a scientific sense, there were *four*. The HCA avoided this difficulty by consistently carrying through the "genetic information" comparison from gDNA to cDNA, leading to a principled, logical conclusion. Yet the SCOTUS was not similarly constrained – demonstrated by the sheer number of 'Judging Difference' comparisons made.[233]

Putting the desirability of patentability of cDNA isolates aside, the *process* by which conclusions are drawn is of similar importance. 'Judging Difference' is a taxonomical, categorical exercise which *seems* principled, but in actuality is an incredibly malleable test as demonstrated by the sheer number of applications and non-falsifiable conclusions drawn by the HCA and SCOTUS. The test contains numerous, important cross-roads at which judicial decision-making can be exercised, but with little explanation or insight into *how* the judiciary are exercising such discretion to reach conclusions.

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[230] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173.
[231] The point that cDNA is derived from mRNA when it is made *in vitro* was previously recognised by the SCOTUS (*Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2112).
[232] The process of creation of a cDNA molecule, described in Section 5.2, highlights the hybrid nature of this synthetic biomolecule.
[233] Above n 226.

8.4.2. Labour-centric

The 'Labour-centric' test was also implemented by the SCOTUS to ultimately deem cDNA patent-eligible, as:[234]

> "[T]he lab technician *unquestionably* creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but is distinct from the DNA from which it was derived."

Of the two variations of the 'Labour-centric' test described in Section 6.2.2, the SCOTUS adopted the low-threshold version in which almost any amount of work is sufficient to render the subject matter patentable.[235] The test begins and ends with the presence or absence of mere work. End of discussion. Well, not quite. In a similar vein to the way 'Judging Difference' was applied by the SCOTUS, the adoption of this version of the 'Labour-centric' test was internally inconsistent. The Court noted, when discussing gDNA, that "extensive research efforts alone [are] insufficient to satisfy the demands of § 101";[236] and clarified that:[237]

> "To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention".

So, something *more* than work was required for gDNA isolates to be transformed into a patentable subject matter. Moreover, the SCOTUS acknowledged that each of the intricate and complex scientific techniques used to create cDNA *in vitro* were not patentable and did not display any special level of 'human ingenuity and creativity':[238] in of themselves such 'processes were well understood by geneticists, widely used and fairly uniform'.[239] Thus, based on the Court's interpretation of the work involved to

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[234] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2119 (emphasis added).
[235] Brief for the United States as Amicus Curiae in Support of Neither Party, *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 9.
[236] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2118.
[237] At 2117.
[238] Brief for the United States as Amicus Curiae in Support of Neither Party at 9, *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173.
[239] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2119, with similar comments also noted at 2112.

create cDNA, is it unclear where the something *more* came from that allowed the SCOTUS to find gDNA unpatentable, but cDNA patentable: what work did Myriad display that "unquestionably" confirmed the patent-eligibility of cDNA? The logical conclusion is that work is enough when it is, and not enough when it is not. Again, infallibility is not in and of itself a fault, but it is when it leads to guidance issues and masks the internal reasoning processes of the judiciary.

At first glance, the 'Labour-centric' test appears to afford an opportunity to side-step challenges inherent in the line-drawing exercise aspect of 'Judging Difference'. Instead, similar problems simply reappear in a different guise. A consequence of the 'Labour-centric' test is a real lack of reasoned, line-drawing to establish patentable from unpatentable subject matter.[240] The SCOTUS treated gDNA and cDNA as though they were apples and oranges: two unrelated, inherently different products.[241] Such opposing treatment of gDNA and cDNA suggests conclusions may have been drawn for other, potentially policy-based reasons, which were never referenced explicitly, but are often implicit in the § 101 inquiry.[242]

8.4.3. Judging Difference (from "nature") vs Labour-centric

After analysis of how the HCA and SCOTUS implemented the 'Judging Difference' and 'Labour-centric' tests, this dissertation suggests the 'Labour-centric' test is not a desirable proxy for the inquiry as to whether a nucleic acid 'invention' exists.

First, the 'Labour-centric' test diverts the focus away from the products (i.e. BRCA1/2 isolates) in question, and instead directs it towards the inventive process. Such a

[240] Alternatively, it may be suggested that no lines needed to be drawn during the line-drawing exercise as it was "unquestionable" that cDNA was a new creation. But other portions of the judgment suggest otherwise and undermine the validity of any such proposition.
[241] Indeed, the SCOTUS suggested such a belief, stating "cDNA does not present the same barriers to patentability as naturally occurring, isolated DNA segments" (*Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2119).
[242] 35 USC § 101. See commentary in Dreyfuss, Nielsen and Nicol "Patenting nature – a comparative perspective", above n 111 for how policy-centric considerations are taken into account in the United States but in an implicit manner.

diversion does not align with the "manner of manufacture" inquiry, which is solely concerned with the subject matter and not how the subject matter came into being.

Secondly, while both tests involve a taxonomical exercise of classification and line-drawing – echoing aspects of pre-*NRDC* rigidity[243] – the 'Labour-centric' test does not have the benefit of drawing on the long-established category of inherently unpatentable subject matter: "products of nature". While 'Judging Difference' can derive stability from this steady, non-contentious category, it is unclear from the outset what 'work' (if any) would be inherently unpatentable, to establish a lower threshold for the threshold-eligibility requirement of the existence of an 'invention'.

Thirdly and finally, the 'Labour-centric' test is particularly troublesome in the area of nucleic acid 'inventions' as it seems to magnify the 'gap' in knowledge of the courts when it comes to biotechnological innovation. Common-place, widely-used processes can be dressed up to appear complex and technical to lead the judiciary astray. 'Labour', as demonstrated throughout the SCOTUS analysis, does *not* equate to the existence of an 'invention' – but in the area of nucleic acids innovation, it is particularly challenging to distinguish the 'right' quantity and quality of work, from the 'wrong'.[244] Out of the two tests which involve a line-drawing exercise, 'Judging Difference' appears more suited to the task of establishing what is, and is not, a nucleic acid 'invention' under s 14(a) of the Patents Act 2013, s 18(1) of the Patents Act 1990 (Cth) or 35 USC § 101.

8.5. Post-*Myriad* developments

In 2015, *Myriad* was handed down by the HCA and subsequently "welcomed, derided and hotly debated".[245] After a period of consultation, the Australian Patent Office (APO)

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[243] The pre-*NRDC* rigidity being how taxonomical categories were applied post *Boulton v Bull:* see Section 4.2.2 above.

[244] In *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2120 Justice Scalia filed an opinion concurring "in part" of the judgment delivered by Thomas J. The portions which Justice Scalia did not concur with were "Part I-A" and "portions of the rest of the opinion going into fine details of molecular biology". Justice Scalia was unable to concur based on his "own knowledge", or lack thereof, of molecular biology. Perhaps the lack of understanding was not limited to Justice Scalia – the Court implemented 'Judging Difference' (Section 8.4.1) in a manner inconsistent with the basic nature of cDNA.

[245] Dreyfuss, Nielsen and Nicol "Patenting nature – a comparative perspective", above n 111, at 571.

updated the 'Manual of Practice and Procedure' (the Manual) to reflect changes which the decision instituted. The Manual stated that 'isolated nucleic acid sequences (gDNA) were not patent-eligible subject matter, and nor were cDNA and other synthetic nucleotide sequences that merely replicated genetic information of naturally occurring organisms'.[246] To better understand the consequences and ramifications of the 'Un(der)articulated tests', post-*Myriad* developments are crucial.[247] It is argued below that the multi-factorial, policy-laden framework constructed by the HCA created guidance issues for further courts in two distinct areas.[248]

The HCA identified two, broad categories of subject matter – with varying considerations attached – that the BRCA1/2 isolates may have fallen into: Factors 1 and 2 are "necessary *and* sufficient" to find patentability (Category 1), and Factors 1 and 2 are "necessary *but not* sufficient", whereby Factors 3-6 are engaged (Category 2).[249] Unfortunately, it was unclear how future courts were to determine which category of subject matter they were dealing with.[250] In *Commissioner of Patents v RPL Central Pty Ltd*[251] (the first Australian

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[246] Australian Patent Office, "Examination Practice Following the High Court Decision in *D'Arcy v Myriad Genetics Inc.*" (19 August 2020) IP Australia <https://www.ipaustralia.gov.au/sites/default/files/examination_practice_following_the_high_court_decision_in_darcy_v_myriad_genetics_inc.pdf?acsf_files_redirect>.

