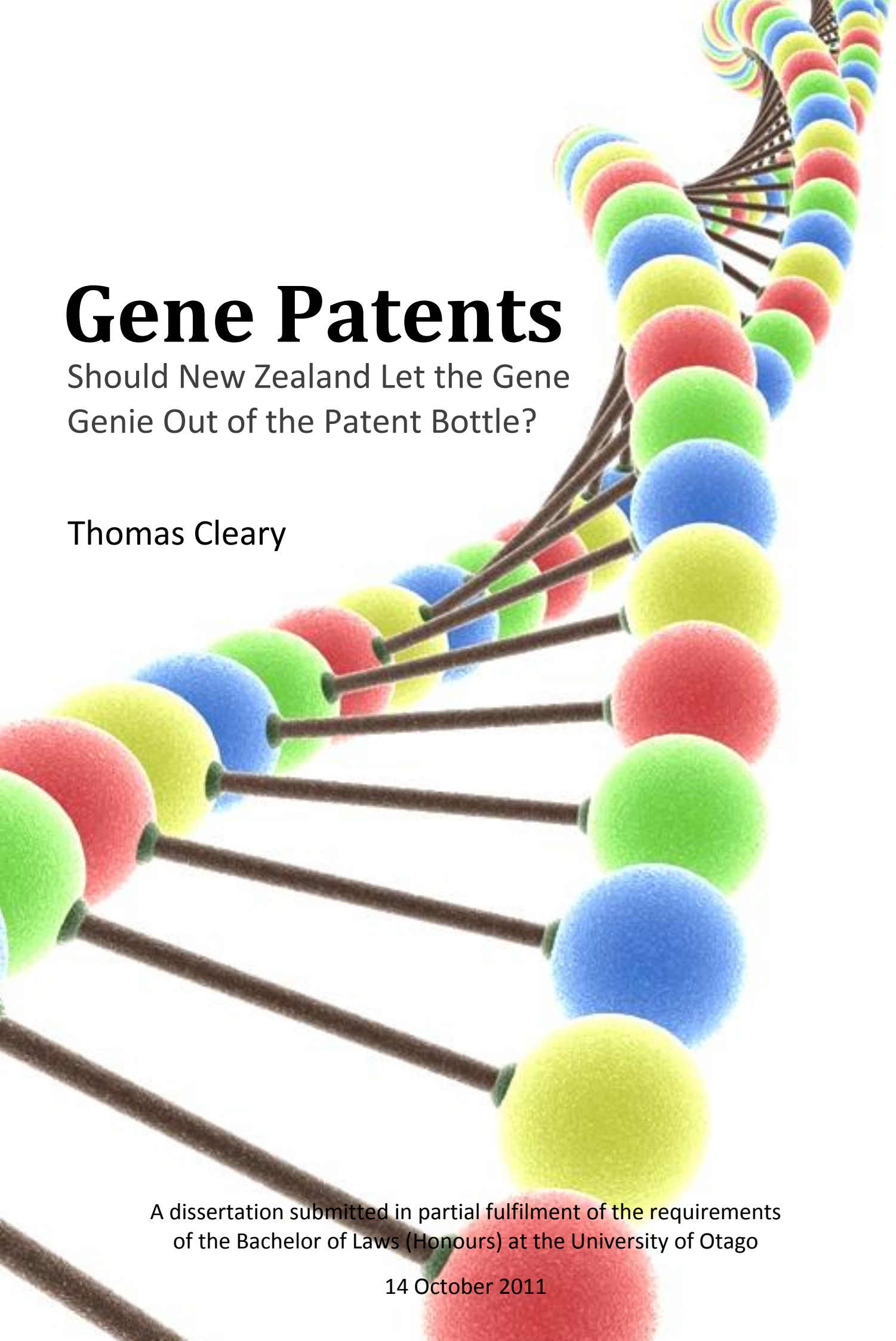

Gene Patents

Should New Zealand Let the Gene Genie Out of the Patent Bottle?

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Introduction

Gene patents push the boundaries of the patent system in New Zealand. They raise questions about the ability of the concept of "manner of manufacture" to determine what an invention is[1] and pose unique ethical, social and economic issues.[2] Gene patents illustrate the difficulties that a patent system faces in accommodating new knowledge-based technologies. While the number of patents granted over genetic material might be in decline in New Zealand,[3] gene patents are a useful barometer of the ongoing strength and relevance of the patent system.[4]

The problems raised by patenting genetic material have not gone unrecognised. In 2002, the Ministry of Economic Development (MED) examined these issues and recommended a substantial overhaul of the Patents Act 1953.[5] Many of these recommendations have been incorporated into the Patents Bill[6] currently before Parliament. However, it is not clear if the proposed legislation will properly address some of the unique problems posed by gene patents.

The issues posed by gene patenting are not unique to New Zealand. Internationally, gene patenting has been the subject of several reports about whether genetic material should be patented.[7] Further, several legislatures have moved to either ban or restrict the scope of patenting genetic material.[8] Gene patents have been the subject of extensive litigation in the United States, the United Kingdom, and Europe. Of particular importance is the recent

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1 The definition of "invention" ins s 2 of the Patents Act 1953 includes the subject matter being a "manner of manufacture".

2 Timothy Caulfield and Yann Joly "Human Gene Patents and Genetic Testing" in G Patrinos and W Ansorge (eds) *Molecular Diagnostics* (2nd ed, Elseiver, London, 2009) 527 at 529.

3 See Appendix 1.

4 Justine Pila "Bound Futures: Patent Law and Modern Biotechnology" (2003) 9 BUJ Sci & Tech L 326 at 357.

5 Ministry of Economic Development *Review of the Patents Act 1953: Boundaries to Patentability* (2002); Organisation for Economic Co-Operation and Development *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002) at 7.

6 Patents Bill 2008 (235-2).

7 Organisation for Economic Co-Operation and Development, above n 5; Nuffield Council on Bioethics *The Ethics of Patenting DNA* (Nuffield Council on Bioethics, London, 2002); Secretary's Advisory Committee on Genetics, Health, and Society "Gene Patents and Licensing Practics and Their Impact on Patient Access to Genetic Tests" (Bethesda, 2010); Senate Community Affairs Committee "Gene Patents" (Canberra, 2010).

8 In Australia the Patent Amendment (Human Genes and Biological Materials) Bill 2010 was introduced into Australian Senate on 24 Nov 2010 which would ban human gene patents. In the United States, a bi-partisan Bill, the Genomic Research and Accessibility Act (HR 977), was introduced to prohibit the patenting of human genetic material, however it did not get passed.

Court of Appeal of the Federal Circuit's decision in *The Association for Molecular Pathology v United States Patent and Trademark Office*[9] (*AMP*) that some genetic material is patentable subject matter. *AMP* illustrates some of the difficulties that gene patenting poses for the courts in applying legal concepts to new technologies like genetics.

In this dissertation I explore whether gene patents can and ought to be patented in New Zealand. Chapter 1 explains what genes are, why genes are patented, and why these patents are controversial. Chapter 2 examines whether genetic material is patentable in New Zealand under the Patents Act 1953 and what problems patenting genetic material exposes in the current patent system. Chapter 3 assesses whether the proposed changes in the Patents Bill will rectify the issues exposed by gene patents and whether further legislative changes are necessary. I conclude that gene patents often do not satisfy the requirements for patentability, that patents over genetic material continue to be granted because of flaws in the current patent system. Further, I argue that the proposed changes remedy most of these problems but fail to provide a mechanism for the broader public policy and moral concerns relating to granting a patent monopoly to be addressed.

[9] *Association for Molecular Pathology v United States Patent and Trademark Office* 99 USPQ2d 1398; 2011 WL 3211513 (Fed Cir 2011).

Chapter One | Genetics and the Gene Patenting Controversy

1.1 What are Genes?

Genes are composed of deoxyribonucleic acid (DNA). DNA is a complex molecule that is made up of subunits called nucleotides.[10] Each nucleotide consists of a sugar-phosphate backbone and of one of four bases: adenine (A), guanine (G), thymine (T), and cytosine (T). These nucleotides are covalently bonded to each other to form linear strands called a "polynucleotide". In DNA, two polynucleotides are intertwined with the bases facing each other to form a double helix as shown in figure 1.[11] In this double helix, each base on one of the polynucleotides normally only interacts with another specific base on the opposite polynucleotide. Adenine base pairs to thymine and guanine base pairs with cytosine based on the number of hydrogen bonds (two and three respectively) each base pair can form. In other words, each polynucleotide is the mirror image of the other. This is called complementary base pairing which is an exceptionally useful property as will be explained later.

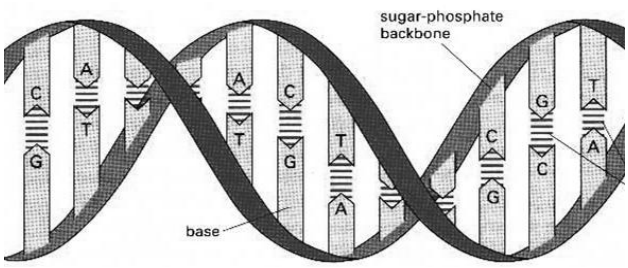

Fig. 1. Structure of DNA

DNA's main function is encoding the information required to make proteins which are the building block of a cell. DNA encodes this information in the sequence of bases on each polynucleotide. In order for a protein to be made, the DNA helix has to be unwound and the DNA transcribed into messenger ribonucleic acid (mRNA). [12] Transcription uses complementary base pairing to produce mRNA with the complementary sequence to the transcribed single-strand of DNA with the minor change of replacing thymine (T) with uracil (U). This initial mRNA is called pre-mRNA. Following this transcription, non-coding sections,

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[10] See generally Donald Voet and Judith G Voet *Biochemistry* (3rd ed, John Wiley & Sons, Hoboken, 2004) ch 29.

[11] James D Watson and Francis Crick "Molecular Structure of Nucleic Acids: A Structure of Deoxyribose Nucelic Acid" (1953) 171 Nature 737.

[12] See generally Donald Voet and Judith G Voet, above n 10, ch 31.

called introns, of this pre-mRNA are excised leaving only the protein-coding sections, called exons. This mRNA is then translated into a protein.[13]

In translation, three bases of the mRNA code for one amino acid. These three bases are called a codon. Each codon is associated with one amino acid. However, because there are 64 codons and 20 naturally occurring amino acids, multiple codons code for a single amino acid.[14] For example the amino acid serine is coded for by the codons UCU, UCC, UCA, UUG, AGU, and AGC. Once the amino acid is translated from its codon it is then joined to other amino acids sequentially translated from the mRNA to form a linear polymer which after some modifications forms a protein. Because multiple codons code for a single amino acid, the amino acid sequence (the protein) can be deduced from the DNA sequence, but the DNA sequence cannot be deduced from the amino acid sequence. This is termed the degeneracy of the code.

Traditionally a "gene" has been defined as the linear sequence of DNA that codes for a particular protein.[15] Originally it was assumed that one gene codes for one protein. However this model is inaccurate. Following the sequencing of the human genome it is now estimated that there are only 20,500 genes in the human genome.[16] However there are over 500,000 proteins in the human body.[17] This is explained by recent studies showing that a gene (defined by the protein produced) can comprise of several DNA sequences interspersed within the genome and even occasionally overlapping with other coding sequences.[18] Further, there are multiple regulatory elements that control when or how some or all of these sequences are translated.[19] Thus a gene is more properly defined as the sequences of DNA coding for a particular protein in the presence or absence of certain regulators.

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13 See generally Donald Voet and Judith G Voet, above n 10, ch 32.

14 Three codons code for a stop signal and do not code for an amino acid.

15 Helen Pearson "Genetics: What is a Gene?" (2006) 441 Nature 398.

16 International Human Genome Consortium "Finishing the Euchromatic Sequence of the Human Genome" (2004) 431 Nature 931.

17 Michele Clamp "Distinguishin Protein-Coding and Noncoding Genes in the Human Genome" (2007) 104 PNAS 19428; Leslie A Pray "Eukaryotic Genome Complexity" (2008) 1 Nature <www.nature.com>.

18 Elizabeth Pennisi "DNA Study Forces Rethink of What it Means to be a Gene" (2007) 317 Science 1556.

19 Ibid.

1.2 The Biotechnology Industry and Gene Patents

The modern biotechnology industry is built on exploring and exploiting the properties of DNA. The rapid developments in the understanding of how DNA codes for proteins and is regulated has forced the biotechnology industry to evolve. Rebecca Eisenberg identifies three broad generations in the evolution of how the biotechnology industry uses DNA.[20] The first generation is based on the concept that a gene codes for a protein and focuses on identifying a gene and then using it to produce a desired protein using recombinant DNA technology. The second generation is based on the idea that certain variations in the sequence of gene correlates with a certain disease[21] and uses this correlation to diagnose the existence or a predisposition to that disease. Finally, the third generation uses automated sequencing to identify genetic material in order to control or manipulate DNA for medical and research purposes.

This evolution of the uses of genetic material has allowed the biotechnology industry to grow. This is especially true in New Zealand where the industry is continuing to grow and is an important contributor to the New Zealand economy, employing more than 2,200 people and providing between 300 and 400 million dollars per year to the New Zealand economy.[22] Despite its relatively small size,[23] in the international arena the New Zealand biotechnology industry punches above its weight and has been ranked among the top ten countries for biotechnological innovation.[24]

One of the most important foundations for this biotechnology industry is gene patents.[25] The growth of the biotechnology industry has corresponded to an explosion in patents over

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[20] Rebecca S Eisenberg "Why the Gene Patenting Controversy Persists" (2002) 77 Acad Med 1381 at 1381-2.

[21] Certain mutations in the genetic sequence can change the amino acid sequence which subsequently can affect the functionality of the protein. However, not all changes in the genetic sequence do affect the amino acid sequence (because of the degeneracy of the genetic code) and even those that do, do not always affect the functionality of the protein.

[22] LEX Consulting *New Zealand Biotechnology Industry Growth Report 2008* (NZBio, 2008) at 7.

[23] Compared to the biotechnology sector in the United States which supports 310,000 jobs and generates approximately $67 Billion USD per year: Robert M Cook-Deegan and Stephen J McCormack "Intellectual Property: Patents, Secrecy and DNA" (2001) 293 Science 217.

[24] New Zealand is ranked 6th equal with 4 other countries: Yali Friedman "Worldview Scorecard" (2009) *Scientific American Worldview,* 36.

[25] Alphra Green "The Impact of Patents on New Zealand Genetic Services and Research Sectors" in Mark Heneghan (ed) *Genes, Society and the Future* (Brookers, Wellington, 2009) 152 at 170; Timothy Caulfield and Yann Joly, above n 2, at 527; Robert M Cook-Deegan and Stephen J McCormack, above n 23, 217; M

genetic material, especially over human genes. It is estimated that over 20% of human genes are patented.[26] Gene patents can be grouped into four main categories based on their uses, namely:[27]

1. Producing therapeutic proteins. Here a certain sequence of DNA or mRNA that codes for a specific protein like insulin is inserted into an organism to produce that protein.
2. Diagnosing disease. For example comparing a sequence of a gene to specific variations of that sequence that are associated with disease as is done in breast cancer tests.
3. Gene therapy. For example using an engineered section of DNA to either replace or regulate a mutated sequence that is causing a disease.
4. Research tools. For example expressed sequence tags (ESTs) can be used to locate a gene. Alternatively fragments of DNA or RNA can be used to control other DNA in replication or transcription.

