Myriad Claims: Discovery, Invention and Innovation in Biotechnology.

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October 2014

A dissertation submitted in partial fulfilment of the requirements for the degree pf Bachelor of Laws (Honours) at the University of Otago

Acknowledgements

Thanks for this dissertation are owed to a great number of people, only a few of whom are named here. I would not have been capable of completing such a task without their friendship, support, and teaching. So far as my work succeeds it is because of these friends, who have my heartfelt gratitude. To the extent that my work is flawed, however, the fault is mine alone.

Thanks to Shelley Griffiths, for her unwavering optimism, support, and assistance, even in the face of adversity.

Thanks to Lauren Farmer, for loving me, looking after me, and being a constant friend and companion.

Thanks to the delightful inhabitants of 7C13—Josie, Kim and Stacey—for keeping me entertained, enthused, gossiped, and supplied with coffee and chocolate.

Thanks to the eleventh-hour proofreading team, for making things readable.

Thanks to Simon Hoffman, for the 2010 study group and all the food, wine and banter since then.

Thanks to Nicola Peart, who convinced me to do this in the first place, then compelled me to do my best.

Finally, thanks to Mum and Dad, for getting me here.

Contents

Chapter 1

Introduction

The past two years have seen two Courts of significant standing—the United States Supreme Court and the Full Court of the Australian Federal Court—issue decisions on the often-controversial area of gene patents.[1] The decisions focused on the inherent patentability of isolated DNA: whether it can be considered appropriate subject matter for patentability. Despite a growing push for consistency in intellectual property law worldwide, the courts disagreed, with the Supreme Court unanimously deciding that isolated DNA is not patentable while the Full Court unanimously decided that it is. This divergence could perhaps be represented as nothing more than a reflection of the differences in the legal environments of the respective countries. However, both courts were endeavouring to solve the same fundamental question: where do we draw the line between the work of nature, and the invention of man?

The answer to this question has significant implications. The primary means to protect and monetise innovation is the patent system. Patents provide an incentive to develop and disclose new technology in return for a time-limited monopoly over the invention.[2] At its ideal, the patent system results in a net benefit to society. The economic incentive results in higher levels of investment and innovation, and disclosure requirements allow new knowledge and innovation to disseminate.[3] Overall, the benefit to society outweighs losses due to monopoly pricing over the patent's term.

Unfortunately, this is not always or necessarily the case. It has been suggested that patents can limit the rate of innovation by preventing oth-

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[1] Both cases were in fact based on disputes over the same technology, protected by very similar patents: *Association for Molecular Pathology v Myriad Genetics Inc* [2013] US (slip op) No 12-398, 133 S Ct 2107 (2013); *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115.

[2] PC Sumpter *Intellectual property law: principles in practice* (CCH New Zealand Limited, 2006) at p 231.

[3] This rationale is given as a purpose of the Patents Act 2013, s 3(a).

ers from building on newly-invented technologies.[4] Licensing requirements and litigation risk can disincentivise new development by increasing costs. Uncertainty as to whether a particular technology is patented or not can inhibit further research, even where it would not infringe. This is particularly true in New Zealand given that, until recently, patents were not examined for inventive step or utility prior to grant.[5] Once granted, challenges to patent validity can result in expensive litigation.[6] This litigation is likely to be cost-prohibitive and high-risk, especially to small organisations.[7] At their worst, patents may stifle innovation through the creation of "patent thickets" leading to the "tragedy of the anti-commons", where the costs associated with patent compliance are so high as to preclude new research and development.[8] The need to maintain the balance between the benefits and downsides of the patent system thus requires a clear understanding of where patent protection begins and ends. Private actors need to be able to determine the scope of protection to make decisions as to what to patent, research, and litigate.

The problem is especially fraught in the area of biotechnology, where innovation and invention is closely linked to natural processes and discoveries. The industry has produced significant gains in medicine, food, and the environment, and shows the promise to provide many more. In New Zealand, biotechnology is a thriving industry, accounting for $611 million in revenue directly, and $39 billion when firms using biotechnology are included.[9] Working within a research- and knowledge-based industry, biotechnology companies are dependent on patents in order to raise capital and earn income. However, the patenting of biotechnology has been heavily criticised

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4 See, for example, Michele Boldrin and David K Levine "The Case Against Patents" (2013) 27 The journal of economic perspectives 3–22 (arguing that there is limited evidence to suggest higher rates of innovation have resulted from the patent system, while negative effects have appeared), and Michael A Heller and Rebecca S Eisenberg "Can patents deter innovation? The anticommons in biomedical research" (1998) 280 Science 698–701 (describing the 'anti commons' in biotechnology research).

5 Under the Patents Act 1953, patent examination only required an investigation of the novelty of the invention. The inherent patentability, non-obviousness, and utility of the invention could only be challenged in opposition or revocation proceedings.

6 Although applications can be made for the Commissioner to re-examine patents on specified ground after grant (Patents Act, above n 3, s 95).

7 In 2011, 102 of 147 bioscience companies had fewer than 10 employees, with approximately 50% reporting access to capital as the primary limitation to R&D or commercialisation.

8 Where the commonly-understood "tragedy of the commons" relates to the overuse of shared resources, the tragedy of the anti-commons occurs where resources are underutilised due to the exclusionary nature of property rights. This problem is especially relevant to patenting, given that information is an inherently non-rivalrous good. See Michael A Heller and Rebecca S Eisenberg "Can patents deter innovation? The anticommons in biomedical research", above n 4.

9 Statistics New Zealand *BioScience Survey: 2011* (2012).

for raising the price of food,[10] reducing access to medicine,[11] preventing research,[12] and, more fundamentally, offending moral values.[13] The dividing line is critical to both industry and society in New Zealand.

Finally, the decisions overseas arrive just as New Zealand's new patent legislation, the Patent Act 2013, fully enters into force.[14] The Act represents a significant update to the Patents Act 1953, based on over two decades of consultation and new international norms, and strengthens examination requirements while explicitly dealing with the patentability of certain matters, such as methods of medical treatment. However, the Act remains silent on the patentability of genes. New Zealand courts will need to decide on a path to take.

The limits of patentability lie at the heart of the patent system, and biotechnology sits at the edge of those limits. Gene patents are a means of exploring where the limits lie, and how they are determined. In Chapter One, I explain the development of the patent system and its structure in New Zealand. Chapter Two covers the background science necessary to understand the facts and arguments at issue in the cases discussed. Chapter Three outlines the key cases related to inherent patentability in the Commonwealth and in the United States. Chapter Four aims to be an in-depth exposition and discussion of the various arguments put forth and the conceptions of inherent patentability formed in the opposing *Myriad* cases. Finally, in Chapter Five I conclude that the best test is that conceived by the minority of the Federal Circuit in the United States and adopted by the Supreme Court.

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10 Eamon Murphy "Bowman v Monsanto: The Price We All Pay for Roundup Ready Seeds" (2013) Daily Finance <http://www.dailyfinance.com/on/monsanto-gmo-roundup-ready-seeds-patents-food-prices/>.

11 Médecins Sans Frontières "The impact of patents on access to medicines" MSF Access Campaign <http://www.msfaccess.org/content/impact-patents-access-medicines>.

12 Michael A Heller and Rebecca S Eisenberg "Can patents deter innovation? The anticommons in biomedical research", above n 4.

13 G Marchant "Genomics, ethics, and intellectual property" [2007] Intellectual property management in health and agricultural innovation: A handbook of best practice, Oxford: MIHR. Available from www. ipHandbook. org.

14 Patents Act, above n 3, s 2 (commencement). The Act received Royal assent on 13 September 2013 and thus entered force on 13 September 2014.

Chapter 2

Legal Background

2.1 The BRCA Patents

Myriad Genetics has gene patents over two genes implicated in breast and ovarian cancer: BRCA1 and BRCA2. Mutations in either gene dramatically increase the risk of a person developing cancer.

BRCA1 was first mapped in 1990, locating it within a 15-million nucleotide range on chromosome 17.[15] Participants at the Chromosome 17 workshop in 1992 narrowed the range to within 8 million nucleotides based on further studies, but this range was still too wide to allow identification and isolation of the specific gene sequence.[16] Myriad Genetics identified the precise location of the gene, based on studies of large families ('kindreds' in the patent specification) with histories of breast and ovarian cancer. The data allowed identification of BRCA1 as a specific gene, its isolation, and so its sequencing and the production of collateral biotechnological tools such as cDNA, primers and antibodies.[17]

In 1994, Myriad and its research partners applied for patents covering the isolated DNA of the BRCA gene and its methods and tools for diagnosis. Several US patents were filed, in addition to two PCT applications covering 61 countries.[18] After grant, Myriad began serving infringement notices on other companies providing tests for breast cancer susceptibility based on the gene, reducing availability and driving up prices. Coverage of

[15] D.M. Shattuck-Eidens and others *In-vivo mutations and polymorphisms in the 17Q-linked breast and ovarian cancer susceptibility gene* (AU Patent 686,004) at pp 3–4.

[16] AU Patent 686,004. In contrast, the BRCA gene sequences are approximately 80,000 nucleotides each.

[17] AU Patent 686,004.

[18] M.H. Skolnick and others *DNA and cloning vectors for production of cloning vectors and gene expression for screening potential cancer therapy* (US Patent 5,747,282); D.M. Shattuck-Eidens and others *Linked breast and ovarian cancer susceptibility gene* (US Patent 5,693,473); D.M. Shattuck-Eidens and others *In-vivo mutations and polymorphisms in the 17Q-linked breast and ovarian cancer susceptibility gene* (PCT Patent WO/1996/005306).

the enforcement and early litigation acted as a lighting rod for criticisms of genetic patenting on ethical, economic, and policy grounds.

Over the last two years the various infringement and counterclaimed revocation proceedings reached the Full Bench of the Federal Court of Australia as well as the United States Supreme Court. While the patent has been granted in New Zealand, it has been neither enforced nor litigated here. The enforceability of the claims made in the patent is based on a wide body of patent law.

2.2 Patent Law in New Zealand

New Zealand passed its first Patent Act in 1860, providing patent protection for a term of 14 years.[19] It was been replaced several times, finally culminating in the Patents Act 1953 under which most contemporary patent jurisprudence proceeded. Last year, the Act was replaced by the Patents Act 2013, which entered into force on 13 September 2014.[20] The 2013 Act has a number of changes over its predecessors.

Patents can be awarded for new products, processes of manufacturing, process improvements, chemical compounds, electrical devices, second pharmaceutical uses for known chemicals,[21] improvements in computer technology, and "biotechnological matter."[22] To qualify for patentability, an invention must be "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies."[23] The ability of something to pass this test is referred to as its *inherent patentability*. In addition, the patentable invention must pass three tests, which determine the patent's validity: novelty, inventive step, and utility.[24]

Novelty requires that the invention does not already exist in the "prior art base".[25] The prior art base includes everything—including products, processes and information—that has been made available to the public anywhere in the world. Material may be made available by any means including written or oral communication, or use.[26]

Inventive step requires that the invention must not be obvious to a person

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19 Patents Act 1860; Intellectual Property Office New Zealand "History of intellectual Property in New Zealand" (2012) What is IP? <http://www.iponz.govt.nz/cms/what-is-ip/history-of-intellectual-property-in-new-zealand>.

