

Patenting DNA and Amino Acid Sequences - An Australian Perspective

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I. Introduction

In the clear brilliant waters of the Great Barrier Reef lies a humble cone shell, *Conus magus*. Its colourful shell disguises a more sinister purpose. As an unsuspecting fish floats past, it is suddenly dealt a deadly blow. The proboscis of the shell fires like a miniature harpoon, delivering a fatal dose of neurotoxin.¹ The lethal weapon of this cone shell did not go undetected. A group of scientists from Utah² soon recognised its potential: a precursor for drugs that control pain and inflammation, and a possible treatment for schizophrenia and epilepsy. Unbeknown to that tiny marine snail, the small peptides which form its neurotoxin,³ peptides it had used for thousands of years, were recognised as an invention by the United States Patent Office.⁴ Despite being native only to the Indo-Pacific, it is a group in the United States that has been granted an exclusive monopoly over the conotoxins that are produced by that inconspicuous cone shell. It is one of several conotoxins, native to Australian waters, but patented by groups in the other countries. As scientists, pressured by commercial agendas, frantically patent new amino acid and gene sequences, we need to stop, think and reflect. Are gene and amino acid sequences really inventions? Will such patent grants restrict future research? Does the patenting of gene sequences encourage exploitation of other countries' genetic resources? Will the horrors of colonialism in the last millennium be replaced with biocolonialism in this one? Is the human genome destined to be "owned" by a group of large transnational corporations? In short, should we patent the building blocks of life?

This paper focuses on the patentability of genetic sequences, primarily from an Australian perspective. Part II of the paper canvasses the arguments both for and

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¹These neurotoxins are known as conotoxins or conotokins.

²This group is lead by Baldomero Olivera. See V.D. Monje *et al.*, "A new *Conus* Peptide Ligand for Ca Channel Subtypes" (1993) 32:11 *Neuropharmacology* 1141; B.M. Olivera *et al.*, "Diversity of *Conus* Neuropeptides" (1990) 249 *Science* 257-263; B.M. Olivera *et al.*, "Conotoxins" (1991) 266 *J.Biol.Chem.* 22067-22070.

³Omega conotoxins subtypes MVIIC and MVIID. A close relative, omega conotoxin MVIIA also found in *Conus magus*, is currently being trialed by Neurex Corporation to treat neurogenic pain. Code named SNX-111 it is said to be 100-1000 times more powerful than morphine, but lacks the addictive qualities. The amino acid sequence for omega conotoxin MVIIA has not been patented.

⁴U.S. Patent 5591821. This patent is in respect to a number of omega conotoxins, specifically MVIIC and MVIID.

against the patenting of gene sequences. Following an assessment of these arguments, Part III of this paper turns to the relevant patent law in Australia, analysing the legal requirements to patent genes. Part IV briefly compares Australia's stance on the patentability of genetic sequences with the USA, Canada and Europe. Finally, Part V evaluates some recent recommendations and policy options for the future regulation of patents on gene sequences. The scope of this paper has been extended to amino acid sequences because they are biologically closely linked to DNA sequences and because many of the arguments and the law which are applicable to patenting DNA sequences also apply to amino acid sequences.⁵ However, the primary focus of the paper remains DNA sequences.

It is the thesis of this paper that the threshold for patenting gene and amino acid sequences has been set too low, that more often than not the determination of a gene or amino acid sequence alone amounts to a mere discovery and that the process of doing so is often obvious to a person skilled in the art of molecular biology. It is further argued that the current patent framework fails to take into account ethical and policy considerations, and that broad patent grants on gene sequences threatens to inhibit future scientific research. The author advocates international guidelines which limit gene patents based on utility in conjunction with the recognition of the human genome as falling within the Common Heritage Principle.

II. Should Sequences be Patentable?

1. Arguments in Favour of Patenting Genes

a) Genetic patents are an incentive for innovation

The primary argument in favour of patenting is that patents provide an incentive for research and development. This was most eloquently explained in the preamble to the 1474 Venetian Statute, the origin of modern patent law, which states:

We have among us men of great genius, apt to invent and discover ingenious devices..... Now, if such provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventors' honour away, more men would then apply their genius, would discover, and would build devices of great utility to our commonwealth.⁶

⁵In addition, there are also instances when patents have been granted over amino acid sequences, but not DNA sequences, as is the case with conotoxins.

⁶Quoted in F.M. Scherer, *The Economic Effects of Compulsory Licensing* (New York: New York Graduate School of Business Administration, 1977) at 4.