These four main types of gene patents exploit different properties of DNA. Using genetic material to produce proteins and in diagnosis utilises the information ability of DNA to code for a protein or to know what protein is coded for. However in using DNA as research tools or in gene therapy, DNA is used primarily for its ability to replace, regulate or bind to other sections of DNA. These different uses correspond to the developments in genetics described earlier and are relevant to the debate about what subject matter is being patented.

1.3 Why Are Gene Patents Controversial?

It is now over 30 years since the first gene patent was granted.[28] While the practice of gene patenting "began without public debate,"[29] it has become one of the most contentious issues in patent law. There are three main reasons for this. The first is that many people

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Stott and J Valentine "Impact of Gene Patenting on R&D and Commerce" (2003) 21 Nature Biotech 729; FM Scherer "The Economics of Human Gene Patents" (2002) 77 Acad Med 1348.

[26] Robert Cook-Deegan "Gene Patents" in Mary Crowley (ed) *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Camapaigns* (The Hastings Center, Garrison, 2008) at 80.

[27] Nuffield Council on Bioethics , above n 7, at 47-48.

[28] The first gene patent was granted in 1980: Robert Cook-Deegan, above n 26, at 70.

[29] David Koepsell *Who Owns You? The Corporate Gold Rush to Patent Your Genes* (Wiley-Blackwell, Chichester, 2009) at 40.

view patents over genetic material, especially human genes, as being morally wrong. Some argue that patenting genetic material is tantamount to owning it and so these patents treat people as commodities and are a form of "modern slavery."[30] However, this view relies on the idea that a person's genetics is the equivalent to their identity,[31] and confuses the nature of a patent, which is merely an exclusory right, with ownership. What is more, these patents only attach to DNA once isolated from a person and so do not amount to ownership of the person.[32] Others argue that gene patents restricts their autonomy in being able to test for their predisposition to a genetic disease which is contrary to their human rights and therefore immoral.[33] The problem with this consequential moral argument is that many restrictions are placed on autonomy in life. This restriction of autonomy is purely monetary rather than absolute. However, in some cases where a patentee charges high fees or where there are multiple patents involved in a diagnostic test this monetary restriction can become so high that it is an absolute restriction for most people.

Secondly, it is argued that gene patents hamper scientific endeavour and restrict access to medical diagnosis and therefore granting patents over genetic material is not in society's best interests. Proponents of this view argue that genetic material is a public resource, like air or water, and so a "commons" unable to be owned by individuals.[34] While this commons argument relies on genetic exceptionalism dismissed above,[35] these concerns about the effects of granting a monopoly over genetic material are valid.

The third reason that gene patents are controversial is that gene patenting often push the boundaries of patent law and so it is likely that there are patents granted over genetic material that are invalid. The realisation of this is is extremely likely in New Zealand with the

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30 Senator Brownback quoted in Timothy A Caulfield "From Human Genes to Stem Cells: New Challenges for Patent Law?" (2008) 21 Trends Biotech 101 at 103.

31 Dorathy Nelkin and M Susan Lindee *The DNA Mystique: The Gene as a Cultural Icon* (2nd ed,Univeristy of Michigan Press, Ann Arbor, 2004) at 199.

32 Patents Act 1953, s10(7). Annabelle Lever "Is It Ethical To Patent Human Genes?" in Axel Gosseries, Alain Marcian and Alain Strowel (eds) *Intellectual Peperty and Theories of Justice* (Palgrave Macmillan, Houndmills, 2008) 246 at 248.

33 Hans Morten Haugen "Patent Rights and Human Rights: Exploring their Relationships" (2007) 10 JWIP 97 at 98.

34 David Koepsell, above n 29, at 29. This idea is seen in article 1 of the United Nations Educational, Scientific and Cultural Organisation's (UNESCO) Universal Declaration on the Human Genome and Human Rights 1997 which states that the "human genome underlies the fundamental unity of all members of the human family" and so "is the heritage of humanity."

35 David Koepsell, above n 29, at 29.

low threshold for granting a patent under the Patents Act 1953. Thus there is the potential for patent holders to be able to restrict others from using the genetic material for fear of infringing the patent.[36] This is the central focus of this dissertation. In the following chapters I will assess whether gene patents fit within the current boundaries of patenting, whether they should, and whether any issues are dealt with adequately by the proposed Patents Bill.

[36] Dianne Nicol "On the Legality of Gene Patents" (2005) 24 MULR 809 at 810.

Chapter Two | Patenting Genetic Material in New Zealand Under the Patents Act 1953

2.1 The Purpose of the Patent System

A patent is a monopoly right. It grants the owner of the patent (the patentee) the exclusive right to make, use and sell the patented invention for up to 20 years.[37] Granting this limited monopoly is justified on the basis that patents encourage the flow of scientific and technological innovation and provide society with the benefits associated with these innovations.[38] Ultimately this is a utilitarian calculation by the state which involves weighing the benefits of encouraging innovation against the restrictive effects of a limited monopoly.[39]

Patenting genetic material "exposes fundamental issues about what should count as an invention and what the consequences of allowing the patenting of an invention should be."[40] Granting patents for things that are not truly inventions can stifle innovation and the state is "giving away a valuable property right without receiving anything of comparable value in return."[41] In this chapter, I examine whether isolated and purified DNA is a patentable invention under the current patent system in New Zealand and whether it should be. I will first outline the patent requirements under the Patents Act 1953. I will then examine whether isolated and purified genetic material satisfies each requirement. Finally, I will discuss the limitations of the current patent system in ensuring patents are not granted over DNA that does not meet these requirements.

2.2 Patent Requirements Under the Patents Act 1953

The Patents Act 1953 sets out four main requirements for a valid patent: it must be an "invention" (that is patentable subject matter),[42] that is "novel",[43] involves an "inventive

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37 Patents Act 1953, s 30(3). The exclusive rights are set out in the Deed of Letters Patent.

38 Susy Frankel *Intellectual Property In New Zealand* (2nd ed, LexisNexis, Wellington, 2011) at 392; William Cornish *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (Oxford University Press, New York, 2004) at 9-10.

39 *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) at 389; Susy Frankel, above n 38, at 392.

40 William Cornish, above n 38, at 16.

41 Ministry of Economic Development, above n 5, at 6.

42 Patents Act 1953, s 41(d).

43 Ibid, s 41(1)(a) and (e).

step",[44] and is "useful".[45] However, a patent application is only examined for whether the alleged invention is patentable subject matter and novel before a patent is granted.[46] Obviousness is a ground for opposition[47] and revocation,[48] while lack of usefulness is only a ground for revocation.[49]

To be granted a patent an applicant must file a patent application along with a complete specification describing the claimed invention and how it is used.[50] The application is then examined to ensure the complete description accurately describes the claimed invention, and that the claimed invention is novel.[51] Once the application is filed, the Commissioner of Patents can only refuse to grant the patent if the application clearly does not meet the requirements of the Patent Act,[52] or if the use of the patent is contrary to morality.[53]

Failing to examine whether the alleged invention involves an inventive step and is useful, coupled with giving the alleged invention the benefit of any doubt, sets a low threshold for gene patents.[54] It places great importance on the requirements of patentable subject matter and novelty to act as patent gatekeepers, shutting the door on invalid patents. Whether these requirements currently do this in New Zealand is assessed below.

2.3 "Invention"

In order for something to be patentable it must be an "invention". "Invention" is defined in s 2 of the Patents Act 1953 as "any manner of new manufacture that is the subject of the letters patent and grant of privilege within s 6 of the Statute of Monopolies." Section 6 of the Statute of Monopolies 1623[55] allows a patent to be granted for a manner of new manufacture, unless it is "contrary to law, [or] mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient" (referred to as the "s 6

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44 Ibid, s 41(1)(f).
45 Ibid, s 41(1)(g).
46 Ibid, s 12.
47 Ibid, s 21(1)(e).
48 Ibid, s 41(1)(f).
49 Ibid, s 41(1)(g).
50 Ibid, s 9.
51 Ibid, s 12.
52 *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2002] 2 NZLR 529 (CA) at [15], citing *Swift & Co* [1962] RPC 37 (EWCA).
53 Patents Act 1953, s 17(1).
54 Patents Bill 2008 (235-2) (select committee report) at 1.
55 Statute of Monopolies 1623, 21 Jac 1, c3.

proviso"). Thus something is an invention under s 2 of the Patents Act 1953 if it is a "manner of manufacture" and is not excluded by the s 6 proviso on public policy grounds.

Because both elements of s 2 are phrased in archaic language, the courts have attempted to give these terms contemporary meanings.[56] This has led to the interpretation of invention "becoming focussed more on ... judicial pronouncements" rather than on the statutory words themselves.[57] This is especially true of the element of manner of manufacture because modern technologies have advanced to the point where the concrete applications of manner of manufacture in 1623 can provide only "the more obvious illustrations of the broad sweep of the concept."[58] Instead, manner of manufacture has become an evolving concept that is incapable of being precisely defined,[59] and doing so would be "unsound to the point of folly."[60]

By refusing to define manner of manufacture, the courts have allowed the concept to gradually broaden to encompass new technologies.[61] Despite being an archaic term, manner of manufacture has been "flexible enough to have adapted in the past and apparently to be able to adapt itself in the future to the inevitable progress of human knowledge."[62] Genetics is currently in the vanguard of human progress and advocates for intellectual property rights argue that the concept's ability to not only "accommodate but to embrace modern biotechnology has become a test of [the concept's] ongoing strength and relevance."[63] While flexibility is important in ensuring that manner of manufacture continues to be relevant, it is not a free licence to allow anything under its umbrella.[64] Indeed there is the danger that, If the concept of manner of manufacture is stretched too far for the sake of accommodating new technologies, like biotechnology, it will become irrelevant.

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56 *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 (CA) at [61].

57 Ibid; *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (HCA) at 269.

58 *National Research Development Corporation v Commissioner of Patents*, above n 57, at 271.

59 Ibid.

60 Ibid.

61 *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) at 387; *Pfizer Inc v Commissioner of Patents*, above n 56, at [3] per Anderson J, and at [61] per O'Regan J.

62 *Swift & Co v Commissioner of Patents* [1960] NZLR 775 (HC) at 779.

63 Justine Pila, above n 4,at 357.

64 John Smillie "Patentability in Australia and New Zealand Under the Statute of Monopolies" in Charles E F Rickett and Graeme W Austin (eds) *International Intellectual Property and the Common Law World* (Hart Publishing, Oxford, 2000) 211 at 211; Susy Frankel "Lord Cooke and Patents: The Scope of 'Invention'" (2008) 39 VUWLR 73 at 77.

2.3.1 Is Isolated DNA a Manner of Manufacture?

In order to determine whether isolated and purified genetic material is a manner of manufacture, it is necessary to look at the judicial interpretation of this concept.[65] Originally courts applied the "vendible product test" to determine if a product or process was a manner of manufacture.[66] Under the vendible product test vendible (saleable) products or processes that produced, improved, or restored a vendible product were manners of manufacture.[67] This limited what could be a manner of manufacture. For example, in *Maeder v "Rhonda" Ladies' Hairdressing Salon*,[68] the Court of Appeal held that a process using sulphides to curl hair permanently was unpatentable because hair attached to the human body was not a vendible product. This test restricted patents for biological innovations as they were often not vendible.[69]

The vendible product test was rejected by the High Court of Australia in *National Research Development Corp v Commissioner of Patents*[70] *(NRDC).* Instead the High Court of Australia said the issue was whether the claimed invention was a "proper subject of letters patent according to the principles" the courts had developed.[71] According to the High Court of Australia there were three general principles.[72] First, there must be an artificially created state of affairs. Secondly, the process must be commercially useful. Finally, the process must belong to the "useful arts" in that it is a technological innovation. This approach was subsequently adopted in New Zealand by the Supreme Court (now the High Court)[73] and affirmed by the Court of Appeal.[74]

By rejecting the vendible product test and instead applying these three broad principles, the New Zealand courts have gradually broadened the range of subject matter that is a manner

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65 *Pfizer Inc v Commissioner of Patents*, above n 56, at [3] per Anderson J and at [61] per O'Regan J.
66 *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) at 400.
67 *Re GEC's Application* (1943) 60 RPC 1 at 4.
68 *Maeder v "Rhonda" Ladies' Hair Salon* [1943] NZLR 122 (CA).
69 *Re Lenard's Application* (1954) 71 RPC 190.
70 *National Research Development Corporation v Commissioner of Patents*, above n 57, at 276. While the High Court of Australia did not explicitly reject the test, Gault J in *Pharmaceutical Management Agency Ltd v Commissioner of Patents,* above n 52*,* at [23] held that this was the effect.
71 *National Research Development Corporation v Commissioner of Patents*, above n 57, at 269.
72 Ibid, at 277.
73 *Swift & Co v Commissioner of Patents*, above n 62, at 777.
74 *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 387; *Pfizer Inc v Commissioner of Patents*, above n 56, at [63].

of manufacture.[75] For instance, the Court of Appeal has held that a new use of a known drug is a manner of manufacture,[76] and the High Court has accepted that a new dosage regime of a known drug[77] is patentable subject matter. These decisions illustrate the generous interpretive approach New Zealand courts have adopted regarding manner of manufacture.

Despite their generous approach, the courts have been careful to maintain that manner of manufacture is not a "catch-all" concept. The Court of Appeal in *Pfizer Inc v Commissioner of Patents*[78] (*Pfizer*) reaffirmed that discoveries, natural principles, abstract theories, and mere schemes or plans are not manners of manufacture.[79] While the precise justification for why these types of subject matter are not manners of manufacture is unclear,[80] there are four general justifications for why discoveries, in particular, are not manners of manufacture:[81]

1) All scientific advances are founded on pre-existing knowledge and so granting a patent over the knowledge would prevent further advances.

2) Basic knowledge may have many practical applications. Thus granting a patent over the basic knowledge prevents others from using it and gives the patentee utterly disproportionate financial rewards.

3) Patenting a discovery that others could have made provides an inappropriate market opportunity to the patentee.

4) The patent system requires inventors to carry their work through to the applied stage which provides a material benefit to society rather than simply adding to the collective knowledge.

These four reasons reflect to some degree the basic philosophy of the patent system in rewarding innovations that practically benefit society.

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75 *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 387; *Pfizer Inc v Commissioner of Patents*, above n 56, at [3].

76 *Pharmaceutical Management Agency Ltd v Commissioner of Patents,* above n 52.

77 *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd* HC Wellington CIV-2006-4585-817, 29 September 2006. Susy Frankel has criticised this decision as failing to apply the s 6 proviso: Susy Frankel, above n 64, at 93.

78 *Pfizer Inc v Commissioner of Patents*, above n 56.

79 Ibid, at [103]-[105] per Hammond J.

80 Ibid, at [106] per Hammond J; Susy Frankel, above n 64, at 78-79.

81 William Cornish, David Llewelyn and Tanya Aplin *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (7th ed, Sweet & Maxwell, London, 2010) at 924-925.

On this basis the courts have attempted to distinguish a discovery from a manner of manufacture based on whether knowledge is simply added to or applied.[82] However, this distinction is not always clear.[83] In *NRDC*, the High Court of Australia went so far to say that the distinction is "not precise enough to be other than misleading"[84] because the distinction focussed on the source of the alleged invention rather than the practical benefit.[85] Instead the focus should be on whether the alleged invention has "any suggestion of a practical application of it to a useful end"[86] and whether it is an "artificially created state of affairs."[87]

Gene patenting raises the question: at what point does "scientific knowledge become sufficiently connected with functional outcomes to rank as [a manner of manufacture], rather than discovery?"[88] In New Zealand, the answer to this question is not certain as there have been no judicial decision on gene patents. The current practice of the Intellectual Property Office of New Zealand (IPONZ) is to grant patents on isolated DNA.[89] However, just because IPONZ considers isolated DNA to be a manner of manufacture does not mean that it is. In determining if isolated DNA is a manner of manufacture or simply a discovery it is useful to look at how other countries classify isolated DNA.