20 Patents Act, above n 3.

21 So-called "swiss-type" claims, which depend on a particular form-over-substance method of framing in order to be patentable.

22 Intellectual Property Office New Zealand "What is a patent?" (2009) Patents <http://www.iponz.govt.nz/cms/patents/what-is-a-patent>.

23 Patents Act, above n 3, s 14(a).

24 Section 14(b)–(c). Part 2 of the Act covers matters of patentability in general.

25 Section 14(b)(i).

26 Section 8(1).

skilled in the art, having regard to the prior art.[27] The person is attributed with skill in the field, general knowledge and the prior art, but not with the capacity for invention. If the claimed invention would be recognised by or obvious to the person, it fails to be inventive.[28] The test is referred to as "non-obviousness" in other jurisdictions, and will be used here to avoid confusion with invention in general.[29]

Utility means that the invention must be commercially useful.[30] "Useful" is defined as having "specific, credible, and substantial utility".[31]

In addition to the tests for validity, a patent must specify the new invention in sufficient detail.[32] The specification must disclose the invention "in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art", in addition to disclosing the best method for performing it.[33] It also specifies the patent's claims: the components which delineate the scope of the patent.[34] In this manner the patent fulfils its part of the trade-off for a monopoly: teaching the world the "secret" of the invention.

The Act specifically excludes some inventions from patentability. Section 15 excludes inventions "contrary to public order or morality", while section 16 explicitly excludes human beings (and biological processes for their generation), methods of medical treatment by surgery or therapy, methods of diagnosis practised on human beings, and plant varieties which may be protected under the Plant Variety Rights Act 1987.[35] Several of these recognise the moral and ethical issues at play in biotechnology patents. The exception for human beings was recommended by the Royal Commission on Genetic Modification. Although they considered that human beings would not be patentable under existing standards (at that time, the Patent Act 1953), they thought it desirable to "put the issue beyond doubt."[36]

New Zealand is also subject to a number of international agreements regulating intellectual property rights. The Patent Cooperation Treaty established a system for the worldwide filing of patents.[37] A single application is submitted to the international body, and which forwards the applications to specified states, which perform their own examination before grant.[38]

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27 Section 14(b)(ii).

28 *Ancare New Zealand Ltd v Cyanamid of NZ Ltd* [2000] 3 NZLR 299 at para 43.

29 cf Patents 35 USC, §103 (non-obvious subject matter as a condition for patentability).

30 Patents Act, above n 3, s 14(c).

31 Section 10.

32 Section 39.

33 Section 39(b)–(c).

34 Section 39(d).

35 Section 16.

36 Thomas Eichelbaum and others *Report of the Royal Commission on Genetic Modification* (2002) at pp 284–285.

37 *Patent Cooperation Treaty* 1160 UNTS 231 (19 June 1970, entered into force 24 January 1978).

38 PC Sumpter *Intellectual property law: principles in practice*, above n 2, p 242.

The patents are then enforceable and challengeable in the respective states under their domestic law. While this does not provide a "global patent", it greatly facilitates the ability of firms to obtain patents overseas, and it is in this manner than New Zealand has a significantly larger number of foreign rather than domestically-owned patents, including gene patents.[39]

New Zealand is also a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[40] The agreement is perhaps the most dramatic effort to harmonise international intellectual property law in order to better facilitate trade. TRIPS requires that "patents shall be available for any inventions" in "all fields of technology", a strong statement on the technology-neutrality of the patent system.[41] It does however make allowance for the exceptions available in New Zealand, including order public and morality.[42] Specifically, it allows exceptions for "plants and animals" but not "micro-organisms", accepting (indeed requiring) the patentability of this aspect of biotechnology.[43] Where plants are excluded from patentability, a system must exist to protect plant varieties.[44]

Overall, TRIPS takes a broad view to patentability, which will be relevant to a New Zealand court in its determination.[45] However, the critical test for patentability in New Zealand remains the question of what is a "manner of manufacture" pursuant to the Statute of Monopolies.

2.3 The Statute of Monopolies

The Statute of Monopolies is rooted in the origins of the patent system that exists today. What would become patents began as a means of luring skilled tradespeople from the European continent into England. From the fourteenth century English monarchs issued 'letters of protection' and granted monopolies to skilled immigrants willing to work their trade locally and train local apprentices. In this manner England attracted skilled arti-

[39] Intriguingly, this imbalance is frequently referred to in the context of New Zealand being a "net importer" of innovation. This is almost undoubtably true, however it is important to distinguish between the import of innovation in terms of actual inventions used in New Zealand rather than identifying innovation with the quantity of IP protected.

[40] *Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C* 1869 UNTS 299 (15 April 1994, not yet in force).

[41] Article 27.1.

[42] Articles 27.2, 3.

[43] Article 27.3(b).

[44] Article 27.3(b). New Zealand does allow plant patents, but also provides protection for plant varieties under Plant Variety Rights Act 1987.

[45] Besides general principles of interpretation, an explicit purpose of the Patents Act 2013 is to comply with New Zealand's international obligations (s 3(a)(ii)), and this purpose must be taken into account ("The meaning of an enactment must be ascertained ... in the light of its purpose", Interpretation Act 1999, s 5(1)).

sans such as Venetian silk markers and the makers of Normandy glass.[46] At the same time, the Italian city-states were following a similar path, eventually culminating in arguably the first general patent statute in Venice in 1474.[47]

In the sixteenth century the issue of patents by the English sovereign became more regularised, with the development of bureaucratic systems of issue and appeal, and a requirement that granted monopolies be worked by the grantee.[48] However, the ability to grant monopolies was soon abused, with monopolies issued as acts of patronage and over well-established existing trades.[49] After significant controversy, debate in the House of Commons, judicial action in the *Case of Monopolies*,[50] and finally an extensive review of monopolies, the Statute of Monopolies was passed to constrain the power of the Crown.[51]

The Statute still founds the ambit of patentable subject matter today. It declared all monopoly grants illegal, with an exception of those allowed by s 6:[52]

> Provided also, and be it declared and enacted, that any declaration, before-mentioned, shall not extend to any letters patent and grants of privilege for the term of fourteen 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 patent and grants shall not use so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient. The said fourteen years to be accounted from the date of the first letters patent of grants of such privilege hereafter to be made, but that the same shall be of such force as they should be, if this act had never been made, and of none other.

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46 Justine Pila *The requirement for an invention in patent law* (Oxford University Press, 2010) at pp 15–16.

47 Protecting new and useful devices for 10 years. Prior to the issue of the Statute, Pila gives an example of an Italian monopoly grant in the issue of a monopoly to the engineer Filippo Brunelleschi in 1421, protecting a device he used to transport heavy materials over water while constructing the cupola of the Florentine Duomo (At p15).

48 At p 18. The bureaucracy continued to grow, leading to a complex and expensive maze chronicled by Charles Dickens in "A Poor Man's Tale of a Patent".

49 Including monopolies over the manufacture of salt, starch, vinegar, and playing cards (At pp 18–19).

50 *Darcy v Allin* (1602) 77 ER 1260 [*Case of Monopolies*] cited in Justine Pila *The requirement for an invention in patent law*, above n 46, p 19 n 45.

51 An Act concerning Monopolies and Dispensations with penall Lawes and the Forfeyture thereof 1624 21 Jac 1, c 3.

52 Section 6.

Effectively, the Statute sought to reform the patent system on the basis with which it continues today, protecting new innovation while preventing the grant of wide monopolies. The exclusion became the basis of patent systems across the Commonwealth: New Zealand, Australia, Canada. The United Kingdom retained the definition until it the passage of the Patents Act 1977 (UK), which brought UK law into line with that of the European Union under the European Patent Convention (EPC).[53] The quest to define what is and isn't patentable has since been a question of the ambit of s 6.

2.4 Inherent Patentability in the United States

The foundation of patents in the United States is the ability of Congress to legislate to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries", thus grounding the system in its contemporary justification.[54] Title 35 of the United States Code covers patents in the United States. Patents are granted to "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof".[55] Discoveries that are theoretical or abstract are excluded, as well as those outside the useful arts.[56] The Courts have since stated an implicit limit to the statutory definition, excluding "laws of nature, natural phenomena, and abstract ideas" and so "principles".[57]

2.5 Conclusion

The Statute of Monopolies serves as the legislative and ideological starting point of the fundamental question of what can and cannot be patented. Although the United States and the Commonwealth nations phrase their requirements differently, they each engage in the exercise of determining where, and how, to draw the line between discovery and invention.

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53 *Convention on the Grant of European Patents (European Patent Convention)* 1065 UNTS 199 (05 October 1973, entered into force 07 October 1977).

54 Constitution of the United States, art I, §8, cl 8.

55 Patents, above n 29, §101. As in the Commonwealth, the language has been more-or-less unchanged since the original Patent Act of 1793. Chisum notes that the statutory classes can be traced back to the English Statute of Monopolies (DS Chisum *Chisum on Patents* (Matthew Bender & Company, 2014), §1.01).

56 Ibid, §1.01.

57 The exclusion on nature provides a "bright line" prohibition to protect the building blocks of research and prevent the Court from having to engage in value judgements on the relative importance of different natural laws (*Mayo Collaborative Services v Prometheus Laboratories Inc* 132 S Ct 1289 (2012) at p 1301). See also DS Chisum *Chisum on Patents*, above n 55, §1.01 and the discussion of Mayo below.

Chapter 3

Scientific Background

3.1 The Cell

A cell is the fundamental unit of life, within which the processes necessary for life take place.[58] Human beings, plants, and other complex animals are multicellular, while microorganisms consist of individual cells.[59] A cell is bounded by a barrier known as a plasma membrane enclosing a fluid called the cytosol. Within the cytosol are a number of compartments known as organelles. There are two fundamental types of cell: prokaryotic and eukaryotic. Prokaryotic cells are simpler, with their DNA free-floating in the cytosol, while the DNA in eukaryotic cells is contained organelle known as the nucleus.[60] RNA is present inside and outside the nucleus. In simple terms, DNA stores the information that allows the cell to function, RNA acts as a messenger for that information, and proteins perform actual work within the cell.

3.2 Molecules of Life

DNA stands for deoxyribonucleic acid, and is the genetic material that facilitates inheritance, while RNA—ribonucleic acid—is formed as an intermediate during the production of protein from a gene.[61] Both are large molecules composed of subunits known as nucleotides, and thus may be referred to as polynucleotides.[62] Nucleotides themselves are composed of a nitrogenous base, a five-carbon sugar, and a phosphate group.[63] DNA contains four bases: cytosine (C), thymine (T), adenine (A), and guanine (G), while in

[58] Neil A Campbell and others *Campbell Biology* (Eighth edition ed, 2008) at p 94.
[59] At p 94.
[60] At p 98.
[61] At p 86.
[62] At pp 87–88.
[63] At p 88.