Within the context of biotechnology, proponents in favour of patenting genetic sequences argue that patents facilitate scientific research by encouraging investment in what would otherwise be a risky and financially unrewarding industry. They argue that the financial investment in research, secured by a patent, results in the development of new drugs and treatment, which in turn benefits humanity in general.⁷ Furthermore, it has been argued that it would be fundamentally unfair to require researchers and investors to expend vast resources, publicise results, and provide benefit to the public without the guarantee of a potential return on their investment.⁸

b) Patents encourage dissemination of scientific research

A requirement of a patent application is that the details of the invention must be fully disclosed. Those in favour of gene patents argue that, through this requirement of full disclosure, other researchers are alerted to the invention, thus avoiding unnecessary duplication of research effort,⁹ thereby facilitating research in emerging fields. It has been argued that denying genetic patents would invariably mean that companies wishing to use their knowledge to create products would resort to trade secrecy. This, in turn, would slow research development, with inventors and academics withholding knowledge and delaying the release of drugs, to the detriment of the community in general.

2. Arguments Against Patenting Genes

a) Humans are the invention of God, not man

Religious groups have objected to the patenting of gene sequences on ethical grounds. A coalition representing more than eighty faiths and denominations including Catholics, Evangelicals, Protestants, Jews, Muslims and Buddhists, have declared their opposition to the patenting of genetically engineered animals, humans, genes, cells and organs.¹⁰ They believe, that humans and animals are creations of God, not humans, and as such should not be patented as human inventions.¹¹ Patenting of genomic sequences, in their view, “represents the usurpation of the ownership rights of the sovereign of the universe.”¹²

⁷G. Poste, “The Case for Genomic Patenting” (1995) 378 *Nature* 536; B. Healy, “Special Report on Gene Patenting” (1992) 327:9 *N. Eng. J. Med.* 664 at 666.

⁸B. Looney, “Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement” (1994) 26 *L. & Pol’y Int’l Bus.* 231 at 240. See also P.A. Lacy, “Gene Patenting: Universal Heritage vs. Reward for Human Effort” (1998) 77 *Oregon L.Rev.* 783.

⁹D. Nicol, “Should Human Genes be Patentable Inventions Under Australian Patent Law?” (1996) 3 *J.L. & Med.* 231 at 232.

¹⁰R. Stone, “Religious Leaders Oppose Patenting Genes and Animals” (1995) 268 *Science* 1126.

¹¹K. Woodward, “Thou Shalt Not Patent!” *Newsweek* (29 May 1995) 68.

¹²Stone, *supra* note 10.

b) A violation of collective and individual privacy

It has been argued that the patenting of genes and gene sequences may interfere with privacy rights in that it permits an interference with a body part. It has been said that allowing ownership in our genome is akin to allowing ownership of another part of the human body such as an eye or nose.¹³ Advocates of this stance argue that genes are inextricably and intimately related to every person's physical body, as well as an individual's intellectual and emotional constitution. They are thus in a zone of privacy that may be violated by assignment of gene patent rights to others.¹⁴

c) Genetic information is the heritage of humanity

The most voiced argument against the patenting of human genetic sequences is that genes are a common, universal possession, representative of humankind's collective heritage,¹⁵ and thus not a subject matter for which individual intellectual property rights should be granted.¹⁶ It has been argued that gene patenting is ethically suspect as it concentrates genome benefits in those few countries and corporations fortunate enough to have the resources to obtain gene patents, when all humans should enjoy such benefits.¹⁷ In support of this argument proponents point to Article 27 of the *Universal Declaration on Human Rights*, which declares that each person in the world should share in the benefits of scientific advancement, and particularly in the "moral and material interests resulting from any scientific, literary or artistic production of which he is an author."¹⁸ In further support of this argument, advocates point towards the international collaboration in sequencing the human genome. That collaboration, it is argued, is reflective of the heritage we all share.

d) Gene patenting encourages biocolonialism

Those against gene patenting have argued that the ability to obtain proprietary rights in genetic information encourages biocolonialism, that is, the exploitation of the biological resources of other countries. This is a particular concern for Australia as it is considered a 'mega-diverse' nation with a wealth of natural resources and

¹³N. Gross & J. Carey, "Who Owns the Tree of Life?" (1996) 4 Bus. Wk. 194 at 196. See also M. L. Sturges, "Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind" (1997) 13 Am. U. Int'l L. Rev. 219 at 250.

¹⁴Looney, *supra* note 8 at 238.