(a) International Approaches

(i) Australia

In Australia, an invention is a manner of manufacture that is not excluded by the s 6 proviso.[90] In *Genetics Institute Inc v Kirin-Amgen Inc*,[91] the Federal Court of Australia accepted that isolated and purified DNA is a manner of manufacture, but did not provide reasons for this. Instead, this has only been addressed in opposition proceedings. In *Kirin-*

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82 *Reynolds v Herbert Smith and Co Ltd* (1903) 20 RPC 123 at 126.

83 Geoff McLay and Susy Frankel *Intellectual Property in New Zealand* (1st ed, LexisNexis, Wellington, 2002) at 336.

84 *National Research Development Corporation v Commissioner of Patents*, above n 57, at 264.

85 Ibid.

86 Ibid.

87 Ibid, at 277.

88 William Cornish, David Llewelyn and Tanya Aplin, above n 61, at 924.

89 Cabinet Paper "Cabinet Paper on Implications of the Granting of Patents over Genetic Material" (6 August 2003) CAB IP 1.7.2.5 at [9]; In *Corvas Interanational Inc* P8/2001 (Assistant Commissioner Hazelwood, 27 March 2001) the Assistant Commissioner assumed that isolated DNA was patentable, but did not directly deal with it. See Appendix 1 for a graphical representation of certain gene patents in New Zealand.

90 Patents Act 1990 (Cth), s 1.

91 *Genetics Institute v Kirin-Amgen Inc (No 3)* (1998) 41 IPR 325 (FCA).

Amgen Inc v Board of Regents of the University of Washington,[92] Kirin-Amgen's patent over the erythropoietin[93] gene was challenged as not being an invention. The Deputy Commissioner accepted that if the claim was directed to the naturally occurring erythropoietin gene, this would be a discovery. However, the Deputy Commissioner held that the claim only extended to the isolated and purified erythropoietin gene. As such the gene was an "artificially created state of affairs" and so was a manner of manufacture.[94]

(ii) Europe

In Europe, the patent system is regulated at a national and international level. The Convention on the Grant of European Patents, known as the European Patent Convention (EPC), creates an international framework providing a single, harmonised procedure before the European Patent Office (EPO).[95] Invention is negatively defined in the EPC.[96] Under Article 52(2) a discovery cannot be an invention.[97] In interpreting whether isolated DNA is an invention or a discovery under the EPC, the European Union's Directive on the Legal Protection of Biotechnology Inventions (the Biotechnology Directive) influences the interpretation of the EPC.[98] Article 5(1) of the Biotechnology Directive states that the discovery of an element of the human body, including genes, is not patentable. However Article 5(2) provides that an isolated "sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." Article 5(2) of the Biotechnology Directive is replicated in Rule 29(2) of the EPC.[99] Because Article 52 of the EPC is interpreted in line with Rule 29(2),[100] the EPO Enlarged Board of Appeals has held that isolated DNA is an invention under Article 52 of the EPC.[101]

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92 *Kirin-Amgen Inc v Board of Regents of the University of Washington* (1995) 33 IPR 557.

93 Known more commonly by its acronym, EPO. However in this dissertation and in patent law EPO refers to the European Patent Office.

94 *Kirin-Amgen Inc v Board of Regents of the University of Washington*, above n 92, at 569.

95 European Patent Convention 2000, art 1.

96 Ibid, art 52(2).

97 Ibid.

98 European Patent Convention 2000, r 26(1).

99 European Patent Convention 2000, Rules of the Implementing Regulations.

100 Ibid, r 26(1).

101 T1213/05 *Breast and Ovarian Cancer/University of Utah Research Foundation* (Board of Appeal, 27 September 2007) at {43]–[45].

While both Rule 29(2) of the EPC and Article 5(2) of the Biotechnology Directive clearly permit member states to patent isolated DNA, both provisions are drafted using the non-mandatory term "may".[102] On this basis France, Switzerland, and Germany have provisions limiting patents over the genetic sequence but allowing patents for uses of the sequence.[103] The result is that there is no clear position in Europe. While patenting isolated DNA is permitted under the EPC and the Biotechnology Directive, it is up to individual states to decide whether isolated DNA is a discovery or an invention.

(iii) United Kingdom

The patent system in the United Kingdom is modelled on the EPC. Section 1(2) of the Patents Act 1977 (UK) is derived from article 52 of the EPC, therefore invention is only defined by what it cannot be, which includes a discovery. In *Genentech Inc's Patent*,[104] the Court of Appeal considered the validity of Genentech's patent of the human tissue plasminogen activator (t-PA) gene sequence and producing t-PA using recombinant DNA technology. In relation to the isolated t-PA gene sequence, the Court of Appeal held that the claim was invalid because isolated genetic material was simply a discovery.[105]

Genentech was decided prior to the Biotechnology Directive, which was included in Schedule A2 of the Patents Act 1977 (UK), and it was uncertain if this would remain good law. However the decision in *Genentech* was affirmed by the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd*.[106] The House of Lords reaffirmed that isolated and purified DNA was a discovery because the isolated DNA molecule was considered to be "information about the natural world" and not a "practical product or process."[107] The House of Lords went on to say that to grant a patent over DNA itself would not "accord with the social contract ... which underlies patent law."[108] However, the House of Lords accepted that the use of that DNA in a process could be an invention.[109] Despite this, the United

[102] For example r 27(1) of the EPC states that Biotechnology inventions "shall" be patentable, while r 29(2) simply states that isolated DNA "may" be a patentable invention.
[103] Philip W Grubb and Peter R Thomsen *Patents For Chemicals, Pharmaceuticals, and Biotechnology* (5th ed, Oxford University Press, New York, 2010) at 313.
[104] *Genentech Inc's Patent* 1989 RPC 147 (EWCA).
[105] Ibid, at 204 per Purchas LJ and 237 per Dillon LJ.
[106] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 26; [2005] RPC 9 at [76]–[77].
[107] Ibid.
[108] Ibid.
[109] Ibid, at [132].

Kingdom Intellectual Patent Office still grants patents over isolated DNA,[110] but it appears that if these gene patents were appealed then, following *Kirin-Amgen*, they would be invalidated.

(iv) United States of America

The position in the United States of America is less clear. While the Court of Appeals for the Federal Circuit (CAFC) in *The Association for Molecular Pathology v United States Patent and Trademark Office*[111] *(AMP)* has held that isolated genetic material is patentable, it is likely that the final decision on this matter will be made by the Supreme Court.[112] In *AMP*, while all three judges agreed that cDNA is patentable subject matter because it is a product of human effort, they disagreed about whether isolated genes are. The majority held that isolated genes are patentable subject matter, but this was based on two different rationales.

In the United States, any new and useful "process, machine, manufacture, or composition of matter" is patentable subject matter.[113] What each term means has been left to the courts to decide. While the courts have adopted an expansive approach in interpreting what is patentable subject matter, they have made it clear that discoveries or manifestations of laws of nature are not.[114] These exclusions from patentable subject matter are based on similar reasons to those in New Zealand.[115]

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[110] Patents Act 1977 (UK) , sch A2, [5] copies Art 5(2) of the Biotechnology Directive and says that an isolated gene "may" constitute a patentable invention. However the House of Lords held that the sequence itself is a discovery and not an invention. However the Intellectual Property Office has relied on sch A2, [5] to allow patents over the isolated DNA: Intellectual Property Office *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office* (Concept House, Newport, 2011) at [102].

[111] *Association for Molecular Pathology v United States Patent and Trademark Office* 99 USPQ2d 1398; 2011 WL 3211513 (Fed Cir 2011).

[112] Simone Rose "Battle Over Gene Patents Most Likely Headed to Supreme Court" *Huffington Post* (United States, 21 August 2011) <www.huffingtonpost.com>; Dianne Nicol "Are the Courts Solving the Emerging Challenges of Biotech Patents" in Kathy Bowrey, Michael Handler and Dianne Nicol (eds) *Emerging Challenges in Intellectual Property* (Oxford University Press, Melborne, 2011) at 145. The Federal Circuit rejected the request for a rehearing: Allison Williams Dobson "Classen: Has the Federal Circuit Lost Interest in Patentable Subject Matter?" *Genomics Law Report* (United States, 14 September 2011) <www.genomicslawreport.com>.

[113] 35 USC § 101.

[114] *Funk Bros Seed Co v Kalo Inoculant* Co 333 US 127 (1948) at 130; *Diamond v Chakrabarty* 447 US 303 (1980) at 308.

[115] *Laboratory Corp of America Holdings v Metabolite Laboratories Inc* 126 SCt 2921 (2006) at 2923, per Bryer J dissenting: "despite its potentially incentive effects" giving patents for discoveries or laws of nature "would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself."

Gene patenting was made possible by the landmark case of *Diamond v Chakrabarty*.[116] In *Chakrabarty* the Supreme Court decided that a modified bacterium that broke down crude oil was patentable subject matter. Burger CJ, writing for the majority, opined that Congress had intended that patentable subject matter included "anything under the sun that is made by man."[117] Based on this broad interpretation, the majority of the Supreme Court held that while natural phenomena cannot be patented, a "non-naturally occurring manufacture or composition of matter" which is the product of human ingenuity having a distinctive character and use is patentable subject matter.[118]

In determining whether a chemical isolated from nature had a distinctive character, the Supreme Court has held that it has to be "markedly different" from the natural version.[119] The Federal Court in *In re Merz*,[120] elaborated on this and said that the differences in properties or characteristics had to be "in kind ... rather than in degree."[121] in *Parke-Davis & Co v HK Mulford Co*,[122] adrenaline precipitated from the adrenal gland was patentable as it was "for every practical purpose a new thing commercially and therapeutically."[123]

This approach to chemicals was applied to genetic material. In *Amgen Inc v Chugai Pharmaceutical Co*,[124] Lourie J in the CAFC observed that "a gene is but a chemical compound, albeit a complex one"[125] and upheld a claim for infringement of Amgen's patent over the erythropoietin gene. Later CAFC cases assumed DNA was patentable subject matter.[126] However, in *AMP* the CAFC had to directly address whether isolated DNA was patentable subject matter.

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[116] *Diamond v Chakrabarty*, above n 114,.
[117] PJ Federico "Testimony on HR 3760 before Subcommittee on the Judiciary" 82nd Congress, 1st Session, 37 (1951).
[118] *Diamond v Chakrabarty*, above n 114, at 309–310.
[119] *American Fruit Growers v Brogdex Co* 283 US 1 (1931) at 11.
[120] *In re Merz* 97 F 2d 599 (2nd Cir 1931).
[121] Ibid, at 601.
[122] *Parke-Davis & Co v HK Mulford Co* 189 F Supp 95 (SD NY1911).
[123] Ibid, at 103.
[124] *Amgen Inc v Chugai Pharmaceutical Co* 927 F 2d 1200 (Fed Cir 1991).
[125] Ibid, at 1206.
[126] *In re Deuel* 51 F 3d 1552 (Fed Cir 1995).

AMP: The District Court's Decision

AMP was an appeal from a District Court's ruling that genetic material was not patentable subject matter.[127] This case dealt with Myriad Genetics' controversial patents over the Breast Cancer 1 and 2 genes (BRCA 1 and 2) and DNA sequences associated with BRCA 1 and 2. In the District Court, Sweet J held that DNA was different from chemicals[128] in that it was the physical embodiment of information.[129] On this basis, Sweet J concluded that isolating and purifying a gene does not make it markedly different as the information encoded remains the same. In relation to cDNA, Sweet J found that while cDNA is different from a gene, because it lacks introns, it was not markedly different to the naturally occurring mRNA that it was reverse transcribed from as the protein coding remains unchanged.[130] Because both the isolated and purified gene as well as the cDNA were not "markedly different" from natural DNA or mRNA they were not patentable subject matter.

AMP: The Federal Circuit's Decision

The CAFC overturned the District Court's decision in relation to the patentability of genetic material.[131] The majority held that genetic material was patentable subject matter by characterising DNA as a chemical (Lourie and Moore JJ) and because of the increased utility of the DNA once purified (Moore J).

Lourie J stated that genes have a chemical nature and "are best described ... by their structures rather than functions."[132] This was in line with Lourie J's judgments in both *Amgen Inc v Chugai Pharmaceutical Co*[133] and *In re Deuel*[134] where he had expressed similar sentiments.[135] By focussing on the structure rather than the function of DNA, Lourie J was

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[127] *Association for Molecular Pathology v United States Patent and Trademark Office* 702 F Supp 2d 181 (SD NY 2010).
[128] Ibid, at 228.
[129] Ibid, at 229.
[130] Ibid.
[131] In the District Court, Sweet J had held that the methods claimed for diagnosing susceptibility to breast and ovarian cancer were invalid as they were simply a mental process: *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 127, at 235. The Federal Circuit agreed. However this was based on claim construction as it was held that these claims for "analysing" and "comparing" did not include the steps of isolating, purifying and testing the DNA.
[132] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 18.
[133] *Amgen Inc v Chugai Pharmaceutical Co* 927 F 2d 1200 (Fed Cir 1991).
[134] *In re Deuel* 51 F 3d 1552 (Fed Cir 1995).
[135] In *Amgen Inc v Chugai Pharmaceutical Co* 927 F 2d 1200 (Fed Cir 1991) at 1206 Lourie J had said ""a gene is but a chemical compound, albeit a complex one."

able to dismiss Sweet J's arguments which for why isolated DNA was not markedly different from the natural DNA as these were based on DNA's function. Proceeding from this structural characterisation of DNA as a chemical,[136] Lourie J said that "a covalent bond is the defining boundary between one molecule and another."[137] In isolating DNA from a genome, covalent bonds are broken and so new molecules are created. [138] Therefore an isolated DNA molecule was markedly different from the naturally occurring DNA molecule in the genome.[139]

Moore J agreed with Lourie J that isolating a DNA molecule resulted in a new molecule, but expressed reservations about whether it was "markedly different." Moore J reviewed the case law and concluded that "markedly different" was not directed just at the structural differences.[140] Instead the test focussed on whether the claimed composition of matter enlarged "the range of utility" or provided "a different use" to the natural substance.[141]

Moore J accepted that isolating a DNA molecule creates a "distinct molecule with different physical characteristics."[142] She used the example that a DNA molecule with the sequence ATCGT is different from a molecule with the sequence TC.[143] Because small fragments of isolated DNA and cDNA have a distinctive structure, name, and use[144] compared to natural DNA, Moore J concluded that they are markedly different and thus patentable subject matter.[145] In relation to the BRCA 1 and 2 genes themselves, Moore J expressed doubt over whether they were markedly different from the natural genes. While the different chemical structures "suggest that claimed DNA is not a product of nature," Moore J did not think that "this difference alone necessarily makes isolated DNA so 'markedly different'."[146] Instead, the isolated gene must have "markedly different properties which are directly responsible

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[136] Lourie J was a trained chemist and so it is unsurprising that he saw DNA in chemical terms: "Alan D Lourie, Circuit Judge" United States Court of Appeals for the Federal Circuit <www.cafc.uscourts.gov/judges>.

[137] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 18.

[138] A covalent bond is a bond characterised by sharing electrons between atoms.

[139] Ibid.

[140] Ibid, at 24.

[141] Ibid, citing *Funk Bros Seed Co v Kalo Inoculant* Co, above n 114, at 131.

[142] Ibid, at 27.