[247] Again, the focus shall be on Post-*Myriad* developments in Australia – given a large portion of analysis in Section 8 was dedicated to the HCA judgment; however consequences and ramifications that are linked to the SCOTUS adoption of the 'Labour-centric' test shall be noted (as the HCA did not adopt this un(der)articulated test.

[248] See for example, Lucas McCallum and Thomas Faunce "Myriad Voices Against Gene Patents in the High Court" (2015) 23 J.L. & Med 322; Charles Lawson "Patenting Nucleic Acid Sequences: More Ambiguity form the High Court in *D'Arcy v Myriad Genetics Inc.*?" (2018) 25(3) J.L. & Med 741; Bartlett "*D'Arcy v Myriad Genetics Inc* [2015] HCA 35: The plurality's new factorial approach to patentability rearticulates the question asked in *NRDC*", above n 187; Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35.

[249] The two categories were not defined as 'Category 1 and 2' by the HCA. The labels were assigned by this dissertation to make discussions clearer. For more details on Category 1 and 2, see Section 8.2 above. As noted in that Section, it was unfortunately, it was unclear from the majority judgment whether the BRCA1/2 isolates were excluded from the concept of a "manner of manufacture" because the 'invention' failed to satisfy Factors 1 and 2, or because it fell into the latter category and consideration of Factors 3-6 militated against such inclusion within the concept: see Charles Lawson "Patenting Nucleic Acid Sequences: More Ambiguity form the High Court in *D'Arcy v Myriad Genetics Inc.*?" (2018) 25(3) J.L. & Med 741.

[250] In *Myriad*, the HCA set out the two broad categories and provided limited guidance as how to transition from one to the next. The only guidance given was that a transition from the former to the latter category should be made when "a new class of claim involves a significant new application or extension of the concept of "manner of manufacture" (at [28]).

[251] *Commissioner of Patents v RPL Central Pty Ltd* [2015] FCAFC 177.

decision to apply the *Myriad* framework), when determining whether a business method fell into Category 1 or 2, the Court stated:[252]

> "This case does not involve a new class of claim involving a significant extension of the concept of manner of manufacture [i.e. Category 2]. It is therefore unnecessary to examine any of these wide-ranging considerations. This is fortunate, because the Court does not have the bases for analyses of this kind."

The "fortunate" occurrence of the subject matter falling into Category 1 has been a common trend in post-*Myriad* decisions,[253] suggesting the true reason behind categorisations might be a reluctance to engage with the broad, open-textured framework created by the HCA, rather than a specific feature of the subject matter in issue.[254] The utility of Categories 1 and 2 was questioned by Justice Beach in two recent cases: *Meat & Livestock Australia Limited v Cargill Inc*[255] and *Sequenom Inc v Ariosa Diagnostics Inc.*[256] Justice Beach could not see a principled way *at first instance* to determine whether the subject matter was in Category 1, which he described as the "plain vanilla concept of *NRDC*", or Category 2:[257]

> "… I do not consider that I am dealing with a new class of claim involving a significant new application of or extension to the concept of "manner of manufacture". But if I

[252] At [119]. This was the very first case post-*Myriad* which dealt with subject matter as a "manner of manufacture" and applied the multi-factorial, policy-centric approach of *D'Arcy v Myriad Genetics Inc*, above n 174.

[253] *Commissioner of Patents v RPL Central Pty Ltd,* above n 251, was the first decision post-*Myriad* in the HCA to express hesitation but further hesitation has been expressed in subsequent decisions: *Meat & Livestock Australia Limited v Cargill Inc* [2018] FCA 51; *Sequenom Inc v Ariosa Diagnostics In*c [2019] FCA 1011.

[254] Dreyfuss, Nielsen and Nicol "Patenting nature – a comparative perspective", above n 111, at 577-579.

[255] *Meat & Livestock Australia Limited v Cargill Inc* [2018] FCA 51. The invention in issue was a method patent for a genetic test. The method was for identifying a trait of a bovine subject through testing for a single nucleotide polymorphism (SNP). The decision as particularly important as it determined post-*Myriad*, that genetic tests are patentable subject matter under s 18(1) of the Patents Act 1990 (Cth).

[256] *Sequenom Inc v Ariosa Diagnostics In*c [2019] FCA 1011. The invention in issue was a method patent for the 'Harmony test', a prenatal test for screening for certain genetic disorders. The decision found diagnostic testing – in addition to genetic testing as found in *Meat & Livestock Australia Limited v Cargill Inc* above n 255 – was patentable subject matter despite being partially-reliant on "genetic information".

[257] *Meat & Livestock Australia Limited v Cargill Inc*, above n 255, at [391] and *Sequenom Inc v Ariosa Diagnostics In*c, above n 256, at [348].

> am wrong, I have been able to apply this "other factors" and in doing so have fortified my conclusion on patentability in any event, which is perhaps unsurprising."

It was only *after* deciding to move on to consider Factors 3-6 (likely in pre-emption of an appeal) that Justice Beach was able to justify the initial conclusion that the subject matter was within the "plain vanilla" concept. So, justification for the jump from Category 1 to 2 can be made retrospectively, but not in the first instance.

A second area where guidance issues arose was in the application of the 'Policy-centric' test through the non-exhaustive list of Factors 3-6. How are the factors to be applied, weighed and balanced? What is the hierarchy of factors? The HCA noted that Factors 3, 4 and 6 are of "primary importance",[258] but what of the others? What if factors of "primary importance" conflict? The list could go on.[259] A possible solution to this guidance issue is described in Section 9.2 below.

While the multi-factorial, policy-laden framework constructed by the HCA may have created guidance issues, it made significant gains towards resolving transparency issues which have plagued the 'Und(der)articulated tests'. In contrast to the judicial approach of the SCOTUS, the HCA implemented the 'Judging Difference' and 'Policy-centric' tests in a clear, principled manner. Moreover, a marked change from *NRDC* through to *Myriad* can be observed: the 'Un(der)articulated tests' – in particular the 'Policy-centric' test – became articulated. The HCA in *Myriad* removed the policy-centric considerations from being 'smuggled' into the "plain vanilla *NRDC*" of Factors 1 and 2, and instead, propounded a transparent approach less dependent upon the challenging "artifice" or "product of nature" line-drawing exercise, an approach in which 'Judging Difference' and 'Policy-centric' tests are now articulated.

[258] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [28].
[259] Beach J made similar observations in *Meat & Livestock Australia Limited v Cargill Inc*, above n 255, at [391] and *Sequenom Inc v Ariosa Diagnostics In*c, above n 256, at [348].

Part III: Recommendations for New Zealand

The *Myriad* litigation re-articulated the inquiry posed in *NRDC*, mandating a transparent policy-based approach, as described and analysed in Part II. However, the *Myriad* developments are not (yet) considerations which formally comprise part of the patent scheme in New Zealand. No curial decision of the courts or non-curial decision by IPONZ has cited the *Myriad* litigation.[260] Should a *D'Arcy*-esque challenge come before the courts of New Zealand – could, would and should the approach of the HCA be readily adopted? New Zealand is in the useful position of being able to assess the *Myriad* litigation based on resultant consequences before formulating its own approach to nucleic acid 'inventions' under s 14(a) of the Patents Act 2013. Section 9 below details a *D'Arcy*-esque approach which New Zealand should adopt in order to address undesirable issues of the judicial approaches identified throughout Part II. Section 10 below discusses how the *D'Arcy*-esque approach could be tailored to fit the unique New Zealand patent landscape, and also addresses potential criticisms of the approach set out.