RNA, thymine is replaced by uracil (U).[64] The nucleotides connect through the chemical bonding of the phosphate on one nucleotide to a carbon atom within the sugar of the other, forming covalent bonds.[65] This allows long strands of nucleotides to be built up, with the sugar–phosphate bonds forming the backbone of the strand and the bases in varying orders. The end of the polynucleotide with a free (unbounded) phosphate group is know as the 5' (five-prime) end, while the sugar end is known as the 3' end.[66] The 'sequence' of the polynucleotide can then be described by listing the order of bases. For example, ATGGTC would represent a polynucleotide containing an adenine nucleotide, followed by a thymine, and so on. The sequence of bases along the polynucleotide forms the basis of the genetic code.

RNA remains in this single-stranded form. DNA, however, is formed of two polynucleic strands wound around one another in opposite directions, leading to the classic 'double helix' structure.[67] The sugar–phosphate backbone winds around the outside of the helix, while inside it each base pairs with its complement on the other strand. Adenine on one strand pairs with thymine on the other; cytosine pairs with guanine.[68] Therefore, the two strands have complementary sequences: a strand carrying the sequence 5'-ATGGTC–3' would be matched by another with sequence 3'-TACCAG–5'. It is this complementarity that allows genetic information to be passed on during cell division, as the complete sequence can be reconstructed from either strand.

DNA does not exist within the cell in long, thin, strands. Instead, it is tightly packed by complexing with various proteins which allow it to wind into a highly coiled structure. At the coarsest level, this packed structure is known as a chromosome. Different organisms have different numbers of chromosomes: human beings have 24 comprised of 22 homologous chromosomes and two sex chromosomes (designated X and Y).

3.3 The Central Dogma of Biology

The central dogma of biology is the process by which a gene becomes a protein. Genes are effectively sections of DNA along the chromosome which contain the information necessary to create a protein.[69] Most genes consist of between hundreds and thousands of individual nucleotides. A gene is

64 Neil A Campbell and others *Campbell Biology*, above n 58, p 88.

65 At p 88.

66 These numbers are derived from the number of the bonded carbon atom in the 5-carbon ring of the sugar group. The phosphate is bonded to the fifth carbon, and then bonds to the third carbon on a neighbouring nucleotide as they connect.

67 At p 88.

68 At p 88.

69 Or proteins, in more complex cases.

transformed into a protein in two stages: transcription, and translation.[70]

In transcription, an RNA strand is created based on the DNA sequence. The new RNA is effectively a "copy" of the information from the DNA, with a complementary sequence and any thymine nucleotides replaced with uracil. In prokaryotic cells this RNA, known as pre-RNA, is then 'capped' with particular nucleotides at each end to form messenger RNA, or mRNA. In eukaryotic cells the pre-RNA is both capped and 'spliced'. In splicing, certain segments of the pre-RNA are cut out of the sequence. The excised segments of the sequence are known as introns, while the segments which remain are known as exons.[71] The capped and spliced mRNA is then exported from the nucleus of the eukaryotic cell for use.

In translation, the sequence encoded in the RNA is used to produce a protein. Proteins perform an enormous number of functions within the cell, including catalysing reactions, transporting substances, receiving signals, and providing structural support.[72] Proteins are constructed of different combinations of 20 amino acids, each with a different composition. Amino acids are linked with covalent 'peptide bonds', and so chains of multiple amino acids are also known as polypeptides. The sequence of amino acids determine the protein's three-dimensional structure, and this structure determines the protein's function. The amino acid sequence of the protein is determined by the sequence of the gene.

Translation makes use of a protein complex known as the ribosome. The ribosome translates the coding sequence of mRNA into an amino acid sequence which forms a protein. Each amino acid is coded for by a three-nucleotide group in the mRNA, known as a codon. For instance, AUG (ATG in DNA) codes for the amino acid methionine. As there are 64 possible combinations of nucleotide and only 20 amino acids, some amino acids are coded for by multiple codons. In addition, some codons serve to signal the 'start' and 'stop' of the protein sequence. Each combination of nucleotides has been mapped to a amino acid, forming the genetic code.[73] To illustrate, an RNA sequence of AUG UGG UUU GGC would code for a polypeptide containing the amino acids Methionine—Tryptophan—Phenylalanine—Glycine.

To summarise, the information within a gene in a chromosome is transcribed to messenger RNA. This mRNA is then translated to produce a protein. The DNA sequence comprising the gene therefore determines the sequence of the protein produced.

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70 At p 328.
71 p 329]Ibid.
72 At p 78.
73 At pp 328–331.

3.4 Mutations

Mutations can occur in a number of ways, but all disrupt the correct sequence of a gene. Point mutations involve a single nucleotide being changed.[74] For instance, in a codon with sequence GAA (encoding a glutamine amino acid) an A to T change will result in the codon having sequence GTA and encoding the amino acid valine. More pernicious are insertions and deletions, which cause 'frameshift' mutations. To illustrate, the sequence ATG AAG TTT GGC could suffer a deletion of the fourth 'T'. As the nucleotides are translated in groups of three, the entire sequence beyond the deletion is thrown off—ATG AAG TTG GC—resulting in a completely different sequence of amino acids in the final protein.[75] Insertion of a new nucleotide has the same effect. The problem is especially pronounced if the mutations results in a premature stop codon appearing, which prevents the rest of the protein from being translated.[76]

3.5 Biotechnological Techniques

These fundamentals have been exploited in a number of ways. DNA can be extracted from the cell and separated from the proteins with which it is associated. Restriction enzymes allow the DNA to be 'cut up' by making breaks in the molecule at certain sequences. DNA can be sequenced from natural sources, and it can also be synthesised artificially from base nucleotides.

DNA may be replicated, through either cloning or the polymerase chain reaction (PCR). In cloning, a DNA sequence is inserted into a 'plasmid', a small circular DNA sequence which operates much like a mini-chromosome. The plasmid is inserted into a microorganism, such as the *E. coli* bacterium. As the microorganism replicates the target DNA is also duplicated. In PCR, the process that cells use to duplicate DNA during cell division is exploited to replicate the a target section of isolated DNA in vitro. The process requires 'primers': short sequences of single-stranded DNA (generally 15–30 nucleotides) which contain the sequences at each end of the target region.

A similar process to cloning can also be used to produce proteins. A gene in a plasmid is inserted into a microorganism, which replicates. The plasmid contains a 'promoter sequence' which facilitates transcription of the gene. The gene is thus transcribed and translated by the host cell, and the produced protein may then be extracted and purified.[77] Proteins produced

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74 Neil A Campbell and others *Campbell Biology*, above n 58, p 344.

75 The sequence of the polypeptide changes in this case from Met—Lys—Phe—Gly to Met—Lys–Leu. The principle can be illustrated in English: the sentence "the red dog ate the hat" becomes "the red ova get heh at" if the first 'D' is removed while retaining the three letter grouping (At pp 344–346).

76 At pp 344–346.

77 The earliest, and perhaps the most famous, use of this technology was Genetech

in this manner are used for research, as well as direct commercial application.

Overall, a sequenced or isolated gene is the base material of most biotechnology.

producing human insulin in E. coli.

Chapter 4

Inherent Patentability

While the statutes have remained more or less the same, the judiciary has had to apply them in the face of rapidly developing technology. Through this application, several tests have appeared.

4.1 Commonwealth

4.1.1 Boulton v Bull

One of the earliest cases to consider inherent patentability as an independent consideration to the requirements of patent eligibility was *Boulton v Bull*.[78] The case concerned a patent granted to James Watt covering his groundbreaking improvements to the Newcomen steam engine, regarded to be fundamental to the Industrial Revolution. Bull had produced imitation steam engines in violation of the patent.[79] The Court of Common Pleas faced the question of whether the patent was "good in law", and whether its specification was sufficient to support it.[80] Watt's patent, rather than specifying a machine to be built, merely described an addition to be made to existing engines, and how this would improve their efficiency. The question was therefore truly directed as to whether "the invention so described was a method or principle."[81] The Court split 2–2 in the result, however their reasoning laid the groundwork for centuries of jurists.

Three of the judges, Eyre CJ and Heath and Buller JJ, considered that in order to be valid the patent must fall within s 6. Both Heath and Buller JJ took a narrow approach to the definition. Justice Heath reduced manufac-

[78] *Boulton and Watt v Bull* [1795] 126 ER 651.

[79] At p 652.

[80] At p 653. The case was somewhat complicated by the fact that Parliament had passed a specific Act extending the patent for an additional 25 years due to its slow time-to-market, in a move that contemporary pharmaceutical companies would surely love to see repeated.

[81] Justine Pila *The requirement for an invention in patent law*, above n 46, p 29.

ture to two classes: machinery, and substances formed by chemical processes where the thing produced is "a vendible substance" which preserves "no permanent form".[82] The Statute was introduced for the benefit of trade, and thus patentable manufactures should be vendible. Justice Buller framed his conception of invention in similar terms, interpreting manufacture as "descriptive either of the practice of making a thing by art, or of the thing when made."[83] Recognising that patent protection would be "impossible ... [to apply] to the invention of mere unorganized principles of science" his Honour would require the principle to be "carried ... into effect and [produce] some new substance."[84]

Lord Chief Justice Eyre took a much more expansive view of the ambit of s 6. The Chief Justice thought that the word "manufacture" applied "not only to things made, but to the practice of making, to principles carried into practice in a new manner, to new results of principles carried into practice."[85] His Honour reasoned that, while Watt had not invented a new machine, he had also gone further than discovering an "abstract notion."[86] He determined a practical means to reduce the fuel requirement of a steam engine. This "principle ... embodied and connected with corporeal substances" fell within the Statute.[87] Method patents should be allowed, because otherwise advantageous improvements could not be patentable, being neither a new substance nor a new mechanism. Overall, Eyre CJ identified several categories under his head of manufacture: new compositions of things,[88] new mechanical inventions, new artificial manners of operating ... new processes in any art producing effects 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. Watt's means of improving the engine was patentable by this standard. Justice Rooke agreed with Eyre CJ, but he relied on the "spirit" of the Statute rather than attempting to interpret its meaning.[89]

The full Court was agreed on one thing: the unpatentability of principles. Their disagreement lay as to where principle ended and product began. Overall, the two sides of the Court established two conceptions that continued through to the twentieth century: on one hand, an invention as a vendible and tangible product; on the other manner of manufacture as extending from the practical application of principle.

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82 *Boulton and Watt v Bull*, above n 78, at pp 660–661.
83 At p 655.
84 At p 663.
85 At p 666.
86 At p 667.
87 At p 667.
88 "[M]anufactures in the most ordinary sense of the word." (At p 666 per Eyre CJ).
89 Justine Pila *The requirement for an invention in patent law*, above n 46, p 40.