[143] Ibid, at 29.

[144] Moore J does not elaborate on what this different use is. For the isolated DNA fragments, the distinctive use could be as primers or probes. For the cDNA, however the distinctive use is harder to see. The cDNA does exactly the same thing as the mRNA except that it can be inserted into a genome. But this confuses the use of the molecule with the use of the molecule in a process.

[145] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 29.

[146] Ibid.

for their new and significant utility."[147] Simply isolating the DNA molecule does not satisfy this. Additionally the gene has to be purified to be used. On this point, Moore J departs from Lourie J's view that isolation alone makes genetic material patentable. Indeed, she concludes by saying that if there was no precedent or established practice she might have held that genes, even once isolated and purified, do not have a new and significant utility, but she decides that any change should be left to Congress.[148]

The third judge, Bryson J, argued that isolated DNA itself was unpatentable. This is because the only material change made to the DNA is "incidental to the extraction of the genes."[149] Bryson J adopted the reasoning of the District Court and argued that the analogy between DNA and chemicals is not accurate or helpful.[150] In characterising DNA, Bryson J stated that genetics rather than chemistry should be used to determine if the isolated DNA is markedly different. Genetically, isolated DNA is identical to natural DNA as it has the same sequence, codes for the same protein, and "represents the same units of heredity."[151] Bryson J attacks the majority's view and argues that isolating a gene is equivalent to "snapping a leaf from a tree" and does not make the isolated DNA markedly different.[152]

(b) What Approach Would a New Zealand Court Take?

Internationally there is no unified position on whether isolated DNA is an invention or discovery. Instead, there are three positions that different countries or courts have adopted. These are:

1. DNA is a chemical and once isolated it is different from naturally occurring DNA. Thus isolated DNA is patentable subject matter (Australia, Europe, United States),

2. DNA is only patentable if the isolated and purified DNA has a markedly increased utility over the natural DNA (Moore J in *AMP*); and

[147] Ibid, at 30.
[148] Ibid, at 31.
[149] Ibid, at 38.
[150] Ibid, at 40.
[151] Ibid.
[152] Ibid, at 41.

3. DNA is the physical embodiment of information and it is merely information about the natural world. Thus it is a discovery, but applications of DNA can be inventions (United Kingdom, Bryson J in *AMP*).

Each position relies on a different characterisation of the nature of DNA. Is it a chemical, the physical embodiment of information, or both? Each position reflects a judgment about "how much weight is allocated to the different structure" of isolated and purified DNA "as compared to the similarity of the function to nature."[153]

It is unclear which position a New Zealand court would adopt because of the scarcity of case law in New Zealand on what amounts to a manner of manufacture. However, as discussed above, New Zealand courts have interpreted manner of manufacture generously in accepting that a discovery of a new use for a known product[154] as well as a new dosage regime[155] are manners of manufacture. By focussing on whether the alleged invention has "any suggestion of a practical application of it to a useful end"[156] and whether it creates an "artificially created state of affairs"[157] the courts have been able to extend the scope of manner of manufacture significantly. Applying this approach, it is arguable that genetic material, once isolated and purified, is an artificial state of affairs because it is structurally different from the genetic material in nature and has involved some degree of human intervention. It is also arguable that this isolated and purified genetic material does have some suggestion of a practical application in that it can be used in processes to produce therapeutic proteins, as diagnostic and research tools, or in gene therapy.

(c) What Approach Should a New Zealand Court Take?

While it is possible isolated genetic material could be considered a manner of manufacture in New Zealand, is this the correct approach? The idea that isolating and purifying the DNA makes it a manner of manufacture relies on the assumption that DNA is simply a chemical. Therefore isolating DNA breaks the covalent bonds in the genome and creates a new

[153] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 31 per Moore J.
[154] *Pharmaceutical Management Agency Ltd v Commissioner of Patents,* above n 52.
[155] *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*, above n 77.
[156] *National Research Development Corporation v Commissioner of Patents*, above n 57, at 264.
[157] Ibid, at 277.

molecule[158] which is an artificial state of affairs. However, this argument ignores the fact that DNA is the unique "physical embodiment of information."[159] This dual nature of DNA causes problems in classifying what is being patented. Is it the chemical molecule itself or the information contained on the molecule?

Most gene patents cover isolated DNA that encodes a protein. These isolated DNA molecules are defined by either their DNA sequence or by the sequences that encodes a specific amino acid sequence. For example in the BRCA2 patent,[160] claim 1 covers "[a]n isolated nucleic acid coding for a BRCA2 polypeptide" which has the "amino acid sequence set forth in SEQ ID NO2" or a modified form that is "functionally equivalent or associated with a predisposition to breast cancer." Thus claim 1 covers many different DNA molecules that have only one thing in common: what they code for. The isolation, purification and synthesis of DNA are simply intermediate steps. The isolated DNA and the natural DNA are identical in the "qualities researchers deem most significant, and distinct in ways that can be fairly characterised as incidental."[161]

Further, the words in the claim "should not be accorded talismanic status."[162] Claims are often written to only claim "isolated" DNA. This is to satisfy the requirement of s 10(7) of the Patents Act 1953 that a claim cannot be construed as extending to a natural product. However, just because claims use the word "isolated" does not mean that "isolated" means anything. In relation to cDNA, "isolated" is redundant as it simply means that that the non-coding regions have been removed, but the non-coding regions do not perform the function being claimed.[163] Similarly, using the word "isolated" to argue that the product is an artificial state of affairs rather than a natural product places too much emphasis on the nature of isolation. For example, Aluminium (Al) is too reactive to be found in elemental form. Instead it is normally found in ore in the form of aluminium oxide (Al_2O_3). Isolating and purifying

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158 *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 18 per Lourie J and at 27 per Moore J.

159 *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 127, at 229; Nuffield Council on Bioethics , above n 7, at 28; Arti K Rai "Intellectual Property Rights in Biotechnology: Addressing New Technology" (1999) 34 Wake Forest L Rev 827 at 836.

160 Patent No 326525 *ENDO RECHERCHE INC/Chromosome 13-linked breast cancer susceptibility gene.*

161 John M Conley and Roberte Makowski "Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)" (2003) 85 J Pat & Trademark Off Society 371 at 395.

162 Ibid, at 392.

163 Ibid.

aluminium requires great effort and involves breaking the covalent bonds between the aluminium and oxygen atoms,[164] but it does not follow that isolated aluminium is patentable subject matter. Similar caution should be applied to isolation in relation to DNA.

Because what is being patented is essentially something performing a specific function, and it is this function which identifies all the claimed molecules, it is illogical to ignore the this function and instead focus on molecular or chemical differences as Lourie J did.[165] Further, the chemical differences caused by isolating and purifying the DNA are not decisive. Isolation does not affect the information encoded by the DNA and it is this information that is being patented. This is simply "information about the natural world" which is a discovery.[166] Therefore I believe that DNA that is isolated and purified from nature should be characterised as a discovery rather than a manner of manufacture.

This would not mean that all claims over genetic material are discoveries. If genetic material is modified to insert a specific regulatory element or to code for a protein with a different active site this could be a manner of manufacture. This would accord with reasoning in *Chakrabarty*[167] and *Funk Bros*[168] that dealt with patentability of organisms. Further, as in the United Kingdom, genetic material applied to a specific use in a specific process, like gene therapy, could be patented but only for that use. Thus there would still be some scope for gene patents, albeit a more limited one.

2.3.2 Are Gene Patents "Generally Inconvenient"?

Even if a New Zealand court decided that isolated DNA is a manner of manufacture, this does not automatically mean it is an invention under s 2 of the Patents Act 1953. Subject matter that is a manner of manufacture can be excluded from being an invention under the s 6 proviso if granting a monopoly over isolated genetic material is contrary to the overall public interest by being "mischievous to the state ... or generally inconvenient".[169] While Gault J in *Pharmaceutical Management Agency Ltd v Commissioner of Patents*[170] (*Pharmac)*

[164] Al_2O_3 has the following structure: O=Al–O–AL=O, where each '–' represents a covalent bond.
[165] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 111, at 18.
[166] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* , above n 106, at [76].
[167] *Diamond v Chakrabarty*, above n 114,.
[168] *Funk Bros Seed Co v Kalo Inoculant* Co, above n 114.
[169] Statute of Monopolies 1623, s 6.
[170] *Pharmaceutical Management Agency Ltd v Commissioner of Patents,* above n 52.

cast doubt on whether the s 6 proviso was still part of the statutory definition of invention,[171] the Court of Appeal in *Pfizer Inc v Commissioner of Patents*[172] *(Pfizer)* reaffirmed that it remains part of the definition.[173] Restricting what can be patented based on the s 6 proviso is intended to ensure that patents are not granted for things that are not in society's best interests.[174] There are two main arguments for why gene patents are not in society's best interests: first, they restrict access to medical diagnosis. Secondly, they inhibit scientific research.

(a) Restricting Medical Diagnosis

The first argument for why patenting DNA is "generally inconvenient", is that gene patents restricts access to medical diagnosis. At the heart of the *AMP* case was Myriad's patent over the BRCA1 and 2 genes and methods to predict a woman's susceptibility to breast and ovarian cancer. Using these patents, Myriad prevented other laboratories from testing for the BRCA1 and 2 genes, and charged twice the amount as other laboratories charged for the same test.[175] This ability to charge a higher price and prevent others from testing for an individual's susceptibility to a disease causes problems for a public health system, like New Zealand, where "global budgets may not be able to accommodate the demanded monopoly price."[176] This may restrict public access to diagnosis.[177]

In New Zealand, this fear has nearly been realised. In 2004, Genetic Technologies Limited (GTG) demanded substantial licence fees for genetic tests carried out in New Zealand. GTG alleged its patents on non-coding DNA had been infringed and sought an upfront payment of 10 million dollars for past infringement, and an annual licence fee of 2 million dollars a year.[178] However issues were raised about the validity of the patents and eventually GTG

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[171] Ibid, at [20]. In *Pfizer Inc v Commissioner of Patents*, above n 56, at [53] O'Regan J interpreted Gault J as simply meaning that the Commissioner of Patents had no power to create a new grounds for generally inconvenient.

[172] *Pfizer Inc v Commissioner of Patents*, above n 56.

[173] Ibid, at [64].

[174] *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 389.

[175] Bryn Williams-Jones "History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing" (2002) 123 Health LJ 131 at 133.

[176] Timothy Caulfield and Yann Joly, above n 2, at 530.

[177] Ibid; In the United States, 25% of laboratories had to withdraw testing due to patents: MK Cho, S Illangasekare, MA Weaver, DGB Leonard and JF Merz "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services" (2003) 5 J Mol Diagnostics 3.

[178] Auckland District Health Board "ADHB Challenges Bio-Tech Co Over Clam For Patent" (press release, 20 August 2004).

settled for a one off payment of $450,000.[179] This is still a large cost for a publically-funded health system with limited resources given the questionable validity of GTG's patents. Further, it illustrates the patentee's ability to demand high fees, which can act as a practical barrier to publically-funded testing for identify a disease.[180]

(b) Inhibiting Scientific Research

The second public policy concern is that gene patents may inhibit scientific research and progress. This is because advances in science build upon pre-existing knowledge and to allow patents over basic information or molecules prevents others from doing this.[181] Because most gene patents claim DNA molecules with certain sequences, they claim all the uses of the claimed DNA molecules not just the uses disclosed in the patent. For example, Human Genome Science (HGS) patented the genetic sequence coding for the CCR5 receptor. This was claimed to be useful in anti-inflammatory therapy. Later, other researchers discovered that the human immunodeficiency virus (HIV) entered a cell through the CCR5 receptor. Because HGS's patent covers the CCR5 gene, any work that involves using the sequence to develop therapies against HIV potentially infringes the patent, despite HGS not knowing of this function of the CCR5 gene.

This restrictive effect of patents in science is compounded by "royalty stacking". Royalty stacking is where multiple patents exist over the same or different elements of an invention. Because scientific progress is "cumulative, and iterative",[182] advances will often utilise several of these patented elements. This can decrease progress by making the cost of obtaining individual licences for using these elements financially unbearable and has been described as the "tragedy of the anticommons".[183]

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[179] GTG "GTG Settles Legal Action in New Zealand" (press release, 7 July 2005).

[180] Alphra Green, above n 25, at 170; In the United Kingdom, the National Health System continues to use tests that could amount to infringement: Human Genetics Commission *Intellectual Property and DNA Diagnostics* (2010) at 1 and 9; Ingrid Torjesen "NHS Laboratories Are Infringing DNA Patents With Cheap "Home Brew" Tests, Says Human Genetics Commission" (2011) 343 BMJ 5080.

[181] William Cornish, David Llewelyn and Tanya Aplin, above n 61, at 924.

[182] Human Genetics Programme *Genetics, Genomics and the Patenting of DNA* (World Health Organisation, Switzerland, 2005) at 12.

[183] Michael Heller and Rebecca S Eisenberg "Can Patents Deter Innovation? The Anitcommons in Biomedical Research" (2000) 280 Science 698.

Patents also reduce information sharing which is important in science.[184] In New Zealand, many researchers view patents as decreasing their ability to publish, increasing the costs of their research, and reducing information sharing among researchers.[185] For all these combined reasons, patents do appear to negatively affect scientific research.

(c) Evaluating Whether Gene Patents are Generally Inconvenient

While gene patents potentially restrict medical diagnosis and inhibit scientific research, does this mean that they are excluded from being inventions because they are generally inconvenient? Answering this question involves weighing the "competing economic, social, and scientific considerations involved"[186] in assessing whether gene patents provide a net benefit to society.[187]

While gene patents might restrict access to medical diagnosis, the Nuffield Council on Bioethics argues that they have encouraged the development of therapies and methods of diagnosis.[188] There is a trade-off between encouraging the development of technology and restricting access to it. Currently in New Zealand, gene patents do not restrict access to medical diagnosis and no laboratories currently pay licence fees.[189] However, if patentees begin to enforce their patents and restrict access then the restrictive effects of gene patents on access to medical diagnosis could begin to outweigh the positive effects of developing new technology.

In relation to the inhibitory effects of gene patents on scientific research, the Royal Commission on Genetic Modification concluded that these effects are not "specific to gene patents."[190] However, gene patents restrict scientific research more than other patents because they cover the building blocks of science rather than applications of it. This makes it difficult for gene patents to be invented around.[191] This inhibitory effect of gene patents

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184 Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson *Royal Commission on Genetic Modification* (2001) at 278.
185 Alphra Green, above n 25, at 178.
186 *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 392.
187 Ibid, at 389.
188 Nuffield Council on Bioethics , above n 7, at 14.
189 Alphra Green, above n 25, at 171.
190 Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 278.
191 Cabinet Paper, above n 89, at [11]; Sirpra Soini, Sègolène Aymè and Gert Matthijs "Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues" (2008) 16 Eur J Human Genet 10 at 15.

could be alleviated if the isolated sequence was held to be a discovery, as I argued for earlier.[192]

Soini argues that these problems are not caused by gene patents per se but arise "out of overly restrictive monopolistic licensing policies."[193] The New Zealand Institute of Patent Attorneys (NZIPA) agrees, and has argued that the restrictive effects of gene patents can be overcome by obtaining licences.[194] However, the GTG fiasco mentioned earlier outlines the problems with relying on individual licences, and this still does not overcome the problem of royalty stacking. There are two ways that the patent system provides for overcoming these issues. These are compulsory licences, and an experimental use exception.