9. Recommendation for New Zealand: a *D'Arcy*-esque approach

Generally, the multi-factorial, policy-laden approach set forth by the HCA in *Myriad* is a desirable rearticulation of *NRDC*. However, to address and ameliorate issues identified in Section 8, this dissertation recommends a *D'Arcy*-esque approach should be adopted in New Zealand. The *D'Arcy*-esque approach incorporates alterations to how both the 'Judging Difference' and 'Policy-centric' tests were implemented in the HCA's framework.

[260] Based on a search of the New Zealand Legal Information Institute where decisions of the Commissioner of Patents on behalf of IPONZ are released. In a short aside, it may be being considered during the application process, pre-acceptance, but it is just too hard to decipher the 'lay of the land' in regards to IPON's internal precedents given the significant agency which IPONZ has (see Section 3 above).

9.1. Judging Difference (from "nature")

Two, broad recommendations are made to suggest how 'Judging Difference', implemented through Factor 1 of the framework, should be applied in the *D'Arcy*-esque approach.[261]

First, the strict, limiting characterisation of *one* substance should be avoided in the context of nucleic acids, and a finding of multiple substances should be open to the court. This would lead to judicial reasoning more reflective of the nature of nucleic acids as multi-faceted biomolecules. Chemical, structural, informational and functional properties would be able to co-exist simultaneously as the substance(s) of the 'invention' and important aspects would not be effectively 'shut out' from consideration or forming part of the court's conclusions. Such an approach is also better positioned to accurately and effectively deal with more complex nucleic acid-based 'inventions', for example an invention in which the substance is predicated on *both* the chemical and informational properties of nucleic acids.[262]

Secondly, the chemical compound/genetic information dichotomy should be avoided, as it constrains the judiciary and does not provide substantial guidance as to what can constitute an 'invention'.[263] The distinction between chemical compounds (inherently

[261] The recommendations of alterations to implementation of 'Judging Difference' are made in response to issues identified in the following portions of this dissertation: 'Rejection of the substance of the subject matter: "chemical compound" *or* "genetic information' (Section 8.3); 'The multitude of un(der)articulated tests applicable to determine patentability of complementary DNA (cDNA)' (Section 8.4); 'Post-*Myriad* developments' (Section 8.5).

[262] Post-*Myriad* in the HCA, several more complex nucleic acid-related 'inventions' came before the APO and eventually the Court. While the framework constructed in *Myriad* by the HCA was applied, the issue around having to choose *one* substance, either chemical compound or genetic information, was still a central consideration: *Arrowhead Research Corporation* [2016] APO 79 (the 'invention' was based on a naturally-occurring RNA sequence. The Court struggled to identify the substance of the invention as it found the invention was partially reliant on *both* "genetic information" and "chemical" features. To solve the conundrum, it instead deemed the substance a pharmaceutical composition).

[263] The chemical compound/genetic information dichotomy was implemented in a somewhat useful manner by the HCA. The suggestion in the above is that the utility of the dichotomy began and ended with the nucleic acid-invention of the BRCA1/2 isolate as it was simple and uncomplicated. But when applied to a slightly more complex nucleic acid-based invention, e.g. cDNA (Section 8.4), the dichotomy did not assist the court but instead, arguably hindered the task of determining whether an 'invention' existed.

patentable) and genetic information (inherently unpatentable) is reminiscent of the state of affairs in relation to the s 6 inquiry pre-*NRDC*.[264] Pre-*NRDC*, the inquiry was typified by a methodology which was solely focused on identifying, categorising and delineating patentable subject matter from unpatentable subject matter. But it was precisely this methodology which was denounced in *NRDC*; just as the basis for exclusion of agricultural and horticultural processes as inherently unpatentable was, on closer examination, considered unjustified, so too might be the exclusion of genetic information as a patent-ineligible substance of the subject matter: as biotechnological developments continue to progress, so too does the ability to alter, create and 'invent' "genetic information".[265]

Factor 1, a proxy for implementation of 'Judging Difference', would be the first step in the *D'Arcy*-esque approach, and thus its fundamental importance cannot be overstated; any further recommendations made by this dissertation only address down-stream considerations, so it is important to get it 'right'. In essence, the 'horse may have already bolted' once Factors 1 and 2 have been considered.

9.2. Policy-centric

A 'Policy-centric' test, as incorporated into the latter half of the framework constructed by the HCA, was a positive development on the precedent of *NRDC*. However, this dissertation recommends slight alterations should be made before incorporation into the *D'Arcy*-esque approach.[266]

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[264] For detailed discussion of the s 6 inquiry pre-*NRDC,* see Section 4.2.2 above.

[265] Recent decisions, post-*Myriad*, have displayed how the assignment of 'inherent patentability' to "genetic information" is unjustified. In, *Cargill Incorporated v Dow Agro Sciences LLC* (2016) APO 43, a fungal sequence was deemed an 'invention' as while the sequence of nucleotides was identical to how it existed in nature, it had been optimized to allow more protein to be produced post-transcription (i.e. codon-optimization) thus it was 'non-naturally occurring' and the "genetic information" was considered to have been "made". Also, in *Sun Pharmaceuticals Industries (Australia) Pty Ltd v Tasmanian Alkaloids Pty Ltd* [2018] APO 7, a specifically mutated sequence allowed a higher output of codeine, and it was deemed an 'invention' because there was no evidence that such a mutation in nature had or would be naturally occurring. There was no ground to oppose the patent as being 'naturally occurring' (at [69]-]71]) and again, the genetic information was "made".

[266] Frankel and Lai *Patents Law and Policy*, above n 17, at 89-91.

First, this dissertation recommends explicit reference to Factor 5 should be removed from the list of factors in the multi-factorial, policy-laden approach. Factor 5, which suggested the court consider whether patentability would enhance or detract from the "harmonisation"[267] of patent law with other jurisdictions,[268] has been set apart and subject to criticism post-*Myriad*.[269] The importance of 'harmonisation' has been described as "bizarre"[270], given the phrase a "manner of manufacture" is to be interpreted via the common law methodology in accordance with the relevant principles and concepts developed over time, not by what overseas jurisdictions have found to be a nucleic acid 'invention'.[271] Removal would address the apparent importance of a factor not well understood,[272] and also solve the conundrum faced by courts when attempting to rank Factors 3-6: the HCA stated *all but* Factor 5 were of "primary importance", so the remaining factors explicitly listed would be of equal weighting.[273] Removal of Factor 5 would not prevent future consideration of "harmonisation", but this dissertation recommends instead of harmonisation simpliciter, it may be more prudent to consider "harmonisation" through the lens of TRIPS and other international legal obligations entered into.[274] The effect would arguably be the same, but it would not require the court to choose and then justify why specific jurisdictions were chosen over others.[275]

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[267] *D'Arcy v Myriad Genetics Inc*, above n 174, at [34]-[35]. The majority discussed the relevance of harmonization with Australia's trading partners (China, Japan, Singapore and India).

[268] Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?", above n 272, at 550-551.

[269] Jocelyn Bosse "In Conversation with Prof. Brad Sherman: *D'Arcy v Myriad Genetics Inc* (2015) and the Future of Australian Patent Law" (20 October 2015) Justice and the Law Society < http://www.jatl.org/blog/2015/10/15/in-conversation-with-prof-brad-sherman-darcy-v-myriad-genetics-inc-2015-and-the-future-of-patent-law>.

[270] Above n 269.