4.1.2 Re GEC's Application

This former conception was taken up by Morton J in *Re GEC's Application*. Justice Morton established 'Morton's Rule': that a process or method is a method of manufacture if it results in the production of some vendible product, improves or restores to its former condition a vendible product or has the effect of preserving from deterioration some vendible product to which it is applied.

4.1.3 NRDC

One hundred and fifty years later, and on the other side of the world, *National Research Development Council v Commissioner of Patents*[90] picked up the mantle of principle.

The case concerned an appeal from a decision of the Commissioner of Patents that claims within a patent for a selective herbicide were invalid. The claimed methods allowed the eradication of certain kinds of weeds growing alongside broad-leafed leguminous crops, which had been expensive and difficult to eliminate. However, the method did not create any new physical product: it merely killed the weeds.

The central question in the case was whether the process of killing weeds fell within the terms of s 6 of the Statute of Monopolies. The arguments of the parties followed the lines of the Court in *Boulton*: the Commissioner argued that the Statute required a vendible product, while the appellants argued for that a method might be patentable wherever a useful physical result is produced.

The Court began from the position that s 6 requirement is exclusive in Australian law: "invention means any manner of new manufacture the subject of letters patent ... within s 6 of the Statute of Monopolies" and nothing else.[91] However, the requirement was defined not by carrying forward the text of the Statute of Monopolies, but by reference to its established scope. It is this scope that must be determined in order to decide whether a claimed process is for an invention, and thus the inquiry is "not into the meaning of a word so much as into the breadth of the concept" laid out by the Statute of Monopolies.[92] On this basis, the word "manufacture" in the Patents Act 1952 merely referred to the ambit of inventions covered by the Statute of Monopolies and not to tangible goods that might normally be considered manufactured on its plain meaning. The exercise is not interpretative, rather the question is "is this a proper subject of letters patent

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90 *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67, (1959) 102 CLR 252.

91 At p 268. The use in the Patents Act 1952 (Cth) is the same as that in New Zealand.

92 *National Research Development Corporation v Commissioner of Patents*, above n 90, at p 269.

according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?"

These principles had yet to be determined. After a survey of prior authority, the Court concluded that attempts to define manufacture are "bound to fail", given that the purpose of patents and the original Statute of Monopolies was to "encourage national development in a field which ... was seen to be excitingly unpredictable."[93] It dismissed Morton J's rules as having a narrowing effect, except to the extent that the word product could be understood as covering "every end produced", and the vendible as "pointing only to utility".[94] This conclusion lead the Court to outline a significantly wider test, albeit one forecasted in *Boulton*: a method may be a manner of manufacture where it results in an "artificially created state of affairs" with resultant economic advantage.[95] The requirement for an artificial state of affairs takes regard of the human contribution, while the Court saw economic advantage, or a gain in utility, as ensuring the process belonged to "a useful art as distinct from a fine art."[96]

On this test, the appellant's method was patentable. Application of the invention resulted in an observable change in the growth of a crop versus the weeds: artificial, and brought about by human action. The "cultivation of the soil for the production of its fruits" being a fundamental to mankind, and the artificial effect providing "a remarkable advantage" in doing so, clearly indicated an economic advantage over a world without the innovation.[97]

The Court addressed two other issues worth consideration. The use of the chemicals as a selective herbicide was obvious once it was discovered that they react in such a way as to kill weeds and not crops. There was thus a question of whether the discovery itself could provide the invention necessary for a patent, or whether invention needed to exist in the application of the discovered principle. The question was especially pertinent given that the chemicals used in the process already existed; their selective effect on weeds and legumes was not, however, known. This lead to the related question of whether a new use for an old product could be patented.

The Court answered the latter question by distinguishing between kinds of new uses. If a product is completely characterised, then a new use merely parallels old uses and so the new purpose "lacks the quality of inventiveness".[98] On the other hand, if the new use exploits a previously unknown quality of the product then invention may be present and the new use may be patentable, "provided a practical method of doing so is disclosed and

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93 *National Research Development Corporation v Commissioner of Patents*, above n 90, at p 271.
94 At pp 271, 276.
95 At p 277.
96 At p 275.
97 At p 277.
98 At p 262.

that the process comes within the concept of ... manner of manufacture". In this case, the claim is for more than the new use: the new use plus a discovery.

This conclusion points to the answer to the larger question. The Court considered that divide between discovery and invention "is not precise enough to be other than misleading..."[99] Rather than seeking an inventive step between the discovery and claimed manufacture, the whole process must be considered, and only one inventive step needs to be made beyond the prior limits of the art. The discovery in the instant case was that certain, previously known, chemicals interacted with enzymes in weeds in such a way that the chemicals would kill the weeds while leaving untouched other plants. Once this discovery was made, the fact that the use of the chemicals flowed naturally was irrelevant. The weed killing process was "distinguished from previously known processes by a feature the suggestion of which ... involved a step plainly inventive."[100] The method was "arrived at only by an exercise of scientific ingenuity, based upon knowledge and applied in experimental research".[101] The identification of an unknown use was sufficient to found invention.

NRDC is considered a watershed case in Commonwealth patent jurisprudence.[102] Its articulation of the approach to be used when interpreting contemporary use of the Statute of Monopolies is laudable. However, in further widening the scope and abstracting the principles of patentability the case also set the stage its overextension.

4.2 United States of America

The United States faced similar challenges in applying tests of patentability as the Commonwealth, albeit differently framed.[103] The Courts were also called upon to decide issues concerning living organisms earlier.

4.2.1 Funk Brothers v Kalo Inoculant Co

Arguably the first biotechnology case occurred in 1948, in *Funk Brothers Seed Co v Kalo Inoculant Co.*[104] The appellants had claimed an inoculant for plants, consisting of a combination of nitrogen-fixing bacteria.[105] By associating with plant roots and fixing nitrogen from the air, the bacteria

[99] At p 264.
[100] At p 265.
[101] At p 268.
[102] In addition to the comprehensive and understandable interpretation of the existing law, the case no doubt benefits from the compelling style of its key passages.
[103] See Chapter 1.3, above.
[104] *Funk Bros Seed Co v Kalo Inoculant Co* 333 US 127 (1948).
[105] At p 128. This description is based on the illustrative claim identified by the Court.

increased nitrogen available to the plants and thus supported growth. Different species of the bacteria were effective for different species of plant, and their use individually had "long been known".[106] While the bacteria would be easier to apply in combination, past attempts to provide a mixed formula were ineffective. The patentee, Bond, discovered particular strains of each species of bacteria which did not affect one anthers' growth and were thus effective in combination. He isolated these strains and produced a mixed culture capable of effectively inoculating multiple species of plant.[107] In proceedings for infringement of the patent, the Supreme Court was tasked with determining whether such a product was patentable, deciding that it was not in a 7–2 split.

Justice Douglas, writing for the Court, found that the composition was not patentable. The invention did nothing more than leverage a discovery of nature in a straightforward manner, and did not provide any additional utility over that of the bacteria individually.

His Honour recognised that the inhibitory effects of various strains of bacteria were not Bond's work:[108]

> "The qualities of these bacteria, like the heat of the sun ... are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."

His Honour drew a line between invention and discovery as requiring the "application of the law of nature to a new and useful end."[109] The Court did not consider that Bond's combination of species met this test, falling "short of invention within the meaning of the patent statutes."[110] The discovery of the non-inhibitory properties of the bacteria was clearly unpatentable, however the application of this discovery was no more than "an advance in the packaging of the inoculants."[111] The individual bacteria gained no new function or utility through their combination into a single inoculant; their natural functioning was not improved.

The product itself was useful, in that it was easier for a farmer to apply, and for distributors to stock. However, this did not mean that its production met "the requirements of invention". Justice Douglas considered that once the discovery was made, the state of the art was "a simple step", and not inventive. His Honour could not identify invention unless it was borrowed "from the discovery of the natural principle itself."[112] This directly

[106] *Funk Bros Seed Co v Kalo Inoculant Co*, above n 104, at p 129.
[107] At p 130.
[108] At p 130.
[109] At p 130.
[110] At p 131.
[111] At p 131.
[112] At p 132.

conflicts with the approach of the High Court of Australia's conclusion that suggesting a new use may found invention. As the product claim did not disclose an invention, it was not patentable.

Justice Frankfurter issued an opinion concurring in the result, but based on the breadth and uncertainty of the claim to composition rather than the natural source of its utility.[113] His Honour considered that terms such as "the work of nature" served only to confuse arguments as to patentability.[114] He considered that the multi-service applicability of the new bacterial formulation could found invention as a new property not present in the natural state of each individual strain. This argument appears to have originated in a broader weariness of denying all claims for compositions. Instead, his Honour denied the claim on the basis that, while a single composition of bacterial strains may have been claimable, the plaintiffs sought to claim all compositions demonstrating the non-inhibitory and useful effects. The dissent agreed with Frankfurter J as to the nature claims, but also found the the claim was specific enough for patentability based on a lower standard for specificity for plant-based claims.[115]

4.2.2 Diamond v Chakrabarty

Thirty-two years after *Funk Brothers*, *Diamond v Chakrabarty* posed a similar challenge but lead to a different result. The case concerned a patent issued for a species of bacteria which had been genetically modified to be able to degrade certain components of crude oil, a capability possessed by no naturally occurring bacteria.[116] Its utility lay in the ability of the bacteria to be used in cleaning up oil spills. The patent claimed the processes used to create the bacteria, the inoculum product, and the bacteria themselves. The claim to the bacteria was denied by the patent examiner on the basis that they were products of nature, and that living things were unpatentable. The Patent Office Board of Appeals upheld the latter determination, but considered that the bacteria were not products of nature due to the genetic modification. After several appeals, the case reached the Supreme Court.[117]

The Court had a single question before it: whether the claimed microorganism constituted a manufacture of composition of matter under §101 of the US patent legislation.[118] The case did not involve other patentability requirements, such as novelty or non-obviousness.[119]

As a starting point, Burger J, writing for the Court, noted that both "compositions of matter" and "manufactures" were to be given a wide scope

[113] At p 132.
[114] At p 134.
[115] At p 135.
[116] *Diamond v Chakrabarty* 447 US 303 (1980) (Diamond).
[117] At p 306.
[118] Patents, above n 29 §101.
[119] *Diamond v Chakrabarty*, above n 116, at p 307.

in terms of §101. The former had been construed as "all compositions of two or more substances" and the latter "the production of articles for use ... by giving to these materials new forms, qualities, properties or combinations".[120]

Despite this broad scope, Burger J was careful to recognise the limits of patentability: particularly that "[t]he laws of nature, physical phenomena, and abstract ideas" were not patentable.[121] Citing *Funk Brothers*, the Judge affirmed that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter" and, likewise, "Einstein could not have patented his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity."[122] On this basis the new bacteria were clearly patentable, given that they were not naturally occurring but rather "a product of human ingenuity having a distinctive name, character and use."[123] In comparison to *Funk Brothers*, the patent covered a completely new strain of bacteria, "with markedly different characteristics from any found in nature" and "having the potential for significant utility". The invention was the result of the inventor's handiwork, rather than that of nature.[124]

This use of "markedly different", has adopted by subsequent courts as the test applied by Burger J. With respect, however, the phrase sits as a component of a wider analysis. The bacterial strain had new and useful behaviour which previously did not exist: the strain was 'new' in the sense of identity, possessed different characteristics (the ability to digest multiple hydrocarbons), and these combined to provide a previously non-existent benefit. His Honour did not focus on the extent of the differences between the claimed strain and its natural predecessor, but rather the connection between the work done by the inventor and the resulting difference in character and effect.