Compulsory Licences

One solution to overly restrictive licensing polices are compulsory licences. In New Zealand, s 46(2) of the Patents Act 1953 allows compulsory licences to be granted if the invention is not being supplied in New Zealand or not supplied on reasonable terms.[195] While this appears to provide an way around the problem of overly restrictive licensing practices, "the costs of securing compulsory licences from unwilling patentees can be a very expensive and long drawn-out process."[196] Probably owing to this, in New Zealand no compulsory licences have been granted.[197] So, in practice, compulsory licences will only rarely alleviate the restrictive effects of a monopoly over genetic material.

Experimental Use Exception

Another possible means of minimising the negative effects of gene patents on science is the common law experimental use exception. The leading case on experimental use in New Zealand is *Smith Kline & French Laboratories v Attorney-General*.[198] In this case, the Court of Appeal stated that if a person uses a patented invention to further his or her own

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[192] Section 2.3.1(c).
[193] Sirpra Soini, Sègolène Aymè and Gert Matthijs, above n 190, at 11.
[194] Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 279.
[195] There are some limits to this, as compulsory licences can only be applied for between 3 years after the grant of the patent and 4 years before the patent expires: Patents Act 1953, s 46.
[196] William Cornish, David Llewelyn and Tanya Aplin, above n 61, at 939.
[197] Tim Stirrup and Katherine Hebditch "Compulsory Licensing in a Nutshell" (2010) 74 Chem NZ 115.
[198] *Smith Kline & French Laboratories v Attorney-General* [1991] 2 NZLR 560 (CA).

knowledge and skill these actions do not infringe the patent.[199] However, if that person uses the invention or makes the invention available to others "in a way that serves to advance him in the actual marketplace then he infringes."[200] So while "bona fide research" does not infringe the patent,[201] if the research provides a commercial advantage it is an infringement.[202] While the line between the two is a "matter of degree",[203] case law indicates that this line is set quite low.[204] Indeed, if the patented invention's use is displayed and this provides an indirect commercial benefit it will infringe.[205] So most disclosures of results obtained using a patented invention will infringe because these provide an indirect benefit in obtaining funding. Thus only in very limited circumstances will research using a patented invention not infringe.[206]

d) Would A New Zealand Court Decide Patenting Genetic Material Is Generally Inconvenient?

The negative effects of granting a monopoly over genetic material are not substantially alleviated by compulsory licensing or the experimental use exception. However, this does not mean that gene patents are generally inconvenient. Gene patents provide some benefits. First, it is argued that gene patents are necessary in encouraging innovation in the biotechnology sector.[207] Indeed, the ability to patent is seen as crucial by investors in financing biotechnology firms.[208] Additionally, if gene patents are not granted, there is the danger that scientific knowledge will remain locked up as trade secrets rather than disclosed to the general public[209] and also New Zealand firms will lose revenue and be unable to compete internationally.[210] Therefore it is not clear if gene patents are generally

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[199] Ibid, at 567.
[200] Ibid.
[201] *Monsanto Co v Stauffer Chemical Co (No 1)* (1984) 1 NZIPR 518 (HC) at 531. Approved of in *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, above n 52, at [61].
[202] Ibid; *Pfizer Corp v Ministry of Health* [1965] RPC 261 (HL) at 320.
[203] *Smith Kline & French Laboratories v Attorney-General*, above n 197, at 567.
[204] Susy Frankel, above n 38, at 446.
[205] *Monsanto Co v Stauffer Chemical Co (No 1)*, above n 200, at 533; *Dunlop Pneumatic Tyre Co Ltd v British and Colonial Motor Car Co Ltd* (1901) 18 RPC 313 (KB).
[206] Susy Frankel, above n 38, at 446.
[207] Alphra Green, above n 25, at 166.
[208] William Cornish, David Llewelyn and Tanya Aplin, above n 61, at 920; Timothy Caulfield and Yann Joly , above n 2, at 527.
[209] J Craig Venter *A Life Decoded* (Viking, New York, 2007) at 127 and 269.
[210] Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 280-181.

inconvenient on public policy grounds and this decision involves "competing economic, social, and scientific considerations."[211]

Because of these complex issues, deciding if granting a monopoly over genetic material is "mischievous to the state ... or generally inconvenient"[212] involves assessing issues that are broader than "Court proceedings can conveniently investigate."[213] In such situations, the Court of Appeal has said that it is up to Parliament rather than the courts to change the legal position.[214] Gene patenting was the subject of a report by the Ministry of Economic Development[215] and has been discussed by Cabinet,[216] neither of which recommended excluding genetic material from patentability. Similarly, Parliament has not taken any action to restrict this practice. While this does not necessarily mean that Parliament endorses gene patents,[217] it indicates that the legislature does not consider patenting genetic material to be seriously contrary to public policy.

Further, excluding all gene patents from patentability could conflict with New Zealand's international obligations under article 27.1 of the TRIPS Agreement[218] which requires member states to not discriminate against granting a patented based on the field of technology. This argument was raised in *Pfizer* where the Court of Appeal accepted that Article 27.1 influences the interpretation of the Patents Act 1953 and restricts when the s 6 proviso can be applied.[219] Anderson P went as far as saying that there is "little if any scope for exclusion, on [the basis of the s 6 proviso], of inventions other than methods of medical treatment."[220] In doing so, Anderson P relied on O'Regan and Hammond JJ's reasoning. However, O'Regan J simply says that the s 6 proviso cannot be interpreted to allow an overly broad exception based on inconvenience.[221] While excluding all genetic material from patentability could breach article 27.1 of the TRIPS Agreement, simply excluding genetic material used in, say gene therapy, would not necessarily be. Because it is unclear whether

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[211] *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 392.
[212] Statute of Monopolies, s 6.
[213] *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 391.
[214] Ibid; *Pfizer Inc v Commissioner of Patents*, above n 56, at [127].
[215] Ministry of Economic Development, above n 5,.
[216] Cabinet Paper, above n 89.
[217] *Pfizer Inc v Commissioner of Patents*, above n 56, at [79].
[218] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
[219] *Pfizer Inc v Commissioner of Patents*, above n 56, at [7] per Anderson J and at [56]-[57] per O'Regan J.
[220] Ibid, at [7].
[221] Ibid, at [57].

granting monopolies over genetic material is in the public's overall best interests, and because of the potential conflict with the TRIPS agreement, it is likely that New Zealand courts would leave any change in the current practice of granting gene patents to Parliament.[222]

2.3.3 Conclusion On Whether Genetic Material Can Be An Invention

Based on my arguments above it appears that, in New Zealand, isolated and purified DNA would be an "invention" under s 2 of the Patents Act 1953. This is because, New Zealand courts would probably accept that once DNA has been isolated and purified it is an artificially created state of affairs and can be a manner of manufacture. It is unlikely that gene patents would be deemed generally inconvenient on public policy grounds because of the complex public policy issues that are involved. However, I have argued that properly categorised, DNA is not just a chemical and is the physical embodiment of information. It is this aspect of what the isolated DNA codes for that unites all the claimed DNA molecules and that is the valuable property. Because this is simply information about the natural world, I have argued that it should be properly classified as a discovery rather than an invention.

2.4 Novelty

Even if isolated and purified DNA is considered an invention, it can only be patented if it is novel.[223] This is because there would be no societal benefit for granting a monopoly over something that is already known.[224] An invention is not novel if it has been published,[225] claimed, or used in New Zealand prior to the patent being filed.[226] However, the patent application is only examined for prior publication or claim[227] with prior use being a ground for opposition or revocation.[228] In examining a patent for novelty, novelty is assessed to a local standard. This is an outdated standard, and with the advent of the internet it has

[222] Ibid, at [127]; Cabinet Paper, above n 89, at 1; *Wellcome Foundation Ltd v Commissioner of Patents*, above n 66, at 391; Susy Frankel, above n 64, at 77.
[223] Patents Act 1953, ss 13 and 14.
[224] Susy Frankel, above n 38, at 423.
[225] Published has a broad meaning encompassing making documents generally available: Patents Act 1953, s 2.
[226] Patents Act 1953, ss 21(1)(b),(c) and (d), 41(1)(a) and (e).
[227] Ibid, ss 13 and 14.
[228] Ibid, ss 21(d) and 41(1)(e).

become a de facto global standard.[229] If any prior publications or claims contain a clear description of, or instructions to do or make, something that will infringe the claimed patent if granted, then the claim will not be novel.[230]

Novelty does not pose any real difficulty for gene patenting. It might seem that with many genomes, including the human genome, being published then most genetic material would have been published and therefore not novel. However, in *Beecham Group Ltd v Bristol-Myers Co*,[231] the Court of Appeal ruled that a chemical is published only if it has been "separately made or isolated."[232] This was because before something is made "its properties cannot be predicted with any confidence" and if so then it cannot "accurately be described as 'published'."[233] Applying this to genetic material, even if a genome is published, individual genes are not published until they have been separately made or isolated and their function determined. Thus, most gene patents that claim a newly identified gene or genetic material will be novel.

2.5 Inventive Step

In New Zealand a patent may be granted even if an invention is obvious because this is not examined prior to grant. However, obviousness can be grounds for opposition and revocation.[234] Obviousness is assessed in relation to what has been published or used,[235] or, in the case the case of revocation, what is known.[236] The rationale for why an obvious development is not a patentable invention is that society is entitled to use and build upon what is known, and the advantage for doing so is a "head start on the competition ... not a monopoly for twenty years."[237]

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[229] *Molecular Plant Breeding Nominees Ltd's Application* (Commissioner's Decision No P25/2005, 12/9/05, Asst Commr Popplewell).

[230] *General Tire & Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 (EWCA) at 485, adopted in New Zealand by *Smale v North Sails Ltd* [1991] 3 NZLR 19 (HC).

[231] *Beecham Group Ltd v Bristol-Myers Co* [1981] 1 NZLR 600 (CA).

[232] Ibid, at 608.

[233] Ibid, at 608.

[234] Patents Act 1953, ss 21(1)(e) and 41(1)(f).

[235] Ibid, s21(1)(e).

[236] Ibid, s41(1)(f).

[237] *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195 (EWCA) at 209. This case was referred to in *Ancare New Zealand Ltd v Cyanamid of NZ Ltd* [2000] 3 NZLR 299 (CA).

There are four steps in determining whether an invention involves an inventive step:[238]

1. Identify the inventive concept embodied in the claim;

2. Impute to the normally skilled but unimaginative addressee in the art the common general knowledge at the prior date;

3. Identify what difference exist between what was known or used and the alleged invention; and

4. Ask whether those differences constitute inventive steps which would not have been obvious to the skilled addressee.

The addressee is a person or group of people that is "skilled in the field but not inventive."[239] They are deemed to have looked at all the prior art, even if most others would not have, never missing the obvious but never stumbling on the inventive.[240] This addressee is not a real person, rather a "legal creation designed to offer a subjective test of whether the invention involved an inventive step.[241]

Step four requires the court to consider whether this fictional addressee would consider the differences between the invention and what was known to be obvious steps to take. In doing so the courts asks whether the addressee would consider that the steps were "something that could be done or is at least worth trying.[242] This element has been criticised on two grounds. The first criticism is that hindsight often makes something seem obvious.[243] Once an invention is disclosed and how the inventions works has been understood, it is "but

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[238] *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 (EWCA) at 73. Adopted in New Zealand in *Smale v North Sails Ltd*, above n 229 and subsequently affirmed in *Ancare New Zealand Ltd v Fort Dodge New Zealand Ltd* [2002] UKPC 8 and *Peterson Portable Sawing Systems Ltd (In Liq) v Lucas* [2006] NZSC 20; [2006] 3 NZLR 721 at [54].

[239] *Ancare New Zealand Ltd v Cyanamid of NZ Ltd* [2000] 3 NZLR 299 (CA) at [43].

[240] *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195 (EWCA) at 209. This case was referred to in *Ancare New Zealand Ltd v Cyanamid of NZ Ltd*, above n 236.

[241] Ibid.

[242] Ibid, at [43].

[243] Ying Pan "Note: A Post-KSR Consideration of Gene Patents: The 'Obvious to Try' Standard Limits the Patentability of Genes" (2009) 93 Marq LRev 285 at 287.

a short step to finding it obvious."[244] This is a legitimate concern, and one courts have acknowledged they must guard against.[245]

The second criticism is directed at the "obvious to try" standard. The Court of Appeal has stated that "[a]nything may be worth a try, depending on the acceptable cost for the potential benefit", whereas, "inventiveness may lie in deciding what to try."[246] Hugh Laddie argues that this means that if the potential benefits are high, then it may be worthwhile to examine all the potential avenues, even though the probability of success is very low.[247] However, this mischaracterises test. Commercial benefit versus risk is irrelevant.[248] Instead, the focus of the "obvious to try" test is on whether a scientist would pursue the course of action devoid of commercial success.[249] Thus, in *Biogen Inc v Medeva PLC*,[250] the House of Lords accepted that producing the Hepatitis B virus in bacteria using recombinant DNA technology was not obvious, because, while the means were known, it was not thought possible (at that time) due to the existence of introns and the inability of bacteria to remove introns.[251]

Obviousness is problematic for gene patents.[252] This is because scientific progress is iterative, with advances building upon other advances.[253] Also the techniques used to identify genes have become standard techniques and so it has become "increasingly difficult to characterise as anything other than routine" identifying the sequence and function of genes

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[244] Hugh Laddie "Patents-What's Invention Got To Do With It?" in David Vaver and Lionel Bently (eds) *Intellectual Property in the New Millenium* (Cambridge University Press, Cambridge, 2004) 91 at 94.

[245] *Smale v North Sails Ltd*, above n 229, at 40; *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] RPC 346 at 362.

[246] *Peterson Portable Sawing Systems Ltd v Lucas* CA64/03 and CA97/03, 4 March 2005 at [85].

[247] Hugh Laddie, above n 243, at 93.

[248] *Biogen Inc v Medeva PLC* [1996] UKHL18; [1997] RPC 1 at [53] per Lord Hoffman; *Genentech Inc's Patent*, above n 104, at [13.14].

[249] Ibid; *Ancare New Zealand Ltd v Novartis New Zealand Ltd* HC Auckland CP 480/97, 19 June 1998 at [57].

[250] *Biogen Inc v Medeva PLC,* above n 246.

[251] Ibid, at [53].

[252] William Cornish, Margaret Llewelyn and Michael Adcock *Intellectual Property Rights (IPRs) and Genetics* (Prepared for the United Kingdom Department of Health, 2003) at 32; Hugh Laddie, above n 243, at 93.

[253] Human Genetics Programme *Genetics, Genomics and the Patenting of DNA* (World Health Organisation, Switzerland, 2005) at 12.

using these techniques.[254] Therefore, while in the 1970s and 1980s finding a gene was inventive,[255] "perhaps it can no longer be regarded as inventive."[256]

This was the opinion of the District Court in *Association for Molecular Pathology v United States Patent and Trademark Office*.[257] Sweet J accepted that the isolation of the BRCA1/2 genes "required considerable effort ... as well as ingenuity in overcoming technical obstacles associated with the isolation process."[258] However, he said that "the process and techniques used were well understood, widely used and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilised a similar approach."[259] Similarly, in *Genentech Inc's Patent*,[260] the English Court of Appeal held that that a patent over using recombinant DNA technology to produce the t-PA protein[261] in bacteria was invalid because it was obvious. All of the steps taken by Genentech in identifying, isolating and then inserting the DNA were applications of known technology towards a known end, and therefore obvious.[262]

While the using routine methods makes it harder for isolated genetic material to have an inventive step, so too does the addressee possessing all the common general knowledge. For example, it might seem that adding a piece of DNA (called Z) from species *z*, into gene-X from species *x* and then inserting this construct into species *y* in order to get species *y* to produce gene-X is non-obvious. An example where this might occur is where a promoter from yeast is added to the human insulin gene to allow insulin to be expressed in bacteria. Because the fictional addressee is deemed to know all the prior art, then these steps, while not obvious to a scientist, can be legally obvious. If the aim is to insert gene-X from species *x* into species *y*, the literature might show that gene-X from species *x* does not express well in species *a* unless a piece of DNA called Z from species *z* is added into gene-X. The literature

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[254] William Cornish, Margaret Llewelyn and Michael Adcock, above n 251, at 32.