[271] Bosse "In Conversation with Prof. Brad Sherman: *D'Arcy v Myriad Genetics Inc* (2015) and the Future of Australian Patent Law", above n 269. In fairness, while seemingly "bizarre" as patents are national rights, not international rights, increased harmonisation would be beneficial as it would allow inventors to obtain the monopoly more consistently across jurisdictions which may incentivise innovation more readily: increased harmonisation would increase certainty of protection, or lack of protection, for inventors.

[272] Jessica Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?" (2016) 47 IIC 537 at 549-551.

[273] The relative weighting of Factors 3-6 was noted as an issue, particularly from a guidance perspective in Section 8.5 above.

[274] TRIPS, above n 6. Other international legal obligations may include those under the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention), the General Agreement on Trade and Tariff (GATT): see Frankel and Lai *Patents Law and Policy*, above n 17, at 56-71.

[275] Bosse "In Conversation with Prof. Brad Sherman: *D'Arcy v Myriad Genetics Inc* (2015) and the Future of Australian Patent Law", above n 269. In response to a question, Sherman noted the seemingly

Guidance issues also stemmed from the two broad categories of subject matter (Category 1 and 2) created by the HCA.[276] Two possible avenues are available to New Zealand to address this issue. Either, the conditional application of Category 2 is removed and the list of non-exhaustive factors are *always* considered, or clarity is instilled to allow a principled transition from Category 1 to 2.

First, removal of the conditional application requirement (i.e. requirement for a significant new application or extension of the concept of a "manner of manufacture") would effectively mean the two broad categories of subject matter are reduced into one. This compaction would quickly resolve the guidance issue, highlighted by Beach J[277], as to what a "significant extension" entailed. The compaction would also benefit the court insofar as it would afford an opportunity to *always* carry out the cost-benefit analysis inherent within the policy-centric factors. The analysis would also be transparent, unlike the SCOTUS in *Myriad*[278]*,* or pre- and post-*NRDC* when such considerations were smuggled into Category 1. Constant inclusion would also provide a 'second bite at the cherry' to unearth instances where cleverly-crafted claims may in fact be attempting to monopolise something which had met the Category 1 requirements, but was closely aligned with,[279] or even squarely within (upon reflection), an inherently unpatentable category – a 'reflection' that would *not* occur based on a strict reading of *Myriad* where the court does not move past Category 1 if satisfied.[280]

unprincipled task of selecting countries to harmonise with. In the HCA judgment, the regional trading partners of China, Japan Korea, Singapore and India were specifically referenced (at [34]), but as Sherman jokingly noted, "why not…North Korea?".

[276] See 'Augmentation of *NRDC*: a multi-factorial, policy-laden approach' (Section 8.2) and 'Post-*Myriad* developments' (Section 8.5) for what Category 1 and 2 entail.

[277] Beach J in *Meat & Livestock Australia Limited v Cargill Inc,* above n 255; and *Sequenom Inc v Ariosa Diagnostics Inc*, above n 256. Kenny, Bennett and Nicholas JJ in *Commissioner of Patents v RPL Central Pty Ltd*, above n 251, also expressed doubt over the utility of the distinction and whether it was at all possible, in a principled manner, to navigate between the two categories (at 251).

[278] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173.

[279] Factor 1 and 2 being closely aligned to the two-part 'test' of *NRDC*, for "an outcome as a result of human action" of "economic utility", above n 189.

[280] This was the precise worry in the *Myriad* litigation. The SCOTUS expressed concern in *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173, at 2118, and the HCA in *D'Arcy v Myriad Genetics Inc*, above n 174, at [6] and [27].

Secondly, an alternative recommendation is the conditional application requirement (i.e. requirement for a significant new application or extension of the concept of a "manner of manufacture") should be replaced by 'whether the class of claim is aligned to a long-established, inherently unpatentable category of subject matter'.[281] Such categories could include "discoveries" and "products of nature".[282] If a party was to assert with substantial foundation that one such category was brought into play, then the transition would be made from Category 1 into Category 2 and policy-centric factors engaged. It is hard to envisage a nucleic acid 'invention' that, no matter how mundane, would not rely on "principles of nature" or "products of nature", meaning the court would receive an opportunity to consider, and benefit from such consideration, of broader policy-centric factors.

Either way, the 'Policy-centric' test should be included in a structured, nuanced, way in a judicial approach to nucleic acid 'inventions'. Both recommendations realise this.[283] Policy considerations are so fundamentally baked into the patent scheme itself that,[284] in order to understand what the judiciary are *doing* when determining whether an 'invention' exists, it is far easier to follow along when such factors are explicitly noted rather than implicitly 'hidden' or 'disguised' in amongst the 'Judging Difference' or 'Labour-centric' tests.

[281] The long-established, inherently unpatentable categories being those which discussed in Section 4.2 above.
[282]See Section 4.2.2 for specific discussion of the categories and cases in which they were first recognised.
[283] Dreyfuss, Nielsen and Nicol "Patenting nature – a comparative perspective", above n 111, at 577-579.
[284] The "patent system is a *public* instrument of economic and social policy and the rights it confers must advance overall public welfare, not undermine it" (Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies", above n 129.

10. Pitfalls: responses to potential criticisms and challenges of implementation

To ensure the applicability of the *D'Arcy*-esque approach under s 14(a) of the Patents Act 2013, Section 10 shall consider how well the approach may be sewn into the existing fabric of New Zealand's patent scheme, along with some potential challenges of implementation, and how such challenges might be addressed and overcome.

In the context of nucleic acids, 'Judging Difference' has been viewed as a 'line-drawing' exercise which produces "illogical",[285] "arbitrary"[286] conclusions and has led commentators to question the entire utility of the test.[287] An intuitive way forward may be for the *D'Arcy*-esque approach to abandon any reliance on 'Judging Difference'.[288] While a meritorious suggestion, this dissertation has identified numerous strengths of the test.

'Judging Difference' is a useful means to orientate and constrain the breadth of the inquiry before it transitions into the 'Policy-centric' portion of the multi-factorial, policy-laden framework.[289] 'Judging Difference' celebrates the application of common law methodology and instils a modicum of principality to an inherently 'elastic, unformulaic, undefinable inquiry in an inherently uncertain area of law'.[290] The case-by-case methodology draws on the taxonomical category of "products of nature", a stable

[285] Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?", above n 272, at 557.
[286] Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc:* Patenting Genes in Australia", above n 69, at 144.
[287] "Illogical" and "arbitrary" conclusions most notably being the substance of the claimed invention (i.e. chemical compound *or* genetic information (Section 8.3)) and why genetic information could not be "made" (per *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [6] (Section 8.5).
[288] The suggestion of an approach dominated by 'Policy-centric' considerations can be found in Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35, at 192-193 and Dreyfuss, Nielsen and Nicol "Patenting nature – a comparative perspective", above n 111, at 577-579.
[289] The multi-factorial, policy-laden approach of the HCA in *Myriad* described in Section 8.2.
[290] Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 166.

category of inherently unpatentable subject matter,[291] and, along with using previous decisions in an unprincipled manner, forms principled precedents upon which future courts can rely. In this sense, 'Judging Difference' implements *how* history has shaped the understanding of a "manner of manufacture",[292] to constrain and orient the court before it wanders into the lofty heights of policy-centric considerations, whether it be "morality issues"[293] or "conflicting public and private interests".[294] Both the HCA and SCOTUS were acutely aware of the difference between interpretation and law-making, the latter being solely reserved for the legislature. 'Judging Difference' prevents sole reliance on the 'Policy-centric' test as a means to justify the existence or otherwise of an 'invention' – an approach which would clearly blur the line distinguishing the inherent role of the courts and the legislature.