The Judge ruled out an argument that the Plant Patent Act and Plant Variety Protection Act, both of which provided protection for species of cultivated plant, indicated a legislative intention that livings things generally were excluded from IP protection.[125] His Honour noted that plants were previously considered excluded from patent protection because, even when artificially bred, it was considered that the resultant plants were still products of nature; and that plant species were not considered amenable to

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120 *Diamond v Chakrabarty*, above n 116, at p 308 citing *Shell Development Co v Watson* 149 F Supp 279 (1957) and *American Fruit Growers Inc v Brogdex Co* 283 US 1 (1931) respectively.

121 *Diamond v Chakrabarty*, above n 116, at p 309.

122 At p 309.

123 At p 309 citing *Hartranft v Wiegmann* 121 US 609 (1887) at p 611 (internal quotation marks removed).

124 *Diamond v Chakrabarty*, above n 116, at p 310.

125 At p 311.

written description.[126] The Acts were passed in order to make protectable the product of natural process, albeit aided by man. The Judge concluded that Congress did not intend to draw a line between living and inanimate things, but between "products of nature, living or not, and human-made inventions."[127]

He also refused to engage with an argument that the modified organisms should not be patentable due to the potential harms of their future development.[128] The Court was ill-equipped to consider such broad issues, and while patentability of the subject matter might alter the pace of development it was unlikely to prevent it, or its risks, entirely. Congress could act to limit patentability, but the principles of the law supported it.[129]

The dissent, penned by Brennan J, was focused on the argument that life was not patentable and that the ambit of patentability should not be extended without legislative action. Accepting the petitioners' argument, Brennan J considered that the two plant-related Acts would not have been necessary had living organisms been patentable generally.[130] With respect, his Honour misunderstood the reason for excluding plants. Applying the principles of the majority, plants would be unpatentable not by virtue of being alive, but because a new plant is generated by the action of natural processes: evolution, sexual recombination, and so forth. While a farmer could put considerable work into characterising plants and selecting those with the most desirable qualities, the underlying change in utility was due to the operation of nature and not the inventive hand of mankind. The first Act especially, was passed at a time when it was not possible to interfere with plant function outside of the mechanisms that existed and operated without human intervention. In suggesting that the artificially modified bacteria at issue was identical to these plants, Brennan J misunderstands both the nature of the intervention and the argument of the majority.

The majority in *Diamond v Chakrabarty* supported a test for patentability that considers the effect of human intervention on a natural object, rather than the object's vitality or lack thereof. This test is fundamentally the same as that in *Funk Brothers*, but was met on the facts. Where the patentee in *Funk Brothers* did not produce any new result by his actions, the intervention in this case actively produced a useful effect.

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126 At pp 311–312. The Plant Patent Act explicitly made patentable plants invented or discovered and reproduced, while the Plant Variety Protection Act provided sui generis protection to "any novel variety of sexually reproduced plant" along the lines of the New Zealand Plant Variety Rights Act and the UPOV treaty.

127 At p 313.

128 That "genetic research ... may spread pollution and disease ... result in the loss of genetic diversity, and ... depreciate the value of human life." (At p 316).

129 At p 318.

130 At p 320.

4.2.3 Mayo v Prometheus

Mayo v Prometheus was concerned with patents covering methods of determining the proper dosage of autoimmune drugs. The claims covered an application of natural laws which describe the relationship between concentrations of blood metabolites and the efficacy of the drugs. Justice Breyer delivered the Court's opinion, finding that the claimed processes had not transformed the natural laws into patentable applications. After establishing the exemption of natural phenomena, mental processes and abstract concepts from patentability, Breyer J noted that all inventions must, at some level, make use of them.[131]

The key discovery of the patentee, Prometheus, was the specific concentrations of various metabolites in the blood that would indicate that the drug dosage was either too high or too low for a particular patient. This was particularly important for the thiopurine drugs at issue, as the required dosage varies based on the patient's metabolism, making it difficult to determine the correct dose a priori. It was already known that the metabolite concentration related to drug efficacy, however the specific correlation was unknown. The patentees determined the exact correlation, and claimed the process of testing.[132] Although human action was required for the correlation to manifest—the administration of the drug—the relationship was a natural process and thus a patent describing it was merely setting forth a natural law.[133] The question before the Court was whether the patents added enough to this relationship for their claims to be patent-eligible applications of this law, rather than mere recitations of it.[134]

Justice Breyer stated that for a process describing a law of nature must have "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[135] At its most transparent, a patent may not simply describe a law and then add "apply it". The patents at issue went further than this, detailing a process involving administering the drug, determining the metabolite level, and then outlining the law as it related to the result of those actions. Both the administration and determination steps were already known in the art,

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131 "For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena or abstract ideas." (*Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at p 1293.

132 Claim 1 of this patent was considered representative by the Court: "[a] method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder." E.G. Seidman and Y. Théorêt *Method of treating IBD/Crohn's disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage* (US Patent 6,355,623) quoted in *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at p 1295. Prometheus filed two patents covering the method.

133 At p 1297.

134 At p 1297.

135 At p 1297.

and in use in clinical settings. These steps in combination added nothing more than when considered separately. Overall, the Court found that the claims merely "inform a relevant audience about certain laws of nature", that "additional steps consist of well understood, routine, conventional activity..." and that they "add nothing significant beyond the sum of their parts taken separately."[136]

The Court considered two prior cases concerning the application of natural laws in industrial processes: *Diehr* and *Flook*. *Diehr* related to a process for rubber moulding integrated the Arrhenius equation[137] into a system which determined when rubber could be removed from a press after continuously monitoring. The process was patentable.[138] In *Flook*, on the other hand, alarm limits on an industrial monitoring process were updated based on the output of a proprietary formula. Despite the framing of the claims, the Court in that case found that the patent merely claimed the formula for updating the limit. While the claimed process in *Diehr* monopolised only a specific and tangible application of the equation, the process in *Flook* monopolised the equation itself, without provided an advance upon it.[139] This distinction provides another means of analysing patentability: by looking at the scope of the monopoly granted. If the monopoly covers all possible uses of the discovery or idea, then the claim not for invention but for nature. Overall, the Court formed the view that "simply appending conventional steps ... to laws of nature" could not make them patentable.[140]

These considerations are relevant to the patentability of isolated DNA. While isolation provides some secondary utility in that it is more immediately useable, its primary utility is in the natural sequence (parallel to the 'natural law' embodied in a formula). The method of isolating a gene once its sequence is known is well known and commonly practised in the art. Thus by claiming the isolated gene a patentee is effectively 'applying' the knowledge of its natural sequence. Furthermore, at the present state of the art, isolation is required in order to pursue most other uses of the gene. As a result, a claim to the isolated gene forecloses on, if not all, a significant number of uses of the natural sequence.

The Court was also concerned with inhibiting further discovery or innovation by closing off future use of the laws of nature, citing *Morse* as an example: the broad claim made could have effectively precluded any new or other means of electronic communication.[141] Laws of nature are "the ba-

[136] At p 1298.

[137] Relating the temperature of a reaction to the reaction's rate.

[138] *Diamond v Diehr* 450 US 175 (1981) at pp 177–187 cited in *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at pp 1298–1299.

[139] *Parker v Flook* 437 US 584 (1978) at pp 586–594 cited in *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at p 1299.

[140] At p 1300.

[141] The claim being for "the use of the motive power of the electric or galvanic current ... for making or printing intelligible characters ... at any distances." *O'Reilly v*

sic tools of scientific and technological work", allowing their monopolisation "will inhibit future innovation premised upon them", and this is danger "becomes acute" when the claimed process merely applies the natural law.[142] While analysing metabolites is a reasonably specific task, patenting of the formula could prevent others from improving the process, using better methods of metabolite analysis, or taking advantage of other new physiological discoveries.

Intriguingly, the US Government as amicus curiae argued that "virtually any step beyond a statement of a law of nature" should be inherently patentable, with the eligibility requirements of novelty and non-obviousness serving to further protect future research interests.[143] This arguably contrasts to the Government's approach in *Myriad*, where it argued against the patentability of isolated DNA (although not cDNA).[144] Insofar as isolated DNA is at least minimally different from the natural substance, it would seem that the argument for eligibility-related rather than inherent exclusion would also apply there. Regardless, the Court considered that this approach would make the nature exception "a dead letter".[145]

While *Mayo* concerned claims for a process rather than a product or composition of matter, its analysis of has broader applicability. The dual prongs of testing for invention beyond the discovery and assessing the scope of the monopoly are no doubt the reason that the Supreme Court remanded the first Myriad appeal it heard to the Federal Circuit for reconsideration in the light of *Mayo*.

Morse 56 US 62 (1854) at p 86 cited in *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at p 1301.

142 At p 1301.

143 At p 1303.

144 See discussion on *Association for Molecular Pathology v Myriad Genetics Inc*, above n 1, below.

145 *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57, at p 1303.

Chapter 5

Myriad Claims: The BRCA Genes

5.1 United States: Myriad

5.1.1 Introduction

In *Association for Molecular Pathology v Myriad Genetics Inc* the United States Supreme Court unanimously decided to disallow patents over isolated DNA as being a product of nature.[146] They did, however, allow cDNA patents on the basis that cDNA is not naturally occurring. While the initial case challenged multiple claims, only the challenge to claims for isolated DNA was sustained beyond the first appeal.

At first instance, the District Court granted summary judgement to the petitioners, invalidating Myriad's claims on the basis that they covered products of nature. This included the claims for cDNA.[147] This decision was reversed by the Federal Circuit,[148] and certiorari was granted by the Supreme Court, which remanded the case back to the Federal Circuit for reconsideration in the light of its decision in *Mayo v Prometheus*.[149] At all levels the question before the Court was whether isolated DNA is patentable per 35 USC §101.[150]

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146 *Association for Molecular Pathology v Myriad Genetics Inc*, above n 1.

147 At p 7.

148 *Association for Molecular Pathology v United States Patent and Trademark Office* 653 F 3d 1329 (2011).

149 *Association for Molecular Pathology v Myriad Genetics Inc* 132 S Ct 1794 (2012); *Mayo Collaborative Services v Prometheus Laboratories Inc*, above n 57.