[255] Francis Collins, the head of the Human Genome Project said "[Locating, from scratch, the gene related to a disease is like] trying to find a burned-out light bulb in a house located somewhere between the East and West coasts without knowing the state, much less the town or street the house is on.": Francis Collins quoted in Philip Elmer-Dewitt, David Bjerklie, Andrea Dorfman, Chrine Groman, and J Madeline Nash "The Genetic Revolution" *Time* (17 January 1994), 46.

[256] Nuffield Council on Bioethics *,* above n 7*,* at 29.

[257] *Association for Molecular Pathology v United States Patent and Trademark Office*, above n 127.

[258] Ibid, at 202-203.

[259] Ibid.

[260] *Genentech Inc's Patent*, above n 104,.

[261] t-PA is the human tissue plasminogen activator which helps dissolve blood clots.

[262] *Genentech Inc's Patent*, above n 104, at [13.08].

might also show that species *a* is closely related to species *y.* So in solving the problem of inserting gene-X into species *y,* by inserting pieces of DNA (Z) from species *z* into gene-X in order to express gene-X in species *y,* the literature has made these steps "obvious to try". As the scientific literature continues to expand, the chance for this continues to grow.

Even if the methods used were obvious and the literature made the steps obvious to try, this does not necessarily mean that the genetic material itself or the use of the DNA is obvious. In *Beecham Group Ltd v Bristol-Myers Co*,[263] the Court of Appeal held that an isolated isomer of a previously patented racemic mixture that provided a "sufficiently distinctive advantage"[264] was not obvious and could be patented. While isolating the isomer was an obvious step, it was not obvious that this isomer had a significantly higher oral absorption over the other isomers.[265] Thus, this unexpected property meant that the use of this isomer in an orally-administered drug was not obvious. However, because most genetic material is first identified based on its function and subsequently isolated and purified this means that that discovering a new distinctive advantage of that genetic material is highly unlikely.

From the above discussion, many gene patents could be obvious. However, under the Patents Act 1953, obviousness is not examined prior to grant. Therefore there is the distinct possibility that many patents granted over genetic material in New Zealand are invalid for being obvious.

2.6 Usefulness

While usefulness is not examined prior to grant, a patent can be revoked if the patented product or process is not useful.[266] An invention is useful if it "does what it is intended ... to do and the end attained is itself useful."[267] As most gene patents claim DNA for coding for therapeutic proteins, as diagnostic or research tools, and for use in gene therapy most gene patents will be useful. This is because these ends are useful. However patents, like GTG's patents over non-coding DNA, might not satisfy this requirement unless a use can be

[263] *Beecham Group Ltd v Bristol-Myers Co*, above n 230.
[264] Ibid.
[265] Ibid, at 609.
[266] Patents Act 1953, s 41(1)(g).
[267] *Fawcett v Homan* (1896) 13 RPC 398 (EWCA) at 405.

ascribed to them. Further, hypothetical usefulness, predicted by bioinformatics, would also not satisfy this requirement.[268] However because usefulness is not examined, this requirement has little practical scope for limiting gene patents.

2.7 Contrary To Morality

While an invention might satisfy these four main patent requirements, the Commissioner of Patents or a court can refuse to grant a patent if the use of the invention is contrary to morality.[269] Only the use of the invention, not the grant of the patent monopoly itself, can be considered.[270] Thus many of the concerns mentioned in chapter 1 about the effects of granting gene patents in commodifying the human body or limiting an individual's autonomy cannot be considered because these are concerns with the grant of a patent monopoly rather than the use of the invention.

IPONZ has issued guidelines for deciding when a use will be contrary to morality.[271] These guidelines allow the Commissioner to take account of polls, concerns of interest groups, and also foreign legislation, cases and guidelines. These guidelines also set out a list of specific uses of specific subject matter, including human embryos and cells and tissues within a human, that would be considered contrary to morality.

However gene patents do not fall within these specific exclusions, and overseas case law has held that the use of gene patents is not be contrary to morality.[272] While it is improbable that the uses of patented genes in producing therapeutic proteins, diagnosing disease, and as research tools are contrary to morality, the use of patented genetic material in gene therapy can conflict with certain religious and cultural values and raise ethical concerns around eugenics and harm.[273] Religious and cultural objections are often based on the view that adding new genetic material (often including viral DNA) into an organism and altering that organism's genetics is "playing God" or interfering with the "life-force" or "nature" of the organism. Also, there is the fear that altering an individual's genetics is a form of

[268] *Eli Lilly v Human Genome Sciences Inc* [2010] EWCA Civ 33 at [157].
[269] Patents Act 1953, s 17(1).
[270] Ibid, see *Pfizer Inc v Commissioner of Patents*, above n 56, at [66].
[271] Intellectual Property Office of New Zealand "Raising Objections Under Section 17(1)" Practice Note 2009.
[272] C-377/98 *Kingdom of the Netherlands v European Parliament and Council* [2002] FSR 36 at [75].
[273] Kaini Mehrzad, Bazmi Shabnam and Sheikh Azadi Ardeshir "Gene Therapy, Ethical Considerations, Challenges and Solutions" (2010) 4 Medical Ethics 6

eugenics, and the harms of gene therapy might outweigh the possible benefits as some gene therapy trials in humans have caused cancer and even death and it is not clear if gene therapy is effective.[274] Thus the use of genetic material in gene therapy could be contrary to morality.

A possible guide to how IPONZ would determine whether to refuse a patent under s 17(1) of the Patents Act 1952 is *Wisconsin Alumni Research Foundation v The Commissioner of Patents*[275] *(WARF).* In *WARF,* the claimed invention was a method for differentiating embryonic stem cells into endothelial cells. The Assistant Commissioner held that this was not contrary to morality based on several factors. First, there was no "deeply rooted" belief against stem cell research in New Zealand. Secondly, there were other statutory controls on the use of stem cells in research and so the Assistant Commissioner held that where there are these statutory controls IPONZ should not also try to regulate the use of stem cells."[276] Finally, when assessing the application the benefit of any doubt must be given to the applicant.[277] As this claim was not clearly contrary to morality the Assistant Commissioner held that this application should be allowed to proceed.

This general approach to morality is significant for gene therapy. First, it is not clear if New Zealanders are opposed to gene therapy, as it has already been used in New Zealand. Secondly, the use of gene therapy is regulated by statute[278] and can only be permitted by the Genetic Technology Advisory Committee.[279] Giving the benefit of any doubt to the applicant, means that because there are these other controls and no clear societal position on the morality of gene therapy it is unlikely that a patent over genetic material used in gene therapy would be refused under s 17(1) of the Patents Act 1953.

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[274] Erika Check "Gene Therapy: A Tragic Setback" (2002) 420 Nature 116 at 116. This is often due to the vectors that are used, and so there is research on what vectors do not have these detrimental effects.

[275] *Wisconsin Alumni Research Foundation v The Commissioner of Patents* [2007] NZIPOPAT 22 (20 August 2007).

[276] Ibid.

[277] Susy Frankel has attacked giving the benefit of any doubt to all requirements, pointing out that the source of this idea only applied the benefit of the doubt only to novelty and obviousness: Susy Frankel, above n 38, at 394-395.

[278] Medicines Act 1981, s 30.

[279] Health Research Council "Guidelines on Ethics in Health Research" (2002) at [4.11].

2.7 Conclusion

Inventive step (non-obviousness) is the "requirement which will do most to retain genetic patenting within acceptable bounds."[280] However, under the Patents Act 1953 this is not examined prior to grant. Instead the requirements of patentable subject matter and novelty, which are examined, supposedly act as the gatekeepers to valid patents but they fail to do this. IPONZ currently treats isolated and purified DNA as a manner of manufacture, but this fails to take into account the dual nature of DNA. What is essentially being patented is the information coded by the DNA sequence and this is an unpatentable discovery. However, because there has been no judicial decisions, IPONZ continues to grant patents over isolated and purified genetic material.[281] Because patents are being granted over discoveries which are often obvious, these patents "represent dead weight costs to the economy that serve only to suppress competition and stifle progress."[282]

The problems with the limited examination prior to grant are compounded by the examiner giving the applicant the benefit of any doubt for whether an application satisfies these requirements. Thus, only alleged inventions that clearly do not satisfy the patent requirements will not be granted a patent. Because of this, as well as the limited grounds, the forum for testing whether a patent is valid is not examination or opposition but revocation.[283] Revocation is costly and it will normally be used only in cases where the benefit of getting a patent revoked outweighs the cost of the proceedings. This allows many patents to be granted for products or processes that might not be valid, like GTG's patents over non-coding DNA.

Finally, s 17(1) of the Patents Act 1953 excludes many legitimate moral concerns. Only the use of the invention can be challenged, which does not allow broader moral concerns relating to the grant of the monopoly over genetic material including infringing human dignity or restricting autonomy to be listened to.[284] Instead, the public's only recourse is

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[280] John Smillie, above n 64, at 215.
[281] Appendix.
[282] Ministry of Economic Development, above n 5, at 6.
[283] *Saxpak Foods Ltd v J Wattie Canneries Ltd* HC Wellington M 454/85, 11 July 1988, 11 July 1988 at 8–9; *Assa Abloy New Zealand Ltd v Aluminium Systems NZ Ltd* HC Wellington CIV-2010-484-2, 7 March 2011 at [6].
[284] ER Gold and TA Caulfield "The Moral Tollbooth: A Method That Makes Use of the Patent System To Address Ethical Concerns In Biotechnology" (2002) 359 Lancet 2268.

relying on Parliament.[285] Judging from the slow progress of the Patents Bill,[286] this reliance is not well placed.

Gene patenting exposes deficiencies in the Patents Act 1953. While the New Zealand patent system is based on ensuring that patents are only granted for things that are in the overall best interest of society, the Patents Act 1953 fails to do this in relation to modern technology, especially genetics. In patenting genes, IPONZ is stretching the concept of manner of manufacture to include what is essentially information which has several negative effects, as discussed earlier. Before IPONZ and the courts decide to extend patentability to new and controversial types of subject matter, they need to assess whether these are in the public's overall best interests.[287] This is because, once granted, the Patents Act 1953 fails, in practice, to provide adequate avenues to challenge these monopolies, or to give voice to the unique moral and public policy concerns that patenting DNA raise.

[285] Under s 41 of the Patents Act 1953, revocation proceedings can be brought by "any person interested".
[286] Patents Bill 2008 (235-2).
[287] John Smillie, above n 64, at 234.

Chapter Three | Will The Patents Bill Address the Problems Exposed By Gene Patents?

3.1 Reforming the Patent System

Gene patenting exposes significant defects in New Zealand's patent system.. The Patents Act 1953 is out of step with international patent law[288] and is "in need of a substantial overhaul."[289] The Patents Bill[290] is Parliament's attempt at this overhaul. The Bill, if enacted, will significantly revamp the patent system by changing the substance of some patent requirements, as well as increasing the scrutiny provided by the examination process. In this chapter I examine whether these proposed changes will fix the problems that gene patenting exposes.

3.2 Changes

Under the Patents Bill, only patentable inventions can be patented.[291] Clause 13 defines a patentable invention as:

1. A manner of manufacture within s 6 of the Statute of Monopolies; that
2. Is novel
3. Involves an inventive step
4. Is useful; and
5. Is not excluded under cls 14 (contrary to morality or public order) and 15 (specific exclusions).

A patent can only be granted if all five requirements are satisfied.[292] This moves the assessment of the validity of all patent requirements forward from revocation proceedings to the examination of the patent application. The Patents Bill also increases the examination standard. No longer will the applicant receive the benefit of any doubt. Instead, the examiner must be satisfied on the "balance of probabilities" that an application fulfils the

[288] Ministry of Economic Development, above n 5, at 10.
[289] Ibid, at 1.
[290] Patents Bill 2008 (235-2). Currently it is waiting for its second reading, and is 58th (out of 68) on the Government Order of Bills: "Order Paper" No 224 (15 September 2011). Possibly it is being delayed until the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is passed in Australia to ensure that the patent legislation is the same in New Zealand and Australia to further a joint examination system.
[291] Ibid, at cl 12.
[292] Ibid, at cls 13 and 60.

patent requirements.[293] In the following sections I will examine whether genetic material will satisfy each requirement.

3.2.1 Manner of Manufacture

Unlike the Patents Act 1953, the Patents Bill does not define invention. However, manner of manufacture is retained allowing IPONZ and the courts to apply existing case law. Therefore, as I argued in chapter 2, it is likely that IPONZ will continue to consider isolated and purified DNA a manner of manufacture. Given the generosity of courts in interpreting manner of manufacture, it is likely if the patentability of isolated DNA was challenged, the court could accept that it is a manner of manufacture.

3.2.2 Novelty

The definition of novelty is taken from the Patents Act 1977 (UK).[294] The only major change, is that novelty is assessed on a global standard rather than the current local standard, and the scope of the prior art is expanded to include what has been used or made available to the public by written or oral description.[295] However, even with broadening the prior art that is considered, novelty, as I argued in chapter 2, will not restrict granting patents over isolated DNA unless the DNA has previously been isolated and its function identified .

3.2.3 Inventive Step

Like novelty, the definition of inventive step[296] is borrowed from the Patents Act 1977 (UK).[297] Something "involves an inventive step if it is not obvious to a person skilled in the art," having regard to the prior art base.[298] Because inventive step will be assessed prior to grant, when coupled with the change in examination standard, this requirement will "reduce the likelihood that patents will be granted over generic material."[299] This is because most techniques for identifying and isolating DNA are routine and so DNA sequence identified using these techniques will be obvious. Examining for inventive step and the

[293] Ibid, at cl 60.
[294] Patents Act 1977 (UK), s 2.
[295] Patents Bill 2008 (235-2), cl 8.
[296] Ibid, cl 7.
[297] Patents Act 1977 (UK), s 3.
[298] Patents Bill 2008 (235-2), cl 7.
[299] Cabinet Paper, above n 89, at [24].

increased examination standard, is a positive change and will mean that New Zealand is not granting patents to obvious developments of technology that are not patentable elsewhere.

3.2.4 Usefulness

Usefulness is defined as requiring a "specific, credible, and substantial utility."[300] This definition is taken from the United States' patent guidelines for utility.[301] An invention will have "specific" utility if its use is clearly identified, not simply asserted. For example a claim over DNA used as a probe will not have specific utility. Only if the gene it probes for is identified, will it be specific.[302] A claimed utility will be "credible" unless the logic underlying the assertion is flawed or the facts are inconsistent with the assertion,[303] and it will be "substantial" if has a real world use.[304] This change will prevent non-coding DNA, unidentified probes, expressed sequence tags, or genes identified solely by bioinformatics from being patented because their exact function and use has not been identified. Therefore these types of genetic material lack specific and substantial utility.[305]

3.2.5 Exclusions From Patentability

Clauses 14 and 15 provide general and specific exclusions from what can be a patentable invention.[306] Both clauses are derived from Articles 27.2 and 27.3 of the TRIPS agreement.[307] Clause 14 allows a patent to be denied if the commercial exploitation of the invention would be contrary to public order or morality. Clause 15 sets out specific subject matter that is excluded from patentability. Both clauses mark a subtle yet significant change to patenting in New Zealand as public policy arguments are shifted from being part of the invention requirement[308] to a reason for not granting a patent.