The *D'Arcy*-esque approach allows for multiple substances of an 'invention' to coexist, thus a further criticism may be that it would lead New Zealand courts to make similar mistakes to the SCOTUS in *Myriad.*[295] The SCOTUS, when applying 'Judging Difference' to cDNA, compared multiple substances[296] between multiple different natural nucleic acids,[297] which produced a plethora of comparisons leading to different conclusions. In a similar vein, if unconstrained by one substance, an analogous problem may ensue in New Zealand. Unfortunately, this *potential* shortcoming must be accepted as the only reasonable way forward which 'does not raise form over substance is to allow various characterisations in order to recognise the multi-faceted nature of nucleic acids'.[298] While it may increase the chances of the courts having to choose between various characterisations and comparisons – and potentially choosing wrongly – it firmly

[291] 'Products of nature, or products that are too closely communicative of the natural properties of their antecedent biomolecule, are inherently unpatentable': Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?", above n 272, at 564-565.
[292] Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc:* Patenting Genes in Australia", above n 69, at 141.
[293] Sumpter *Intellectual Property Law: Principles in Practice*, above n 7, at 299-300.
[294] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [28].
[295] *Association for Medical Pathology v Myriad Genetics Inc.*, above n 173.
[296] The SCOTUS found the substance to be a chemical, genetic information and in a lesser sense, also focussed on the structural and functional properties of nucleic acids: Section 8.4.1 above.
[297] The SCOTUS focussed on differing comparisons between cDNA and both DNA and mRNA: Section 8.4.1 above.
[298] Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?", above n 272, at 558.

resolves issues stemming from the chemical compound/genetic information dichotomy which is nonsensical from a scientific perspective.[299] This shortcoming is also arguably more tolerable in the *D'Arcy*-esque approach as the court would have an opportunity to militate any downstream consequences through application of the explicit 'Policy-centric' test – an opportunity not available to the SCOTUS as policy-centric factors never transitioned from being un(der)articulated to articulated.[300]

New Zealand's patent scheme is full of areas to consider 'Policy-centric' factors, which may lead to criticism that the *D'Arcy*-esque approach is duplicative as it replicates a 'Policy-centric' inquiry which already occurs in established areas of the Patents Act 2013.[301] Under the Act, s 14(a) by virtue of s 6 of the Statute, has two limbs – the first being a "manner of manufacture", and the second a proviso which includes an allowance to exclude "generally inconvenient" inventions.[302] Secondly, s 15 of the Act[303] permits exclusion of inventions "contrary to public order or morality".[304] Simply, would it not be more appropriate to limit the influence of proviso-type, policy-centric factors when considering a "manner of manufacture", and confine them to the proviso or s 15? Well, the answer is not straightforward.

The standing and scope of the two provisions is uncertain due to changes instituted through the transition from the Patents Act 1953 to the Patents Act 2013. Under the Patents Act 1953, *both* limbs were confirmed to inform the definition of an "invention" in the case of *Pfizer Inc v Commissioner of Patents* (*Pfizer*),[305] but it is still to be confirmed

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[299] Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter?", above n 272, at 557.

[300] The SCOTUS did not implement the 'Policy-centric' test, but instead smuggled in such considerations into the 'Judging Difference' and 'Labour-centric' tests.

[301] Sumpter *Intellectual Property Law: Principles in Practice*, above n 7, at 278-284.

[302] Despite s 6 being one definition, the two limbs are often recognised. The first is a "manner of [new] manufacture" and the second is the proviso of "not contrary to the law, or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient". Traditionally, the limbs are treated as separate elements, both of which inform the concept of an 'invention' (above n 19).

[303] Patents Act 2013, s 15. See Section 17 of the Patents Act 1953 for the somewhat analogous repealed provision.

[304] Patents Act 2013, s 15. See and Frankel and Lai *Patents Law and Policy*, above n 17, at 114-128 for discussion of this, and other, express exclusions to patentability under the Patents Act 2013.

[305] *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104 at [63]-[64]. Glazebrook, William Young and O'Regan JJ confirmed the entirety of s 6 informed the meaning of an 'invention'.

under the Patents Act 2013.[306] The ambit of s 15 is also unknown as no decision of the court has defined its scope under the Patents Act 2013 – but guidance can be found in application of the somewhat equivalent section of the Patents Act 1953, s 17(1). "Use"[307] or "commercial exploitation",[308] in the language of the 1953 and 2013 Act's respectively,[309] must be contrary to public order or morality, not the 'invention' itself.[310] Under the Patents Act 2013, opportunities to exclude an invention in a comparable fashion to the *D'Arcy*-esque approach are simply not offered: all are somewhat restrictive and do not allow broad, expansive consideration of policy factors.

The potential criticism that the *D'Arcy*-esque approach is duplicative inevitably endorses the adoption of the 'Abandonment approach'.[311] The 'Abandonment approach' would remove all duplication by clarifying when an 'invention' exists, whether that be through removal of s 14(a) or establishing a clear line (i.e. 'isolation' is sufficient);[312] either way, the role of a "manner of manufacture" would not be of importance. Given the long-established requirement for an 'invention' in New Zealand's patent law landscape – and the most recent endorsement via inclusion of s 6 in the Patents Act 2013 – it would be highly challenging and disruptive to now adopt the 'Abandonment approach'. Such an adoption would require strong justification, and the potential of duplication arguably does not satisfy the bar.

Now, the ease with which the *D'Arcy*-esque approach may be sewn into New Zealand's existing patent landscape shall be considered. Encouragingly, the approach is more reflective of current trends in New Zealand, as opposed to Australia, in two distinct respects.

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[306] Lai "Gene-related patents in Australia and New Zealand: Taking a step back", above n 35, at 184-185.
[307] "Use" being the term used in s 17(1) of the Patents Act 1953.
[308] "Commercial exploitation" being the term used in s Patents Act 2013, s 15(1).
[309] Patents Act 1953, s 17(1) and the Patents Act 2013, s 15.
[310] By way of example, take the BRCA1/2 isolates from the *Myriad* litigation. To exclude under s 15, it must be said that "commercial exploitation" of providing women with BRCA1/2 diagnostic testing is "contrary to public order or morality" – a task which, when phrased like so, would be challenging.
[311] See Section 6.3 above.
[312] 'Isolation' being the process of removing nucleic acid fragments from the *in vivo* environment to enable *in vitro* studies (above n 90).

First, New Zealand courts have more readily engaged with policy-centric considerations in a less un(der)articulated manner than Australia. Most obviously, the difference can be observed through varied engagement and application of the s 6 proviso. Traditionally, Australian courts shied away from reliance on the proviso to exclude an otherwise patent-eligible invention.[313] Yet in New Zealand, courts have affirmed the importance of the proviso to 'colour' and inform the concept of an 'invention'.[314] In *Wellcome v Commissioner of Patents*[315]*,* when discussing the proviso, Cooke J stated that:[316]

> "...we cannot realistically shut our eyes to the possibility that in the language of the Statute of Monopolies the change sought by the respondent might result in "raising prices at home" or be "generally inconvenient".

The willingness of Cooke J in 1983 to engage with the proviso set the stage for years of acknowledging the importance of explicitly addressing policy concerns, even when there was a mere "possibility" such concerns would be realised. Unfettered engagement with the proviso is a unique part of New Zealand's patent law landscape, and while the precise standing of it under the Patents Act 2013 is unconfirmed, this dissertation suggests endorsement of the proviso in the *D'Arcy*-esque approach would be a positive edition in keeping with current trends in New Zealand.[317]

In a short aside, a potential challenge with endorsement of the proviso would be the dissonance between the court's and IPONZ's understanding of *Pfizer* – the case which confirmed how the proviso informed the meaning of an "invention".[318] In *Pfizer,* Anderson P expressed caution at reliance on the proviso as it potentially created a wider exception to exclude subject matter than allowed under TRIPS, specifically Article 27.[319]

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[313] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524. See Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 178-180 as to how Australian courts have been 'reluctant to engage with public policy arguments rooted in s 6'.

[314] *Pfizer,* above n 305, at [63].

[315] *Wellcome Foundation v Commissioner of Patents* ("*Wellcome*") [1983] NZLR 385 (CA).

[316] At 391 per Cooke J.