150 Stating that "whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement thereof, may obtain a patent ..." The scope of the section is a matter of delineating the boundary between the words of the section and the implicit exceptions for abstract ideas and laws of nature recognised by the Courts. See Chapter 1.3, above.

5.1.2 Federal Circuit: Introduction

The Court of Appeals for the Federal Circuit split 2–1 in favour of allowing patents on isolated DNA. It also reversed the District Court on its decision to invalidate methods claimed for screening potential cancer therapeutics. It upheld the District Court's judgements that methods involving the mere comparison or analysis of DNA sequences for the presence of mutations were ineligible due to their abstract nature.[151] The lead judgement was written by Lourie J, with Moore J concurring in part and a dissent from Bryson J. The central question was whether the isolation DNA is an inventive act.[152]

Three conceptions of DNA were provided by the parties to the case. Myriad argued that isolated DNA should be patentable given that it does not exist in nature and has uses which native DNA does not. The plaintiffs argued that "a product of nature is not patent eligible even if ... it has undergone some highly useful change" and instead that it must have "a distinctive name, character and use, making it markedly different from the natural product".[153] They submitted that isolated DNA was not "markedly different" because it retained the same nucleotide sequence.

The US Government in its amicus brief forged a middle ground, suggesting a "magic microscope" test.[154] The test would look at whether a hypothetical microscope capable of seeing into a live cell would be able to locate the claimed molecule. In the case of DNA it could, as the DNA sequence exists in the human genome, however cDNA molecules representing the exonic sequence do not and so could be claimed.[155]

5.1.3 Federal Circuit: Lourie J

Judge Lourie's reasoning as to the patentability of DNA is straightforward: isolated DNA molecules are not found in nature and are man-made, therefore they do not fall into the product of nature exception and are patentable as compositions of matter.[156] He put significant weight on the breaking of covalent bonds between the isolated gene and the rest of the chromosome, and the corresponding structural and chemical difference in the DNA molecule.

The Judge interpreted *Funk Brothers* and *Chakrabarty* as stating that inventions may be distinguished by "a change in the claimed composition's

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[151] *Association for Molecular Pathology v United States Patent and Trademark Office* 689 F 3d 1303 (2012) at p 1309.

[152] Compare to D'Arcy, which accepted that isolation is not inventive but considered the discovery of the gene location sufficient (*D'Arcy v Myriad Genetics Inc*, above n 1, discussed above).

[153] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 151, at p 1326 (internal quotation marks removed).

[154] At p 1326.

[155] At p 1326.

[156] At p 1325.

identity" from its natural state.[157] This distinction was found in the "distinctive chemical structure and identity"[158] of isolated DNA, with a significantly smaller size than a full chromosomal DNA molecule and severed covalent bonds.[159] He also noted the difference between the situation of isolated DNA, which undergoes a chemical change, and mere purification which "may or may not qualify" for patentability. Based on this analysis, the Judge also held that cDNA, being even further manipulated from the native DNA and not existing in any form in the cell, was also patentable.[160]

Judge Lourie considered that by focusing on the identical gene sequence between isolated and genomic DNA the plaintiffs were focusing on a single similarity rather than a number of differences, albeit conceding that the similarity was "key".[161] His position was that "genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than by their functions", noting that many different chemicals can have the same function.[162] With respect, this statement is inadequate, especially given the framing and scope of Myriad's gene claims. The claims are designed to cover different materials—different lengths of isolated DNA with different chemical properties—but connected in nature and claimed by Myriad by their common sequences and thus common utility.

The Judge also dismissed the Government's "magic microscope" approach as not recognising the difference between the in-situ sequence of the DNA and "an isolated DNA molecule that is in hand and usable."[163] Again, this framing of the issues fails to correctly connect the utility of the invention to what is claimed. While an isolated molecule is required for BRCA diagnosis in reality, the magic microscope would be equally as effective at providing the benefit by virtue of being able to identify the predisposing gene mutations identified by Myriad. The benefits of the discovery flow from what the DNA stands for, not from the DNA molecule itself. This conception provides a more principled view of why a molecule may be patent ineligible without falling into the problems Lourie J identifies with the "magic microscope" approach.[164]

Overall, Judge Lourie's reductionist approach appears to have excluded

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157 As discussed above, a preferable interpretation of these cases is that the distinction arises where a change in the natural product results in new utility.

158 Presumably referring to chemical name in this usage.

159 At p 1327

160 At p 1329.

161 At p 1330.

162 At p 1330.

163 At p 1331.

164 Such as being able to make any portion of any complex molecule patent ineligible merely by hypothesising that it could be looked at with the magic microscope. Non-DNA complex molecules, such as pharmaceuticals or dyes, will be useful by virtue of their absolute chemical structure rather than the informational content of their composition.

a key piece of the analysis, allowing a small structural difference to found patentability while overlooking the need, not just for a change from nature, but for a new and inventive utility. Isolation of DNA is not new, and its benefits are well understood in the art. Thus the benefit of the BRCA sequence must accrue not from its isolation per se, but from the information encoded within it.

Applying Lourie J's conception of the test would result in what is effectively a de minimis approach, where the smallest change from the natural form is sufficient to found patentability.

5.1.4 Federal Circuit: Moore J

Judge Moore concurred in the result but provided her own reasons. Despite the characterisation of the Federal Court of Australia,[165] the Judge did not agree with Lourie J with regard to isolated DNA, providing a, with respect, more nuanced judgement. She did not consider that breaking the covalent bonds was sufficient for patentability, but rather concurred with the decision based on a combination of the structural change and other factors.

The Judge concluded that the critical question was whether the isolated DNA had "markedly different characteristics" with potential for "significant utility".[166] As cDNA does not exist in vivo, and has additional utility in that it can be used to produce protein in recombinant systems, she found the test met.[167] While cDNA is "inspired by nature" in the sense that it is derived from naturally occurring mRNA, it is different in both its backbone structure, stability, and sequence.[168]

She next analysed isolated DNA with regard to both claims for short forms of DNA, such as primers and hybrid probes, and the full isolated gene. With regard to the former, Her Honour determined that the chemical change in combination with the "different and beneficial utility" which they provide is sufficient for patentability. She found support for her argument in the metaphors of Bryson J's dissent, comparing a 15 nucleotide primer to a baseball bat, whittled from the wood of a tree and deserving of a patent due to the determination by man "of the parts to be retained and ... to be discarded."[169]

With regard to the full isolated gene, Moore J was less convinced that

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[165] See discussion below.

[166] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 151, at p 1340.

[167] At p 1340.

[168] However, this latter assertion is not strictly true, given that double-stranded cDNA will possess both the complement of the original mRNA and its mirror: the original sequence. In informational terms the content is identical.

[169] At p 1342 per Moore J, quoting Bryson J. The whittled bat was "a product with a function entirely different from that of the raw material from which it was obtained" (At p 1353).

the chemical change provided any additional utility. Instead, it served "the same ends devised by nature, namely to act as a gene encoding a protein sequence."[170] However, she decided that the full genes warranted patentability due to the PTO's longstanding practice of issuing patents for genes, and the significant property interests involved.[171]

5.1.5 Federal Circuit: Bryson J

Judge Bryson agreed with the majority on all heads of argument bar the patentability of isolated DNA. He saw Myriad's discovery of the location of the BRCA genes as "unpatentable fact", and the patent of the isolated DNA as invalid and with the potential for substantial adverse effects on research and treatment. The Judge considered the isolation of genomic DNA as analogous to the extraction of a new mineral found in the earth, or removal of a plant from the wild.[172] He did not see as compelling the breaking of covalent bonds considered important by Lourie J, noting that "there is no magic to a chemical bond" that could not be considered relevant to other molecular forces.[173]

Myriad's claims were "not defined by any particular chemical formula", but identified by their genetic sequence. Claim 1 of the '282 patent covers a dramatic array of different molecules, from a cDNA molecule to the full native gene 60 times its size.[174] The molecules are linked by one "unifying characteristic": each codes for the BRCA1 protein.[175] While this argument was criticised by Lourie J as directed at breadth rather than inherent patentability, it certainly applies to the latter. By claiming a dramatic diversity of molecules, Myriad implicitly confirmed the irrelevance of their specific molecular structure to the useful effect they hoped to monopolise.

In contrast to the majority opinion, Bryson J considered the relevant test to be based on the similarity in structure between the claim and nature, and the similarity in utility, rather than the more abstract test of "marked dif-

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[170] At p 1343.

[171] Judge Moore notes that the Amgen patent covering an isolated gene for human erythropoetin was responsible for billions of dollars in sales in 1997, and considered that patentees might have reliance interests in the validity of their gene patents (At p 1344).

[172] As in *Chakrabarty* (At p 1350).

[173] At p 1351. This factual argument ties in to the discussion above regarding the broad and structurally-agnostic nature of Myriad's patent claims. While isolated DNA differs in its covalent bonds, all DNA varies in terms of its chemical properties including ionisation state, methylation, histone complexing, ubiquitination and so on. To take Lourie J's position further, one could argue that merely denaturing DNA (separating the strands, generally by heating) causes a chemical change by breaking the hydrogen bonding between strands, and therefore results in a marked difference and so a patentable product.

[174] At p 1352.

[175] At p 1352.

ference".[176] In this case, the structural differences of the isolated molecules were irrelevant to their functioning and thus utility. Applying *Mayo*, he argued that a patent involving a product of nature should require "more than merely incidental changes" to the natural product.[177] He considered the focus on the information of the gene—its one similarity per the majority—as appropriate given that it was the "critical aspect" of the molecules. He also noted the lack of invention in the process of isolation, possibly suggesting that he was seeking "inventive step" beyond Myriad's discovery of the gene location.

5.1.6 Federal Circuit: Conclusion

Overall, the decision of the Federal Circuit was characterised by the difference between framing the isolated DNA as a dramatically changed molecule or a slightly-reformed informational sequence. The majority took a wide view of the *Chakrabarty* test of "marked difference", apparently looking for any difference capable of distinguishing the natural product from that claimed in the patent. In contrast, Bryson J focused on the purpose for which the product was altered from its natural state and whether its utility was improved by virtue of the change. Judge Moore, in her concurring opinion, hinted at this same distinction: a focus on how the manipulation of the inventor has affected the new utility of the product.

Although the majority of the Court held that isolated DNA was patentable, the tests for inherent patentability which they developed split differently. Judge Lourie was alone in identifying patentability in the chemical structural change, while Moore and Bryson JJ took a wider view, seeking both a marked difference and a new use.

5.1.7 Supreme Court

The Supreme Court recognised that Myriad's contribution to the art was in precisely locating the BRCA genes within the human genome: the nucleotides existed in order before Myriad found them and were not created or altered by them.[178] Critically, the Court stated that "separating that gene from its surrounding genetic material is not an act of invention", and that "[g]roundbreaking, innovative or even brilliant discovery does not by itself satisfy the §101 inquiry."[179] As the discovery that several species of bacteria did not inhibit one other could not found invention in *Funk Brothers*, Myriad's discovery of the location of the BRCA genes was not enough to render the isolated DNA patent eligible.