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300 Patents Bill 2008 (235-2), cl 10.
301 United States Patent Office Utility Guidelines 66 FR 1092, 5 January 2001.
302 United States Patent and Trademark Office "Revised Interim Utility Guidelines Training Material" (1999) at 5.
303 *In re Fisher* 421 F 3d 1365 (Fed Cir 2005) at 1371.
304 Ibid.
305 Cabinet Paper, above n 89, at [24].
306 Patents Bill 2008 (235-2), cl 13(4).
307 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
308 Patents Act 1953, s 2 which incorporates s 6 Statute of Monopolies 1623.

(a) Clause 14: Public Order and Morality

Clause 14 excludes inventions whose commercial exploitation is contrary to morality or public order from being patented. Not granting patents on the basis of morality and public policy has been criticised on the basis that patents only control the commercial benefit not the actual development or use of the invention.[309] However, it is "disingenuous to view the patent system as some morally neutral form of state aid in recognition of the cleverness of inventors."[310] If it is accepted that patents are necessary for inventors to develop new technologies,[311] then the patent system is not neutral to technologies and should address whether to provide incentives for developing certain types of technology. The Patents Bill provides a mechanism for doing this in clauses 14 and 15. Clause 14 has three elements: the "commercial exploitation of the invention" has to be contrary to either "public order" or "morality".

(i) Commercial Exploitation

Under clause 14 of the Patents Bill, a patent can be withheld if the "commercial exploitation of the invention" is contrary to morality or public order. "Exploit" is defined in clause 17(2) as making, using, selling or otherwise disposing of the product or, if the invention is a process, doing the same to the products of the process. Because a patent monopoly restricts others from exploiting the invention, it could be argued that "commercial exploitation" includes the effects of restricting others from exploiting the invention. A similar argument was made under s 17(1) of the Patents Act 1953. in *Pfizer* it was argued that "use" of the invention included excluding others from using the invention. However the Court of Appeal stated that the focus must be "use of an invention ... rather than on the use of the patent."[312] Similarly, under the Patents Bill, the focus must be on the commercial exploitation of the invention. If not, then the courts would be rewriting the statutory wording of "commercial exploitation of the invention" to "commercial exploitation of the

[309] Donna M Gitter "Led Astray By The Moral Compass: Incorporating Morality Into European Union Biotechnology Patent Law" (2001) 19 Berkeley J Int'l L 1 at 13;Organisation for Economic Co-Operation and Development, above n 5, at 45.

[310] William Cornish, David Llewelyn and Tanya Aplin, above n 61, at 928-929.

[311] This is the whole argument for the patent system in the first place. If this is denied then the justification for granting patents is reduced. See chapter 2.

[312] *Pfizer Inc v Commissioner of Patents*, above n 56, at [66].

patent".[313] Therefore the commercial exploitation of the invention does not include the effects of granting a patent monopoly but is restricted to making, using, selling or otherwise disposing of the invention.

Because "Commercial exploitation of the invention" is broader than "use", as it includes the making of the invention, it provides a greater scope for moral arguments in patent law compared to the Patents Act 1953. The *WARF* decision illustrates this point. In *WARF*, the Assistant Commissioner held that a process for differentiating stem cells into endothelial cells was not contrary to morality. While making this invention necessarily involved creating and destroying embryos, this was not a "use" of the invention and so could not be considered under s 17(1) of the Patents Act 1953. However, under clause 14 of the Patents Bill, the destruction of embryos could be assessed as this would be a "commercial exploitation" of the invention.

While commercial exploitation increases the scope for moral arguments upon which a patent can be denied, it decreases the scope for public policy arguments. Under the Patents Act 1953, if the grant of the patent would be (clearly)[314] contrary to the overall public interest a patent must be withheld.[315] Commercial exploitation does not extend to the grant of the patent.[316] Thus public policy arguments based on the effects of granting a patent monopoly will be excluded. Many of the arguments against gene patenting, outlined in chapter 1 and discussed in chapter 2 will be automatically excluded from being considered.

(ii) Contrary to the Public Order

Public order has the same meaning as *ordre public* in Article 27.2 of the TRIPS agreement.[317] This does not provide any real guidance as there has been no WTO decisions on the meaning of *ordre public* which is probably because there is "no generally accepted standard of '*ordre public*'."[318] In Europe, the EPO has interpreted *ordre public* narrowly to only prevent patenting inventions where "it is probable that the public in general would regard

[313] T1213/05 *Breast and Ovarian Cancer/University of Utah Research Foundation*, above n 101, at [53].
[314] See the discussion in chapter 2 about generally inconvenient.
[315] Patents Act 1953, s 2.
[316] Patents Bill 2008 (235-2), cl 17(1). In T1213/05 *Breast and Ovarian Cancer/University of Utah Research Foundation*, above n 101, at [53].
[317] Patents Bill 2008 (235-2), cl 14(1)(a).
[318] UNCTAD-ICTSD *Resource Book on TRIPS and Development* (Cambridge University Press, Cambridge, 2005) at 379.

the invention as so abhorrent that the grant of patent rights would be inconceivable."[319] In determining this, the EPO Board of Appeals has adopted a utilitarian test for whether the invention benefits society. In *HARVARD/Oncomouse*,[320] the Board held that the benefits to society of a transgenic mouse with a predisposition to cancer, outweighed the suffering of that mouse and so was not contrary to *ordre public*. Further, any public order arguments must be based on evidence rather than assertion.[321] This approach means that public order has a relatively restricted role in excluding patents[322] and will be "invoked only in rare and extreme cases."[323]

Because there is no commonly accepted definition of "*ordre public*", there is "no reason for other WTO members to follow the European approach."[324] The Select Committee supports IPONZ in creating their own guidelines, with reference to the examples set out in clause 14 which are drawn from the Biotechnology Directive.[325] In doing so, IPONZ could adopt a broader approach to public order that encompasses other public policy considerations or a different standard than a utilitarian test.

Even if IPONZ or the courts adopted a broad approach to public order, making, using or selling isolated DNA does not normally raise public policy concerns. Because "commercial exploitation does not include the monopoly effects, then many of the concerns discussed in chapters 1 and 2 cannot be raised. Therefore it is extremely unlikely that genetic inventions will not be granted a patent for being contrary to public order.

(iii) Contrary to Morality

Unlike public order, morality is not defined in the Patents Bill.[326] However, clause 14 provides examples of inventions that would be contrary to public order or morality as guidance including processes for cloning human beings or modifying the germ line genetic identity of humans. Ultimately, deciding whether the commercial exploitation of an

[319] EPO, Guidelines for Examination in the EPO, Part C, Chapter IV, 4.1.
[320] T 19/90 *HARVARD/Oncomouse* [1990] OJ EPO 476.
[321] Ibid; T 0356/93 *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] OJ EPO 545 at {18.6]
[322] Donna Dickenson "Patently Paradoxical? 'Public Order' and Gentic Patents" (2004) 5 Nature Rev Genetics 86 at 86.
[323] Ibid.
[324] UNCTAD-ICTSD, above n 317, at 379.
[325] Patents Bill 2008 (234-2) (select committee report) at 5.
[326] Ibid.

invention is contrary to morality continues to be left to the Commissioner and the courts to decide guided by these examples. While it is not certain how either the courts or IPONZ would interpret this provision,[327] an indication for how IPONZ might assess morality under the Patents Bill is provided by IPONZ's most recent Practice Note on the application of s17(1).[328]

Under the 2009 Practice Note, the use of an invention will be contrary to morality if "New Zealand Society as a whole or ... a significant section of the community" considers it to be.[329] By focussing on what society, or a significant segment of it, considers to be contrary to morality, rather than on what "is" contrary to morality avoids the problem of an examiner or the courts having to apply a personal morality or "define ... the basic values of society."[330] Instead, the guidelines provide objective sources including public polls, research, concerns of interests groups, corresponding foreign legislation, case law and guidelines that the examiner can refer to in determining whether society views the commercial exploitation as contrary to morality.[331]

If the Patents Bill is enacted, there should be two changes to the Practice Note. The first is necessitated by clause 14 and would require the Practice Note to focus on the commercial exploitation rather than just the use. The second change should be removing reference to foreign case law and guidelines. The question is what New Zealand society, or a significant sector of the community considers to be contrary to morality, not what other societies do.

In addition to these criteria, clause 14(3) of the Patents Bill allows the Commissioner to consult with anyone the Commissioner considers appropriate. This could include relevant ethics committees (like the Health Research Council's Ethics Committee) to determine if something was contrary to morality.[332] Unfortunately the Bioethics Council, which the Royal

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[327] Ibid.
[328] Intellectual Property Office of New Zealand "Raising Objections Under Section 17(1)" Practice Note 2009.
[329] Ibid.
[330] Organisation for Economic Co-Operation and Development, above n 5, at 45; Similar criticisms are raised in *Diamond v Chakrabarty*, above n 114, at 317; *Bristol-Myers Squibb v FH Faulding & Co Ltd* (2000) 46 IPR 553 (FCA) at 586.
[331] Intellectual Property Office of New Zealand "Raising Objections Under Section 17(1)" Practice Note 2008; Intellectual Property Office of New Zealand, above n 327.
[332] Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 281-282.

Commission on Genetic Modification recommended IPONZ should consult on ethical issues, has been disbanded. [333]

One remaining problem with the standard outlined in the 2009 Practice Note is that it is not entirely clear what a "significant sector of the community" means. Is this the majority of society, or is it certain significant sectors of the community, like Maori or certain religious groups?[334] I would suggest that under the Patents Bill this would need to be the majority of New Zealanders. This is for two reasons. The first is that the Patents Bill establishes a Maori Advisory Committee to give advice on patenting inventions derived from traditional knowledge and native flora and fauna (discussed below). In doing so, Parliament has indicated that in relation to these forms of inventions Maori views are especially important, but in relation to other inventions Maori concerns are not privileged.[335] This seems to be the view of IPONZ. In 2008, IPONZ issued the 2008 Practice Note on the application of s 17(1)[336] which specifically mentioned Maori as a significant sector of society, however the 2009 Practice Note removed reference to Maori. The second reason is that under the Patents Bill all requirements are assessed on the balance of probabilities. This would imply that the majority (but not the clear consensus as the Assistant Commissioner held in *WARF*) of New Zealanders view the commercial exploitation as contrary to morality to satisfy the balance of probabilities. This would accord with the utilitarian justification of the New Zealand patent system which is intended to promote the overall public's best interests.

If a Practice Note on morality similar to the 2009 Practice Note is issued by IPONZ it is likely that morality would have some real force in the patent system. With the Patents Bill broadening the actions that are examined to include the making of the invention and increasing the standard of examination to the balance of probabilities, the Practice Note would provide a clearer test of what would be contrary to morality. In relation to genetic material, while patenting the genetic material itself would not be contrary to morality, some uses of the genetic material could be excluded. For instance a method, which involves incorporating human genes into an animal embryo or a method for altering the somatic line

[333] Ibid.
[334] Maori make up roughly 15% of New Zealand's population.
[335] To support this it could be pointed out that s 17(1)(c) of the Trade Marks Act 2002 specifically mentions Maori as a significant sector of the community. Clause 14 of the Patents Bill does not mention Maori.
[336] Intellectual Property Office of New Zealand "Raising Objections Under Section 17(1)" Practice Note 2008.

of a human cell (as is done in adult gene therapy) could be held to be objectionable to a significant section of New Zealand. However, the actual genetic material could still be patented if there was another use for it. Thus, under clause 14 of the Patents Bill, patents could only be granted where society was comfortable with the commercial exploitation of the invention and some specific processes using genetic material could be excluded.

(iv) Morality and Maori Values

The Patents Bill also requires the Commissioner to set up a Maori Advisory Committee.[337] This addresses the concerns raised by the Royal Commission on Genetic Modification and the Waitangi Tribunal about IPONZ's failure to consult with Maori.[338] This Committee is supposed to advise the Commissioner, if asked, whether an invention is derived from Maori traditional knowledge or indigenous plants or animals,[339] and if so, whether the commercial exploitation of that invention is likely to be contrary to Maori values.[340] If the Commissioner seeks the Committee's view on these issues, he or she must consider this advice but is not bound by it.[341] This is quite a limited role for the Committee.

Outside of this limited role, it is difficult to see how Maori values could be factored into the patent system given the utilitarian basis of the patent system in New Zealand.[342] Maori have a different worldview from the dominant European worldview causing a "clash of cultures".[343] This is especially true in relation to genetics. Maori values include whakapapa (genealogy in relation to humans, and habitat and morphology in relation to plants and animals),[344] and mauri (life-essence).[345] In relation to both, many Maori view it as wrong to interfere with an organism's genetics.[346] This is because it interferes with the genealogy and

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[337] Patents Bill 2008 (235-2), cl 275(1).
[338] Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 287; Waitangi Tribunal "Ko Aotearoa Tenei: a report into claims concerning New Zealand law and policy affecting Maori culture and identity" (Legislation Direct, Wellington, 2011).
[339] Ibid, cl 276(a).
[340] Ibid, cl 276(b).
[341] Ibid, cl 277.
[342] For more information see Putahi Associates Ltd *Patenting of Biotechnological Inventions* (prepared for the Ministry of Commerce, 1999).
[343] Roma Mere Roberts "Walking Backwards Into the Future: Maori Views on Genetically Modified Organisms" <http://www.win-hec.org/docs/pdfs/Journal/Mere%20Roberts.pdf> at 2.
[344] Ibid, at 3.
[345] Ibid, at 4.
[346] Ibid.

morphology, and mixing life-essences is detrimental.[347] The commercial exploitation of gene patents, in relation to producing therapeutic proteins and in gene therapy, often involves using these inventions to modify an organism's genome by adding genetic material.[348] Thus they would be contrary to Maori morality.[349]

However, as I argued above, clause 14 only allows a patent to be denied if the majority of New Zealand society views the making, using, selling or otherwise disposing of an invention as contrary to morality or public order. While Maori make up roughly 15% of New Zealand's population, even if all Maori viewed a specific use like inserting human genes into cows as contrary to morality, this would still not be sufficient. Thus in practice, except for limited situations involving traditional knowledge and indigenous flora and fauna, Maori views will have little impact on whether a patent is granted or not.

(b) Clause 15: Specific Exclusions

While clause 14 provides generalised grounds to exclude certain things, clause 15 sets out specific subject matter that is explicitly excluded. This subject matter includes human beings, biological processes for generating humans,[350] and methods of treatment or diagnosis practised on humans.[351] These specific exclusions are unlikely to affect gene patents as once isolated and purified, genes are viewed as distinct from a human and so the human being is not being patented nor is the diagnosis being practiced on humans. While no patents over genetic material per se are specifically excluded, some uses of the genetic material might be excluded from patentability. The use of genetic material in a gene therapy can be excluded as this is a method of treatment of human beings by therapy.[352] Thus clause 15 simply excludes some uses of gene patents, but not gene patents themselves.

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[347] Ibid.

[348] In producing a protein, recombinant DNA technology is used to insert the coding sequence into the expressing organism. In gene therapy, often viral vectors are required to carry and insert the genetic information.

[349] Ministry of Economic Development, above n 5, at 23.

[350] Patents Bill 2008 (235-2), cl 15(1).

[351] Ibid, cl 15(3).

[352] Patents Bill 2008 (235-2), cl 15(2).