[317] The state of affairs in *Pfizer, a*bove n 305, being that the concept of an 'invention' is informed by both limbs of s 6: a "manner of manufacture" and the proviso of statutory exclusions.

[318] *Pfizer,* above n 305.

[319] TRIPS, above n 6, Article 27. See Frankel and Lai *Patents Law and Policy*, above n 17, at 127-128 and 375-377 for in-depth explanation as to why the interpretation of TRIPS adopted by Anderson P was incorrect.

Unfortunately, IPONZ – whose internal policies are frequently determinative[320], as demonstrated in Section 3 above – appear to have implemented the words of Anderson P quite literally,[321] to justify turning a blind eye to policy discussions, all the while ignoring the fact the 'words were obiter dictum and that numerous other judgments have urged the importance of analysis of the proviso'.[322] Inclusion and endorsement of the proviso in the *D'Arcy*-esque approach would continue the long-standing tradition of an 'invention' being informed by *both* limbs of s 6, and would also dispel the incorrect practice of IPONZ.[323]

The second trend the *D'Arcy*-esque approach mirrors is the understanding of the institutional role of the courts (i.e. interpretation) and the role of the legislature (i.e. law-making).[324] When exercising judicial discretion and considering broad questions of social, economic and public policy,[325] Australia and New Zealand have diverged in how the understanding of institutional roles influences the fate of the 'invention' being considered.[326] Traditionally, in Australia, when broad policy-centric considerations were raised by an 'invention', the role assumed by the judiciary was to institute a presumption in favour of *inclusion* of such things within a "manner of manufacture" until

[320] Sumpter *Intellectual Property Law: Principles in Practice*, above n 7, at 280-281; Frankel and Lai *Patents Law and Policy*, above n 17, at 375-377 and 395-397.
[321] See *Pfizer,* above n 305, at [56]-[57] per Anderson P; and *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529.
[322] Frankel and Lai *Patents Law and Policy*, above n 17, at 375-377.
[323] At 127-128.
[324] The institutional role of the courts to 'interpret' the law as opposed to be one of 'law-making' was discussed in *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [7]. The line drawn between both roles in *Myriad* by the HCA was more reflective of current trends in New Zealand as opposed to Australia. See Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 174-177, for substantive analysis of the divergence in opinion between Australia and New Zealand on the same issue, namely methods of human treatment.
[325] Van Caenegem *Intellectual and Industrial Property in Australia*, above n 53, at 178-180.
[326] At 178-180.

Parliament stated otherwise.[327] Yet in New Zealand,[328] a presumption in favour of *exclusion* was instituted as given 'the complexity of the area of law and the policy choices required',[329] the matter was viewed as best being left to legislative reform.[330] In *Myriad,* the HCA accorded with the New Zealand position noting that 'where affirmative application of a "manner of manufacture" is likely to involve far-reaching questions of public policy, it is best left for legislative determination'.[331] The line drawn between the courts and the legislature in *Myriad*, and thus incorporated into the *D'Arcy*-esque approach, would assist in seamless implementation of the approach into New Zealand's patent landscape.

In conclusion, the *D'Arcy*-esque approach implements the 'Judging Difference' and 'Policy-centric' tests in a mutually dependent manner where they reinforce one another. The 'Judging Difference' test, which still implicitly contains policy-centric considerations,[332] orients the initial inquiry and prevents the court from undertaking a free-wheeling, unprincipled inquiry reminiscent of the role of the legislature. In turn, the 'Policy-centric' test addresses the concern that the 'horse may have already bolted' once 'Judging Difference' is completed if done in a manner that elevates form over substance to the 'detriment of the developmental function entrusted to the court'.[333]

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[327] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd*, above n 313, at [141] per Finkelstein J. The invention in question was a method of human treatment, a subject matter similarly contentious to the BRCA1/2 isolates. Importantly, Finkelstein J noted: "I do not believe that in a controversial issue such as is raised by the present argument, I would be abandoning my responsibility as a judge to… hold that if public policy demands that a medical or surgical process should be *excluded* from patentability, then that is a matter that should be resolved by the Parliament." (emphasis added). The key word being "excluded" – which highlights the position assumed by the courts in this instance.

[328] The presumption was instituted in the case of *Pfizer*, above n 305. Similarly to *Bristol-Myers Squibb Co v FH Faulding & Co Ltd*, above n 313, the invention in issue was a method of human treatment. The Court affirmed the unpatentability of methods of treating disease or illness in human beings which had been found more than 20 years previous, in the decision of *Wellcome Foundation v Commissioner of Patents* [1979] 2 NZLR 591. *Pfizer* agreed with *Wellcome* insofar as the matter was best left to Parliament and as Parliament had not legislated in the time from 1979 to 2004, such methods were still unpatentable.

[329] *Pfizer*, above n 305, at [84] per Glazebrook, William Young and O'Regan JJ.

[330] At [128] per Hammond J.

[331] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [7].

[332] See Section 6.2 above for explanation as to why the 'Judging Difference' test still contains implicit policy-centric considerations.

[333] *D'Arcy v Myriad Genetics Inc* (HCA), above n 174, at [88].

11. Lessons learnt

Part I of this dissertation began by detailing the fundamental legal and scientific concepts relevant to the patent-eligibility of nucleic acid 'inventions' before showing how courts have struggled with the concept of an 'invention' and instead, used 'Un(der)articulated tests' as proxies for the conceptual inquiry. Part II analysed the *Myriad* litigation to demonstrate the suitability of the 'Un(der)articulated tests' as applied in the context of nucleic acids. The multi-factorial, policy-laden approach of the HCA was contended to be preferable over the SCOTUS approach, as the former clearly articulated the policy factors considered to be relevant in the instant case. The 'Labour-centric' test was also shown, through consideration of its application by the SCOTUS to cDNA, to be an undesirable test when applied to nucleic acid 'inventions'. Part III generally endorsed the HCA approach in *Myriad*, but made recommendations to first, address issues identified in Part II and secondly, tailor the approach to suit New Zealand's patent landscape.

A noteworthy feature of the Patents Act 2013 is the loss of "invention" as a defined term.[334] This loss sets the 2013 Act apart from not only its predecessor, the Patents Act 1953, but also the Patents Act 1990 (Cth).[335] The subtle deemphasis of 'invention' might, at first blush, suggest the difficult concept of an 'invention' to be of diminished importance in New Zealand patent law.[336] However, any suggestion that the concept has been removed entirely is at odds with the legislative intent behind retaining reference to "manner of manufacture" in accordance with s 6 of the Statute.[337] In fact, the move away from an overarching, singular definition of an "invention" may instead better pave the way for a *separate, nucleic acid-specific* concept of an 'invention' to be created.[338] The

[334] See 'Legislative history of the "manner of manufacture" requirement in New Zealand patent legislation (Section 4.1 above).
[335] Above n 34.
[336] The deemphasis does not, however, come close to level of deemphasis required for the Abandonment approach (Section 6.3).
[337] Frankel and Lai *Patents Law and Policy*, above n 17, at 89-91 in support of the "manner of manufacture" inquiry in effect, asking the legal question as to whether an 'invention' exists.
[338] Alain Pottage and Brad Sherman *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, New York, 2010) at 171-182.

D'Arcy-esque approach provides an attractive way forward to achieve this end, or at the least to deal with the concept in a clearer way than the *Myriad* decisions in Australia and the United States.[339] The *D'Arcy*-esque approach implements the two most appropriate proxies in a transparent manner, to afford the court an occasion to consider the tricky balance "between private rights and public benefits which characterise the intellectual property regime – being nowhere better tested than in the field of biotechnology patents."[340]

Curial opportunities to examine the inquiry contained in s 14(a) are uncommon, but when a nucleic acid-based 'invention' presents before New Zealand courts, the *D'Arcy*-esque approach would provide the best opportunity to get the outcome 'right'. 'Right' in the sense it would be easier to understand *how* the judiciary arrive at conclusions; rather than 'right' in terms of a substantive outcome (i.e. recognising validity of a particular patent or not) that the author, or others, would approve of.