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[176] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 151, at p 1354.

[177] At p 1355.

[178] *Association for Molecular Pathology v Myriad Genetics Inc*, above n 1, at p12.

[179] At p 12.

In apparent agreement with Bryson J, and contrary to Lourie J, the Court identified that the claims necessarily focused on sequence over structure, given that otherwise an infringer could merely isolate DNA with minor chemical differences, such as a single additional nucleotide.[180] The Court found that the claims were rather concerned "primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule."[181]

Overall, the Court determined that isolated DNA was not patentable on the basis that its isolation was not an act of invention, and that the value of the claims was in the informational content of the isolated gene and not its chemical structure.

However, they took a different approach to claims directed to cDNA, finding that "the lab technician unquestionably creates something new when cDNA is made. [It] retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived."[182] Complementary DNA does not exist in nature, is synthetically created and is therefore patentable.[183] The Court excluded genes which do not contain introns, and so have the same native and cDNA sequences.[184]

This distinction highlights the fine line of invention. However, based on it does not seem to survive scrutiny. While cDNA differs from native and isolated DNA in its sequence, it is very similar to the mRNA naturally present in a cell, differing only in that it is the complement of the sequence, uracil (U) nucleotides are replaced with thymine (T) and the transformation of the ribose sugar backbone to deoxyribose. The mRNA molecule only contains exon sequence. These changes could be grounds for distinguishing cDNA from isolated DNA, but they indicate that the Supreme Court diverged from Lourie J's reasoning in extent rather than in kind. Both molecules differ structurally from similar native molecules, but cDNA is structurally

[180] At p 15. While it was not mentioned by the Supreme Court, this conception of the claims is supported by Myriad's patents, which describe the polynucleotide compositions (DNA and RNA) of the invention as including compositions which have been "chemically or biochemically modified" as would be "readily appreciated by those skilled in the art". The patents give examples of these modifications, including labelling, methylation, nucleotide substitution, and linkage modification, any of which arguably has a more significant effect on the structure of a polynucleotide qua chemical than the two covalent bonds present in native DNA. See M.H. Skolnick and others *DNA and cloning vectors for production of cloning vectors and gene expression for screening potential cancer therapy* (US Patent 5,747,282) at col 19 l 50 for an example of the definition.

[181] *Association for Molecular Pathology v Myriad Genetics Inc*, above n 1, at p 15.

[182] At p 17.

[183] This is not strictly true, as the reverse transcriptase used to create cDNA is a natural protein. However, the Court considered that the "unusual and rare" possibility of a BRCA cDNA molecule being produced naturally did not preclude patenting one created "synthetically through human ingenuity" (At p 16, fn 8).

[184] At p 17.

further from mRNA than isolated DNA is from DNA within the genome. On the other hand, cDNA contains identical informational content to naturally occurring mRNA, as isolated DNA contains identical information to its native gene.

Another means of differentiating the two results would be to look at the process used to produce the molecules. Complementary DNA is 'synthetic' in the sense that it is produced in vitro by reverse transcriptase using mRNA as a template: effectively assembled from individual nucleotides. The specific nucleotide molecules are not linked in sequence until the mRNA is reverse-transcribed. In comparison, DNA can be isolated while preserving the sequence of linked nucleotide molecules, merely breaking the bonds linking either end of the sequence to the rest of the DNA. While the cDNA is 'created', the isolated DNA is extracted. However, this is not necessarily so. DNA may be 'isolated' through various cloning techniques[185] or PCR.[186] In either case the target DNA is amplified in an artificial system, and while the sequence and informational content is identical to the source the component nucleotides are not identical to those present in the source. The resultant product would fall within Myriad's claims, however it would arguably be as synthetically derived as cDNA.

The rationale for differentiating between DNA and cDNA appears unclear. It can perhaps best be explained by the Court making an implicit distinction between DNA and RNA as genetic material, with DNA being considered more central to life and thus a more natural phenomenon. The Court's informational explanation for the non-patentability of DNA is perhaps the most compelling, but it does not account for the different treatment of DNA and cDNA. It should be noted that while Myriad's US patents claim only isolated DNA, its PCT applications and thus patents in New Zealand and Australia claim isolated nucleic acids, including DNA and RNA. "Markedly different" test from *Chakrabarty.*

5.1.8 Conclusion

In summary, two approaches to patentability were taken in the US *Myriad* litigation. First, an identity test focused on the differences rather than the similarities between the natural product and the invention. Secondly, the test applied by Moore and Bryson JJ, which asks what change was made to the natural law, and how that change is reflected in the claimed utility. It was this latter test that was adopted, albeit in different words, by the Supreme Court.

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[185] Where the DNA is amplified in a microbiological system such as a Yeast Artificial Chromosome.

[186] The source DNA used by Myriad for its BRCA identification was amplified in these systems.

5.2 Australia: D'Arcy v Myriad Genetics Inc

5.2.1 Introduction

The Full Bench of the Australian Federal Court came to the opposite conclusion of the Supreme Court, upholding the decision from the Federal Court. As in the US, the Australian case was brought by a group of medical industry bodies as well as private plaintiffs: in Australia, Cancer Voices Australia and Yvonne D'Arcy, a woman suffering from breast cancer.

Only Ms D'Arcy appealed to the full Federal Bench. The Full Court affirmed the decision of Nicholas J below, holding that isolated DNA falls within the ambit of a 'manner of manufacture' per s 6 of the Statute of Monopolies, and therefore is patentable subject matter under the Patents Act.[187]

The Court fundamentally adopted the approach taken by Lourie J in the Federal Circuit, basing its reasoning on the patent's claims to isolated nucleic acids—DNA or RNA—and that these isolated nucleic acids would have different structural and functional properties to the equivalent nucleic acid sequence in the genome and within a cell. By isolating the nucleic acids Myriad created an artificial state of affairs with economic value: the claimed, isolated, nucleic acids do not exist in nature, and their isolation allows new uses, including the identification of mutations in the sequence and thus the diagnosis of breast cancer. It was not in dispute that locating the BRCA1 gene within a previously-identified region of chromosome 17 was inventive.

Myriad's claim to nucleic acids in the Australian patent was slightly different from that in the United States. They claimed: > An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:l one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

In addition, two more dependent claims specifically focused on DNA coding for the BRCA1 polypeptide with mutations. The patent defines "isolated" as meaning separated from cellular components including, among other things, other human genome sequences.

5.2.2 Australian Analysis

In order to determine whether the claims fell within the Statute of Monopolies, the Court laid out what they considered as the principles of s 6:[188]

- Boundaries must encompass development of science and technology, and human ingenuity—they are not decided based on the technology

[187] Patents Act 1990 (Cth).

[188] *D'Arcy v Myriad Genetics Inc*, above n 1, at p 6.

of a particular age.

- We require human intervention creating an artificial state of affairs that has a discernible effect.
- Utility, ingenuity, and invention inform the context of patentability analysis, and assist in describing claims to processes or products: new principles carried into practice.
- 'Laws of nature' are not a helpful analysis.
- The distinction between discovery of scientific principle and deployment to a useful end is real.

While *NRDC* was focused on methods, the reasoning was applied to products in *Grant v Commissioner of Patents.*[189] The Court in *Grant* stated that a product in which the "new and useful effect" required by *NRDC* can be observed, and that this thing "may be any physical phenomenon in which the effect ... may be observed."[190]

Ms D'Arcy claimed that *NRDC* required an artificial effect for patentability, and that the effect of isolation was not artificial "in the relevant sense". The nucleotide sequence of the isolated product is as in nature, and isolation does not change it. The Court disagreed, noting that *NRDC* requires an artificial state of affairs, not an effect, and that this state of affairs was brought about by the isolation of the gene itself.

The Court also considered Australia's statutory and public history. In 2004 the Australian Law Reform Commission (ALRC) issued a report on gene patenting.[191] The report did not recommend legislating the exclusion of isolated genes from patentability. In addition to stating that the time for excluding isolated biological materials had "long since passed", the report laid out several policy reasons militating against legislative action. These included potential disadvantage to the Australian biotechnology industry, failure to deliver anticipated benefits due to the probably patentability of slightly-altered sequences such as cDNA, the protection of the eligibility requirements and the difficulty of justifying special treatment for genetic technology.[192] As a result of the report, the Australian Government did not amend the Patents Act to exclude genetic materials, although it did pass other reforms.[193]

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189 *D'Arcy v Myriad Genetics Inc*, above n 1, at p 28.

190 *Grant v Commissioner of Patents* (2006) 154 FCR 62 cited in *D'Arcy v Myriad Genetics Inc*, above n 1, at p 28.

191 It is perhaps worth noting that Kenny J sat on the inquiry in her role as part-time Commissioner, while Bennett J sits on the gene patenting advisory committee.

192 See the Court's summary of the ALRC's conclusions (At para 158) based on Australian Law Reform Commission *Genes and Ingenuity: Gene Patenting and Human Health* (Report 99, June 2004) at s 6.

193 Such as an experimental use defence.

The Australian Parliament's consideration and dismissal of legislative changes to gene patenting certainly militate toward their patentability. However, several of the grounds identified by the Court would be less relevant given a judicial determination against inherent patentability of isolated DNA. The global background has changed and thus the effect on the biotechnology industry would be smaller, especially given that a decision against patentability would have aligned Australia with the United States post-*Myriad*. Furthermore, rather than providing a specific exception for genetic technology, the Court would merely have been applying an existing legal principle.

5.2.3 Consideration of Association for Molecular Pathologists

The Court considered the reasoning of the US courts in *Association for Molecular Pathology*, at both the Federal Circuit and in the Supreme Court. In its analysis of the Federal Circuit's decision, the Court was in general agreement with Lourie J. In addition, it focused particularly on the statements made by Moore J which supported its vision of isolated DNA as being structurally different to genomic. With respect, however, this focus lead to a misrepresentation of Moore J's views. It characterised her position as considering that isolated DNA must be created by man and that the isolated molecules are different, with "potentially confounding sequences" removed.[194] To the extent that her Honour was merely describing the science behind isolation, however, her comments are irrelevant to her decision on inherent patentability; and to the extent her Honour was discussing inherent patentability her comments related particularly to primers and other crafted or designed polynucleotide sequences, not to the full isolated gene.[195]

The Court noted that Bryson J focused on "the similarity in structure and the similarity in utility" between isolated and native DNA, versus Lourie and Moore who focused on the differences.[196]

Unsurprisingly, the Court considered the majority judgement of Lourie and Moore JJ "consistent with patent law, and persuasive."[197] It should be noted that Moore J's conclusion on the issue of the isolated gene was based upon the PTO's prior conduct and property rights, rather than her Honours

[194] *D'Arcy v Myriad Genetics Inc*, above n 1, at paras 146–147.