3.3 Remaining Problems and Possible Reforms

While the Patents Bill addresses many of the issues that granting patents over genetic material exposes in the current patent system, there are two weaknesses with the Bill. The first is that manner of manufacture can be interpreted to include isolated and purified genetic material, whereas it is a properly characterised as a discovery. The second weakness is that clause 14 only focuses on the commercial exploitation of the invention. Therefore, whether the grant of the patent is in the public's best interest is cannot be considered. Instead, these concerns will be left to Parliament. While some might view this a good thing, it means that patents might be granted for inventions which do not benefit society due to the restrictions on the availability and use that they create.

In relation to the first issue of isolated and purified DNA possibly being considered a manner of manufacture, clause 15 of the Patents Bill could be amended to explicitly prohibit patents over "genetic material that is isolated and purified from a natural organism". This would prohibit patents being granted for discoveries, but could allow genetic material that is modified to be patented. This exclusion would not conflict with New Zealand's international obligations in Article 27.1 of the TRIPS Agreement, because Article 27.1 of the TRIPS Agreement only applies to inventions, whereas isolated DNA from a natural source is a discovery.

However, this statutory change is unlikely to happen. This is for three reasons. First, issues relating to gene patenting have discussed and Parliament has chosen not to exclude isolated DNA. Secondly, gene patents has dramatically decreased (see Appendix) and so in practical terms, there is no real need to specifically exclude them. Thirdly, examining an application for whether the subject matter involves an inventive step will "reduce the likelihood that patents will be granted over generic material."[353] Therefore, in practical terms there is no need to modify the Patents Bill to specifically exclude some forms of gene patents.

Restricting the scope of public policy and morality arguments to the commercial exploitation of an invention is less easily resolved. This is copied from Article 27.1 of the TRIPS Agreement. Properly interpreted, this provision only extends to the making, using, selling or otherwise disposing of an invention and not to the effects of granting a patent monopoly

[353] Cabinet Paper, above n 89, at [24].

over an invention. In relation to new technologies, the ability to consider the overall effects of granting a patent monopoly is essential. However, the Patents Bill does not provide a mechanism for doing this and instead this is left to Parliament.

Conclusion

It is now thirty years since the first gene patent was granted. Despite this passage of time, gene patenting is one of the most controversial issues in patent law. This is because patent law struggles with applying legal concepts like manner of manufacture to isolated DNA which is a molecule that encodes information. In addition to stretching these legal concepts, patenting genetic material raises unique moral, social and economic issues that the patent system is not particularly well-equipped to deal with.

Gene patenting exposes some serious defects in the Patents Act 1953. The major defect is in how patent applications are examined. Patent applications are only examined for being patentable subject matter and novel, but not for involving an inventive step or being useful. Further, the benefit of any doubt is given to the applicants. This examination process fails to ensure that patent monopolies are only granted for genuine innovations rather than obvious developments or developments that lack any real use. Secondly, the public policy and moral issues surrounding the effects of granting a monopoly over DNA, have not been adequately addressed by either IPONZ or the courts. These effects could have been avoided, or at least alleviated, if IPONZ had properly characterised isolated and purified DNA as an unpatentable discovery rather than a manner of manufacture. DNA is a molecule that encodes information and it is this information that is being patented. This information is simply information about the natural world and as such is an unpatentable discovery.

The Patents Bill will remedy most of these defects exposed by gene patents. First, the Patents Bill will provide a more rigorous examination procedure with all patent requirements examined. Examining for inventive step and usefulness prior to grant will significantly reduce the likelihood of a patent being granted over isolated DNA. This is a positive change and will remedy the mischaracterisation of isolated DNA as a manner of manufacture. Secondly, the Patents Bill requires that the moral and public policy concerns surrounding the exploitation of an invention will be examined before a patent is granted. However, moral and public policy concerns relating to the grant of the monopoly cannot be considered. Instead these concerns will be left to Parliament to deal with.

How a patent system deals with genetic material provides a good test of the patent system's ability to deal with new technologies. As technologies continue to develop it is important that patent law continues to evolve to ensure that only innovations that are in the public's overall best interest are granted a patent monopoly. Gene patenting has shown that the Patents Act 1953 no longer does this. The Patents Bill promises to be able to do this and so it is my hope that the Patents Bill will be enacted soon.

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Appendix | Patent Applications For Genetic Material Filed And Registered With IPONZ

The following classes of patents were referred to by NZIPA in the Royal Commission on Genetic Modification as dealing with gene patents.[354] While these are not all genetic related patents, they do cover many gene patents.

The classes are:[355]

Class Number	Class Description
C12N5/10 538	Cells modified by introduction of foreign genetic material, eg virus transformed cells
C12N15/00 580	Mutation or genetic engineering; DNA or RNA concerning genetic engineering vectors, eg plasmids, or their isolation, preparation or purification; use of hosts therefore
C12N15/12 405	Genes encoding animal proteins
C12N15/29 137	Genes encoding plant proteins
A61K48/00 228	Medicinal preparation containing genetic material which is inserted into cells of the living body to treat genetic diseases; gene therapy

Figure 1 shows the number of filed patent applications per class over the last 10 years.

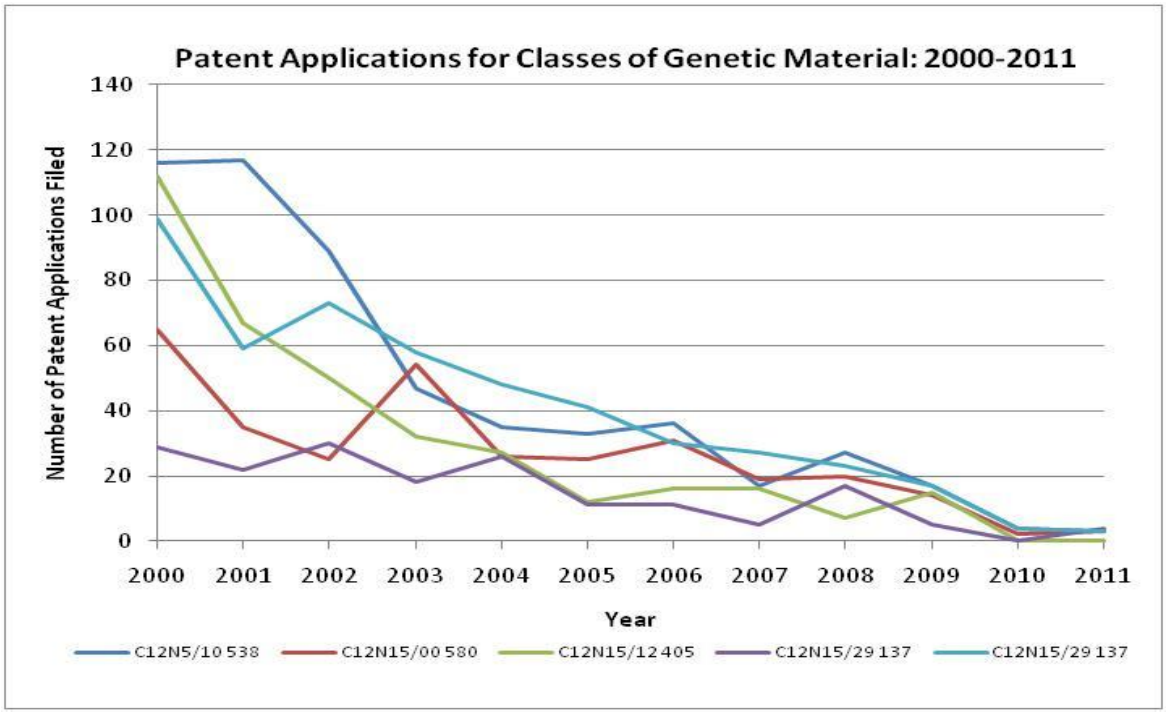

Figure 1: Patent Applications For Class Numbers: This shows that the numbers of patent applications have decreased dramatically over the last 10 years. This could be in part due to the publication of genomes, especially the human genome, or that the SNP Consortium has published many single nucleotide polymorphisms (SNPs).[356]

[354] Thomas Eichelbaum, Jean Fleming, Jacqueline Allan and Richard Randerson, above n 183, at 280.
[355] Ibid.
[356] E. Marshall "Drug Firms to Create Database of Genetic Mutations" (1999) 284 Science 406.

Figure 2 shows the number of patent applications by class registered from 1975–2010.

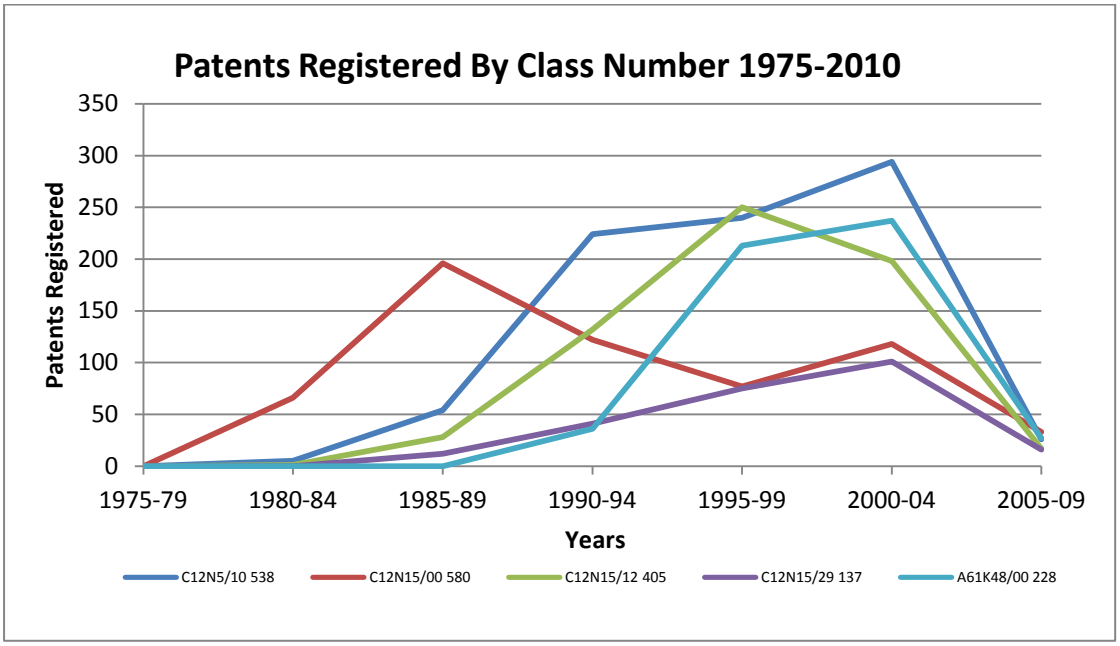

Figure 2: Patents Registered By Class Number. This shows the number of patents registered over the period of 1975-2010. There is a rise in most classes, but at 2000-2004 there is a dramatic drop. This is probably in relation to the human genome being published in 2001.[357]

Figure 3 shows the number of patent applications filed against registered from 1975–2010.

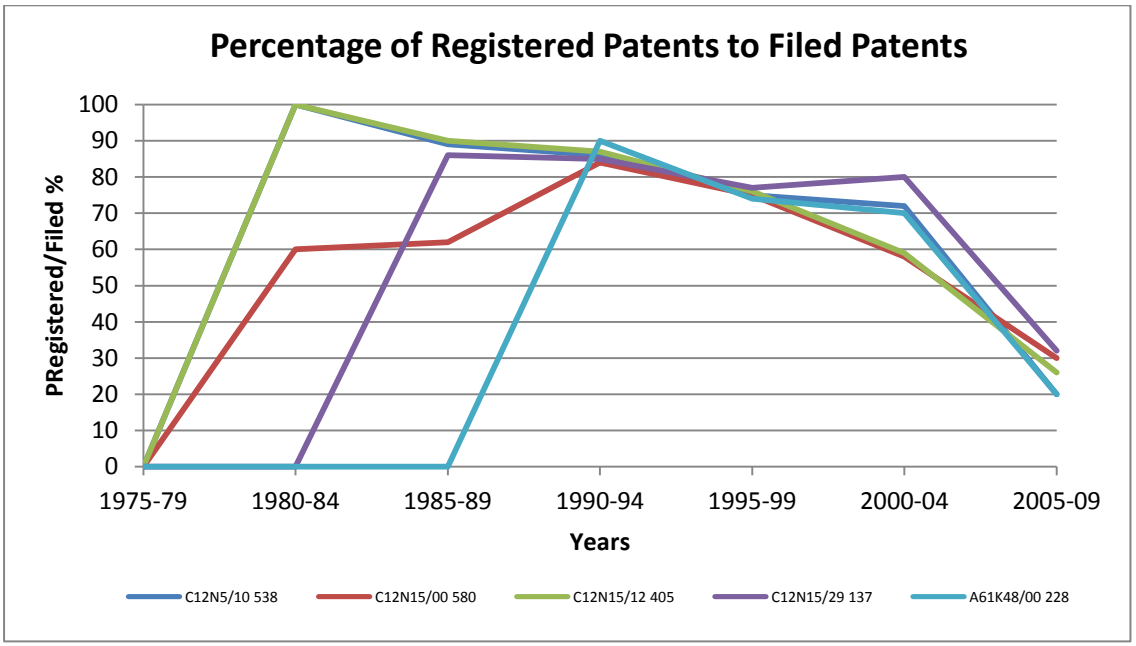

Figure 3: Patents Registered/Filed By Class Number. This shows that the number of patent applications filed that were accepted and registered was initially quite high, but since 2000 the number of patents being filed that finally get registered has dropped considerably. Exactly what has caused this is not clear, however it could be related to publications of human gene sequences, or more stringent examination of patent requirements.

[357] J Craig Venter et al "The Sequence of the Human Genome" (2001) 291 Science 1304; International Human Genome Sequencing Consortium "Initial Sequencing And Analysis of the Human Genome" (2001) 409 Nature 860.

Data Obtained From Searchers of IPONZ Database For Each Class Number:

Patents Filed

	1975-79	1980-84	1985-89	1990-94	1995-99	2000-04	2005-09
C12N5/10 538	0	5	61	256	318	404	130
C12N15/00 580	0	110	316	146	102	205	109
C12N15/12 405	0	1	31	151	331	288	66
C12N15/29 137	0	0	14	48	97	125	49
A61K48/00 228	0	0	0	40	287	337	138

Patents Registered

	1975-79	1980-84	1985-89	1990-94	1995-99	2000-04	2005-09
C12N5/10 538	0	5	54	224	240	294	26
C12N15/00 580	0	66	196	122	77	118	33
C12N15/12 405	0	1	28	132	250	198	17
C12N15/29 137	0	0	12	41	75	101	16
A61K48/00 228	0	0	0	36	213	237	27

Filed/Registered

	1975-79	1980-84	1985-89	1990-94	1995-99	2000-04	2005-09
C12N5/10 538	0	100	89	86	75	72	20
C12N15/00 580	0	60	62	84	75	58	30
C12N15/12 405	0	100	90	87	76	59	26
C12N15/29 137	0	0	86	85	77	80	32
A61K48/00 228	0	0	0	90	74	70	20

Patents Filed Per Class Number From 2000-2011

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011*
C12N5/10 538	116	117	89	47	35	33	36	17	27	17	4	3
C12N15/00 580	65	35	25	54	26	25	31	19	20	14	2	3
C12N15/12 405	112	67	50	32	27	12	16	16	7	15	0	0
C12N15/29 137	29	22	30	18	26	11	11	5	17	5	0	4
A61K48/00 228	99	59	73	58	48	41	30	27	23	17	4	3

*At the time of research there was still 4 months left in 2011, so this is not complete.