Take the BRCA1/2 patents for example. Before the final appellate decisions in the *Myriad* litigation a woman's right of access to healthcare was hampered as availability of BRCA1/2 diagnostic testing decreased while the price increased.[341] And why? An explanation expressed in terms of *NRDC*[342] might describe how Myriad created an "artificially created state of affairs of economic utility" – with the key element of 'artifice' ensuring the isolates were not 'products of nature' or 'discoveries. However, as discussions above have shown, the characterisation of inventions as 'artificial', 'products of nature' or 'discoveries' – all of which are highly contestable – makes such an 'answer' unsatisfactory and conclusory.

In contrast, under the recommended *D'Arcy*-esque approach, the 'answer' might acknowledge similar points but would swiftly shift to explain why the "private rights" of Myriad were prioritised over others' interests (i.e. a woman's right of access to healthcare) in the name of overall "public benefit".[343] The *D'Arcy*-esque approach does several things 'right'; the approach makes it less likely for deficient reasoning to survive and produces an 'answer' which is potentially more acceptable and persuasive – and if

[339] The *D'Arcy-esque* approach as formulated in Section 9 above.
[340] Sumpter *Intellectual Property Law: Principles in Practice*, above n 7, at 301.
[341] Gold and Carbone "Myriad Genetics: In the eye of the policy storm", above n 102.
[342] The terms of *NRDC* as applied by subsequent courts before the HCA's Myriad decision.
[343] "Private rights" and "public benefit" in reference to above n 340.

not persuasive, at least substantially easier for practitioners, commentators and the public generally to understand and challenge. Even if the *same* conclusion is reached, the latter 'answer' provides insight into *how* court acts as arbiters to protect and enforce rights impinged by patents.

The court is the steward of the storehouse of nature: it determines what may trickle from within to be enclosed in legal rights and no longer free to all, reserved exclusively to none.[344] Looking forward, it is a foregone conclusion that scientific developments will continue to uncover the infinite intricacies of nature. Yet the extent to which New Zealand courts will protect nucleic acids, and for whose ultimate benefit remains uncertain. The *Myriad* litigation showed that though the biotechnological potential of nature is vast, small concessions can pave the way for significant encroachments. Therefore, we must hope that when scientists delve further into the storehouse, the great importance of their discoveries does not prevent the courts from exercising caution in ensuring the balance of control is 'right'.

[344] *Funk Bros Seed Co v Kalo Inoculant Co*, above n 115, at 132.

12. Bibliography

Cases

1 New Zealand

Daiichi Sankyo Company Ltd v Alethia Biotherapeutics Inc [2015] NZIPOPAT 24.

Maeder v "Ronda" Ladies Hairdressing Salon [1943] NZLR 122 (CA).

Pfizer Inc v Commissioner of Patents [2004] NZCA 104.

Pharmaceutical Management Agency Ltd v Commissioner of Patents [2000] 2 NZLR 529.

Swift & Co v Commissioner of Patents [1960] NZLR 775 (SC).

Wellcome Foundation v Commissioner of Patents [1983] NZLR 385 (CA).

2 Australia

Arrowhead Research Corporation [2016] APO 79.

Cancer Voice Australia and Yvonne D'Arcy v Myriad Genetics Inc [2013] FCA 65.

Cargill Incorporated v Dow Agro Sciences LLC (2016) APO 43 (5 July 2016).

Commissioner of Patents v RPL Central Pty Ltd [2015] FCAFC 177.

Commonwealth Scientific and Industrial Research Organisation v BASF Plant Sciences GmbH [2016] APO 83.

D'Arcy v Myriad Genetics Inc [2014] FCAFC 115.

D'Arcy v Myriad Genetics Inc [2015] HCA 35.

National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252.

Maeder v Busch (1938) 59 CLR 684 (HCA).

Meat & Livestock Australia Limited v Cargill Inc [2018] FCA 51.

Research Affiliates LLC v Commissioner of Patents (2014) FCR 378.

Sequenom Inc v Ariosa Diagnostics Inc [2019] FCA 1011.

Sun Pharmaceuticals Industries (Australia) Pty Ltd v Tasmanian Alkaloids Pty Ltd [2018] APO 7.

3 England

Boulton and Watt v Bull [1795] 126 ER 651 (Comm Pleas).

Bristol-Myers Co v Beecham Group Ltd [1974] AC 646.

C & W's Application (1914) 31 RPC 235 (SG).

G E C's Application (1943) 60 RPC 1 (PC).

Ralston v Smith (1865) 114 ER 1013 (Comm Pleas).

Young v Rosenthal (1884) 1 RPC 29 (QB).

4 The United States of America

Alice v CLS Bank International, 134 S. Ct. 2347 (2014) (SC).

Association for Medical Pathology v Myriad Genetics Inc, 133 S Ct 2107 (2013) (SC).

Bilski v Kappos, 561 U.S. 593 (2010) (SC).

Diamond v Chakrabarty, 447 U.S. 303 (1980) (SC).

Funk Brothers Seed Co v Kalo Inoculant Co, 333 U.S. 127 (1948) (SC).

In re Roslin Institute (Edinburgh), 750 F.3d 1333 (2014) (Fed. Cir.).

J.E.M. Ag Supply Inc v Pioneer Hi-Bred International Inc., 534 U.S. 124 (2001) (SC).

Mayo Collaborative Services v Prometheus Labs Inc., 132 S. Ct. 1289 (2012) (SC).

Legislation

1 New Zealand

Patents Act 1860.

Patents Act 1953.

Patents Act 2013.

2 Australia

Patents Act 1990 (Cth).

3 England

Patents Act 1949.

Patents Act 1977.

Statute of Monopolies 1623.

4 The United States of America

35 USC § 101 (Supp 1952).

5 European Union

Biotech Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213).

Implementing Regulations to the Convention on the Grant of European Patents.

Books and Chapters in Books

Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts and Peter Walter *Molecular Biology of the Cell* (4th ed, Garland Science, New York, 2002).

William van Caenegem *Intellectual and Industrial Property in Australia* (LexisNexis Buttersworth, Australia, 2009).

Professor William Cornish, Professor David Llewelyn and Professor Tanya Aplin *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (8th ed, Sweet & Maxwell, London, 2013).

Peter Drahos *A Philosophy of Intellectual Property* (Dartmouth Publishing Company, England, 1996).

Ian Finch "James & Wells Intellectual Property Law in New Zealand" (3rd ed, Thomas Reuters, Wellington, 2017).

Susy Frankel and Jessica C Lai *Patent Law and Policy* (LexisNexis, Wellington, 2016).

Stephen Hubicki and Brad Sherman "We have never been modern: the High Court's decision in *National Research Development Corporation v Commissioner of Patents*" in Andrew T Kenyon, Megan Richardson and Sam Ricketson (eds) *Landmarks in Australian Intellectual Property Law* (Cambridge University Press, New York, 2009) 73.

WM Landes and RA Posner *The Economic Structure of Intellectual Property Law* (The Belknap Press of Harvard University Press, Cambridge, 2003).

Justine Pila *The Requirement for an Invention in Patent Law* (Oxford University Press, New York, 2010).

Alain Pottage and Brad Sherman *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, New York, 2010).

Brad Sherman and Lionel Bentley *The Making of Modern Intellectual Property Law: The British Experience 1760-1911* (Cambridge University Press, Cambridge, 1999).

Jeanne Snelling, Nikki Kerruish and Jessie Lenagh-Glue *Judging Genes & Choosing Children:* Revisiting law, ethics and policy in the genomic era (University of Otago, Dunedin, 2017).

John Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies" in Graeme Austin and Charles Rickett (eds) *International Intellectual Property and the Common Law World* (Hart Publishing, Oxford, 2000).