[195] See *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 151, at pp 1340–1342. It is worth noting that the Australian patent at issue did not claim all 15-nucleotide sequences within the gene, although it did claim specific primers, arguably making its claim and Moore J's reasoning as to the difference in patentability between whole genes and primers even more relevant to the Australian case. (It does go into this a p 36 of the judgement, but the initial characterisation is still misleading).

[196] *D'Arcy v Myriad Genetics Inc*, above n 1, at para 153.

[197] At para 155.

principled analysis of inherent patentability.

5.2.4 Encode versus Code For

The Court summarised the parties' different characterisations of the issue, which were broadly similar to the divergent characterisations of Lourie and Bryson JJ in the Federal Circuit. Ms D'Arcy saw isolated nucleic acids as not materially different to the nucleic acids in the cell. She submitted that the isolated gene was not an artificial effect per *NRDC* "in the relevant sense" because its coding did not change, and that *NRDC* requires that a product produce an effect. This can perhaps be interpreted as suggesting that to the extent the isolated gene would produce an effect, its (relevant and useful) effect would be identical to that of the gene in-situ and thus not an artificial state of affairs per *NRDC*. The Court rejected this conception, noting that *NRDC* does apply to products alone and that the relevant question is "whether [the product] consists of an artificially created state of affairs, not whether it produces ... an artificial effect".[198] The state of affairs was the isolated nucleic acid itself, which brings benefit to mankind in its application of the underlying discovery. The benefit evidences the "application of [a natural law] to a new and useful purpose."[199]

The Court dealt with an issue which was clearly in contention at trial: whether there is a semantic difference between "encode" and "code for" in terms of the language used in the patent's claims and therefore the meaning of "isolated nucleic acid coding for" in the claims. Ms D'Arcy submitted that the meanings are the same, and that Myriad's definition of "encode" within the patent is equally applicable to its use of "code for".[200] Her goal was apparently to draw on the inclusion of "native state" in the definition of encode to argue that the function of the gene—coding for a product—does not change when it is isolated.

The Court distinguished the terms, stating that while "code for" means "carry the code" in a passive sense, "encode" means to "actually produce the polypeptide."[201] Whereas the former is passive, "having the potential to produce the polypeptide", the latter is active as in the living cell the machinery for transcription and translation exists and thus mRNA and the encoded polypeptide can actually be produced. According to the Court, this

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198 [para 166]*D'Arcy v Myriad Genetics Inc*, above n 1.

199 At para 169 citing *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* [1998] HCA 19, [1998] 194 CLR 171.

200 The patent states that a polynucleotide encodes a polypeptide if "in its native state or when manipulated by methods well known to those skilled in the art, it can be transcribed and/or translated to produce the mRNA for and/or the polypeptide or a fragment thereof..." (D.M. Shattuck-Eidens and others *In-vivo mutations and polymorphisms in the 17Q-linked breast and ovarian cancer susceptibility gene* (AU Patent 686,004) at p 26 l 7).

201 [para 175]*D'Arcy v Myriad Genetics Inc*, above n 1.

"distinguishes between the polynucleotide in the native state, transcribed and translated without the intervention of man, and the [isolated] polynucleotide, which needs to be manipulated to do so.[202] On this definition, "[t]he isolated nucleic acid ... cannot [encode] the polypeptide without further intervention."[203]

With respect, this distinction does not make sense. Myriad's definition of "encode" in the patent explicitly states that an encoding polynucleotide may be manipulated by those skilled in the art in order to be transcribed and translated. This manipulation could easily take the form of in vitro transcription (if the isolated polynucleotide contained a promoter sequence) or the insertion of the sequence into an expression vector and its expression in a suitable host. In this way, even isolated DNA could be said to "encode" a protein. At a higher level, the semantic distinction still does not hold. Informational sequences, such as the sequences in the patent itself, can be converted in the abstract into the corresponding RNA and amino acid sequences. To an extent these amino acid sequences can be modelled to determine the likely structure of the resultant protein.[204] Both isolated and native DNA are acted upon by other entities in order to achieve any effect. The Court's suggestion that isolated DNA "cannot code" appears artificial.

The Court also noted that the genomic DNA does not code for "fragments" of the BRCA1 polypeptide and that Ms D'Arcy did not challenge the claims for more specific elements of the gene, such as the sequences used for primers. This is perhaps a stronger point, echoing the argument of Moore J in *Association for Molecular Pathology* that human intervention to pare down the gene to a smaller sequence with a defined object is more worthy of invention than isolation of the full gene.[205] With regard to the first claim, Ms D'Arcy argued that the claimed polynucleotides could code for as much as the complete gene, including introns, or as little five codons (fifteen nucleotides). In the former case, the sole difference in the molecule would be its isolation from the chromosome. The Court stated that arguing that the latter polynucleotides were unpatentable conflicted with Ms D'Arcy's acceptance of the patentability of primers. However, the two can be reconciled by again referencing the arguments of Moore and Bryson JJ. Whereas primers are 'designed' by a person to achieve a specific effect and thus benefit, any random fifteen-nucleotide sequence will likely have no additional utility beyond its correspondence to the native sequence.

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202 para [175]Ibid.

203 The Court uses "code for" where encode is inserted, however this usage would conflict with the definition given by the Court directly above the quoted phrase. This transposition implicitly highlights the tenuous nature of the distinction being drawn.

204 Note the identified putative zinc finger domains in the Myriad patent.

205 At paras 178–179.

5.2.5 Decision

The core of the Court's decision related to the question of whether isolated nucleic acid and a naturally occurring gene are the same thing. The question as actually phrased by the Court asks whether they are *precisely* the same thing. The Court dismissed the question of whether "the isolation of a naturally occurring substance by conventional means can constitute an invention" as confusing inventive step with a focus on the subject of the claim and whether it is a manner of manufacture.[206] Ms D'Arcy claimed that isolation was insufficient for artificiality, and that the "substance" of the claim needed to be analysed for the extent of its departure from an abstract idea or principle.[207] She submitted that the isolated polynucleotide was "the same thing in a different place" and that isolation was routine. She focused on the correspondence between the genomic and isolated sequences

The Court highlighted two differences between the forms: the isolated polynucleotide "can be manipulated and utilised in ways that the other cannot", and the isolated gene would have "different beginnings and different ends".[208] It clarified that the patent does not claim the genetic code but an isolated nucleic acid: a physical molecule. The genetic code is "a template for dynamic processes that result in the production of the polypeptide" and not "a static sequence".[209] The Court did not consider that material derived from naturally occurring material was necessarily unpatentable in terms of the decision in *NRDC*.[210]

The Court stated that the comparison required by claim one was of a nucleic acid sequence to the sequence described in SEQ ID No:1—a cDNA and thus artificial sequence. This is not strictly true, however. The comparison is whether a given nucleic acid codes for the same polypeptide as the cDNA. The cDNA merely acts as a shorthand means of specifying the amino acid sequence of the protein, and the comparison is really to a natural sequence—the amino acid sequence of the native protein—and suffices to include a full native gene comprising both introns and exons.

The Court also stated that the gene could not be analysed for cancer-causing mutations without isolation, and that the likelihood of cancer could not be determined without the information provided by the patent. It saw this as "[reflecting] a difference between the gene in its natural state and after isolation."[211]

It did not consider that *NRDC* was to be applied narrowly. Discoveries and ideas were not patentable; but manners of manufacture were.[212] The

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206 *D'Arcy v Myriad Genetics Inc*, above n 1, at para 185.
207 Based in Bilski and Mayo v Prometheus; At para 186.
208 At para 191.
209 At para 194.
210 [At para 196.
211 At para 200.
212 At para 207.

fundamental test laid out by *NRDC* was that it is "sufficient for a product to result in an artificially created state of affairs, leading to an economically useful result." In addition, new uses for old substances may be valid wherever new information exists beyond the previously-known properties of the substance.[213]

The Federal Court found it difficult to reconcile their reasoning with that of the US Supreme Court and their analysis of the decision in *Chakrabarty*. It saw the chemical changes as "critically important" in terms of forming a new, useful, product, and it considered that these changes qualified as a "marked difference" in terms of *Chakrabarty*. It did not, however, consider the marked difference test as involving a connection to utility; rather it appeared to consider it either a matter of (minimal) extent or a binary decision equivalent to the artificiality requirement of *NRDC*.

Overall, the Court considered the claimed nucleic acid as a molecule, removed from the genome and the cell and unable be transcribed or translated. The molecule contains the code for a particular polypeptide, identified by comparison to the information identified by Myriad, and this had economic value.[214] As an artificially created state of affairs providing economic benefit the Court considered isolated nucleic acid inherently patentable.[215]

[213] Referring to Lord Buckmaster's statement that, while new uses for old substances may not be patented if the process is "nothing but" a new use." (*Re BA's Application* (1915) 32 RPC 348).

[214] *D'Arcy v Myriad Genetics Inc*, above n 1, at para 210.

[215] At para 216–219.

Chapter 6

Conclusion

The different results in Australia and the United States highlight both different framing of the facts of the cases, and different understandings of what and how the line between nature and invention should be drawn.

Several different tests emerge of the reasoning of the Courts. First, artificiality: a binary test of artificiality epitomised by the neat phrasing of the High Court of Australia, an "artificial effect". The slightest intervention of man moves a work into the realm of patentability. While the test includes "benefit", the interpretation in both the High Court and the Federal Court merely requires that something new is possible. However, this new capability may be both already known, and obvious to one who knows of the discovery. The "bundle approach" of *NRDC* allows the initial discovery to qualify an invention for patentability.

Secondly, identity: the change-of-structure test articulated by Lourie J in the Federal Circuit supported by the Australian Federal Court. The test carries a slightly higher bar than artificiality. Judge Lourie would have considered a molecule with different chemical properties, but the same covalent bonds, as not qualifying. This moves the extent of a necessary difference further out from the state of nature, however it does not move it far. To the extent that metaphysics does not have an answer to what identity is, it may be impossible to use. Fundamentally, the test focuses on a single difference even in the face of strong similarities related to the core value of the invention.

Thirdly, "marked difference". Both the Full Court in Australia and Lourie J analysed *Chakrabarty* as having a pure test of extent: if the difference is "marked", then the innovation is patentable. However, it is never stated where on this spectrum a difference becomes marked. As in identity test, the distinction becomes a case of framing more than principle.

Finally, the test adopted by the Supreme Court and Moore JJ (in relation to isolated DNA) and Bryson JJ in the Federal Circuit. The test connects the change between discovery and application with the purpose for

which the patent is claimed. The test limits the scope of a monopoly to that which is deserved, by a legitimate application of principle to a concrete problem. It does not conflate the validity requirements of a patent with inherent patentability, but serves to drawn a line between the monopolisation of a principle and the beneficial reward for genuine innovation. It is my submission that this approach is best way to determine inherent patentability, and thus draw the bounds between the work of nature, and the innovation of man.

Chapter 7

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