Paul Sumpter *Intellectual Property Law: Principles in Practice* (3rd ed, CCH New Zealand, Auckland, 2017).

Donald Voet, Judith G Voet and Charlotte W Pratt *Fundamentals of Biochemistry: Life at the Molecular Level* (4th ed, Hoboken (NJ), John Wiley & Sons, 2015).

Amanda Warren-Jones *Patenting rDNA: Human and Animal Biotechnology in the United Kingdom and Europe* (Lawtext, Witney (Oxfordshire), 2001).

Journal Articles

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) JLIS 120.

Dan L Burk "Edifying Thoughts of a Patent Watcher: The Nature of DNA" (2013) 60 UCLA L. Rev. Disc. 92.

Doug Calhoun "The Patents Act 2013: a History and an Overview" *Intellectual Property Law (NZ)* (online ed, LexisNexis).

Lara Cartwright-Smith "Patenting Genes: What Does *Association for Molecular Pathology v Myriad Genetics* Mean for Genetic Testing and Research" (2014) 123(3) Public Health Rep. 289.

H Jared Doster "The English Origins of the Judicial Exceptions to 35 U.S.C. § 101" (2019) 11(4) Landslide (online ed, American Bar Association).

Rochelle Dreyfuss, Jane Nielsen and Dianne Nicol "Patenting nature – a comparative perspective" (2018) 5(3) JLB 550.

JA Duncan, JR Reeves and TG Cooke "BRCA 1 and BRCA2 proteins: roles in health and disease" (1998) 51(5) Mol Pathol 237.

Rebecca S Eisenberg "Why the gene patenting controversy persists" (2002) 77(12) Acad Med 1381.

Richard Gold and Julia Carbone "Myriad Genetics: In the eye of the policy storm" (2010) 12(4) Genet Med. 39.

JM Hall, MK Lee, B Newman, JE Morrow, LA Anderson, B Huey and MC King "Linkage of early-onset familial breast cancer to chromosome 17q21" (1990) 250 Science 1648.

Alison Heath "Preparing for the Genetic Revolution – The effect of gene patents on healthcare and research and the need for reform" (2005) 11 CantLawRw 59.

Martin Jinek, Krzysztof Chylinski, Ines Fonfara, Michael Hauer, Jennifer Doudna and Emmanuelle Charpentier "A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity" (2012) 337 Science 816.

Jessica C Lai "Gene-related patents in Australia and New Zealand: Taking a step back" (2015) 25 AIPJ 181.

Jessica C Lai "Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision" (2015) 5(5) U.C. Irvine L. Rev. 1014

Jessica C Lai "*D'Arcy v Myriad Genetics*: A Demand for the "Made" or "Non-Information" and Clear Subject Matter? (2016) 47 IIC 537.

Charles Lawson "Patenting Nucleic Acid Sequences: More Ambiguity from the High Court in *D'Arcy v Myriad Genetics Inc.*?" (2018) 25(3) J. L. & Med. 741.

Lucas McCallum and Thomas Faunce "Myriad Voices Against Gene Patents in the High Court" (2015) 23 J.L. & Med 322.

Yoshio Miki, Jeff Swensen, Donna Shattuck-Eidens, P. Andrew Futreal, Keith Harshman, Sean Tavtigian, Qingyun Liu, Charles Cochran, L Michelle Bennett, Wei Ding, Russell Bell, Judith Rosenthal, Charles Hussey, Thanh Tran, Melody McClure, Cheryl Frye, Tom Hattier, Robert Phelps, Astrid Haugen-Strano, Harold Katcher, Kazuko Yakumo, Zahra Gholami, Daniel Shaffer, Steven Stone, Steven Bayer, Christian Wray, Robert Bogden, Priya Dayananth, John Ward, Patricia Tonin, Steven Narod, Pam K Bristow, Frank H Norris, Leah Helvering, Paul Morrison, Paul Rosteck, Mei Lai, J Carl Barrett, Cathryn

Lewis, Susan Neuhausen, Lisa Cannon-Albright, David Goldgar, Roger Wiseman, Alexander Kamb and Mark H Skolnick "A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1" (1994) 226 Science 66.

Ann Monotti "The Scope of 'Manner of Manufacture' under the Patents Act 1990 (Cth) after Grant v Commissioner of Patents (2006) 34(3) FedLawRw 461.

Justine Pila "Inherent Patentability in Anglo-Australian Law: A History" (2003) 14 AIPJ 109.

Brad Sherman "Before the High Court: *D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia" (2015) 37 Syd LR 135.

Brad Sherman "What Does It Mean to Invent Nature?" (2015) 5 UC Irvine Law Rev 1193.

SV Tavtigian, J Simard, J Rommens, F Couch, D Shattuck-Eidens, S Neuhausen, S Merajver, S Thorlacius, K Offit, D Stoppa-Lyonnet, C Belanger, R Bell, S Berry, R Bogden, Q Chen, T Davis, M Dumont, C Frye, T Hattier, S Jammulapati, T Janecki, P Jiang, R Kehrer , JF Leblanc, JT Mitchell, J McArthur-Morrison, K Nguyen, Y Peng, C Samson, M Schroeder, SC Snyder, L Steele, M Stringfellow, C Stroup, B Swedlund, J Swensen, D Teng, A Thomas, T Tran, T Tran, M Tranchant, J Weaver-Feldhaus, AKC Wong, H Shizuya, JE Eyfjord, L Cannon-Albright, F Labrie, MH Skolnick, B Weber, A Kamb and DE Goldgar "The complete BRCA2 gene and mutations in chromosome 13q-linked kindreds" (1996) 12(3) Nat Genet. 333.

Andrew J Wallace "New challenges for BRCA testing: a view from the diagnostic laboratory" (2016) 24 European Journal of Human Genetics 10.

Parliamentary and government materials

Patents Bill 2008 (235-1).

Ministry of Economic Development and Ministry of Health, *Implications of the Granting of Patents over Genetic Material* (2003) 16 at 1.

Reports

Ministry of Commerce *The Reform of the Patents Act 1953: Proposed Recommendations, Competition Policy and Business Law Division* (1992).

Ministry of Economic Development and Ministry of Health *Memorandum to Cabinet Policy Committee: Report Back with Recommendations and Options for Addressing Genetic Material Patents* (2004).

Internet resources

Australian Patent Office, "Examination Practice Following the High Court Decision in *D'Arcy v Myriad Genetics Inc.*" (19 August 2020) IP Australia <https://www.ipaustralia.gov.au/sites/default/files/examination_practice_following_the_high_court_decision_in_darcy_v_myriad_genetics_inc.pdf?acsf_files_redirect>.

Breast Cancer Foundation NZ "Breast awareness: Genetic counselling & testing" Breast Cancer Foundation <https://www.breastcancerfoundation.org.nz/>.

Intellectual Property Office New Zealand "History of Intellectual Property in New Zealand" IPONZ <https://www.iponz.govt.nz/about-iponz/history-of-ip-in-new-zealand/>.

Jocelyn Bosse "In Conversation with Prof. Brad Sherman: *D'Arcy v Myriad Genetics Inc* (2015) and the Future of Australian Patent Law" (20 October 2015) Justice and the Law Society <http://www.jatl.org/blog/2015/10/15/in-conversation-with-prof-brad-sherman-darcy-v-myriad-genetics-inc-2015-and-the-future-of-patent-law>.

New Zealand Press Association "Cancer tests will continue despite patent wrangle" *New Zealand Herald* (online ed, Auckland, 16 July 2008).

Other resources

Brief of James D. Watson, Ph.D as Amicus Curiae in Support of Neither Party *Ass'n for Molecular Pathology v Myriad Genetics Inc,* 133 S. Ct. 2107 (2013) (No. 12-398).

Brief for the United States as Amicus Curiae in Support of Neither Party, *Association for Medical Pathology v Myriad Genetics,* 133 S Ct 2107 (2013) (No. 12-398).