¹⁵H. Curien, "The Human Genome Project and Patents" (1991) 254 Science 1710.

¹⁶Looney, *supra* note 8 at 234.

¹⁷*Ibid.* at 240.

¹⁸D. Macer, "Public Opinion on Gene Patents" (1992) 358 Nature 272. See also Looney, *supra* note 8 at 239.

vast genetic diversity.¹⁹ However, in most instances, biocolonialism arises with respect to third world countries who lack the financial and material resources to take advantage of their unique natural assets. Proponents of this argument point towards the attempt by the United States National Institute of Health to patent an unusual variant of HIV obtained from the Hagahai people of Papua New Guinea²⁰; a patent application by a group of German researchers for a different HIV variant obtained from an individual in Cameroon²¹; patents on conotoxins unique to the Indo-Pacific; and more recently a patent granted over a genetically engineered variant of southeast Asian Basmati rice.²² Such patents are viewed as an exploitation of the genetic resources of undeveloped countries, widening the gap between rich and poor. In support of this argument, advocates draw on Article 1 of the *Convention on Biological Diversity*²³ which states that: “the objectives of this Convention... are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.” The ability to patent gene sequences that are unique to another country is, according to this argument, an unfair and inequitable utilisation of genetic resources.

e) Gene patenting restricts scientific research

The Human Genome Organisation (HUGO) is concerned that attempts to patent random DNA sequences may have an inhibitory effect on research and should not be used in a way that may prevent others from following similar lines of research.²⁴ Similar concerns have been expressed by the pharmaceutical giant Merck,²⁵ which has stated that, “there is a real and legitimate concern that the patenting of the majority of human genes by private companies will significantly slow the development of novel therapeutics based on genetic information.”²⁶ A scientist, for instance, may be inhibited or discouraged from pursuing a course of research, or producing a related product, because of an existing patent right over a gene sequence.²⁷ Advocates of this argument also point towards the similarity

¹⁹Commonwealth Department of the Environment, *Australia: State of the Environment* (Canberra: Commonwealth of Australia, 1996) 4-30.

²⁰S. Gray, “Vampires Round the Campfire” (1997) 22:2 Alt. L.J. 60.

²¹Canadian patent application 2107732, “Retrovirus from the HIV Group and its Use.”

²²D. Wertz, “Controversial Attempts at Patenting” (1999) 3:2 The Gene Letter 1, online: <<http://www.geneletter.org>>.

²³*Convention on Biological Diversity*, 5 June 1992, Can. T.S. 1993 No. 24, 31 I.L.M. 818.

²⁴C. Caskey, “HUGO and Gene Patents” (1995) 375 Nature 351.

²⁵D. Dickson, “Open Access to Sequence Data will Boost the Hunt for Breast Cancer Gene” (1995) 378 Nature 425.

²⁶C.P. Austin & J.L. Tribble, “Gene Patents and Drug Development: The Perspective from Merck” in B. Knoppers, ed., *Human DNA: Law and Policy* (The Hague: Kluwer Law International, 1997) 381.

²⁷J. Mertz, “Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine” (1999) 45:3 Clin. Chem. 324; S. Bunk, “Researchers Feel Threatened by Disease Gene Patents” (1999) 13:20 The Scientist 7, online: <http://www.the-scientist.library.upenn.edu/yr1999/oct/bunk_p7_991011.html>.

between gene sequences in different species.²⁸ Because genetic materials reflect the accumulation of evolutionary changes in the genome, gene sequences in one organism are often the same in others.²⁹ As a result a patent on a human gene may also apply to a variety of animal and plant species, or vice versa. This further widens the scope for conflict between patent grants and research interests.

f) Gene patenting is not in the public interest

It has been argued that the monopoly provided by a gene patent comes at the cost of the community in general, as such patents may be used to prevent use of the new invention or other inventions based on gene sequences.³⁰ The Australian case of *Murex Diagnostics Australia Pty Ltd v. Chiron Corporation*³¹ illustrates this argument. This case involved a diagnostic test for Hepatitis C. Chiron Corporation developed and patented, in broad terms, a diagnostic test (including the gene sequence) for Hepatitis C strain 1a. Murex Australia independently developed a diagnostic test for a range of other Hepatitis C strains (2,3 and 5)³², strains which the Chiron test could not detect. Murex then brought an action against Chiron claiming that the original patent was invalid. Chiron cross-claimed for infringement of its pre-existing patent. The case was settled out of court, but illustrates the potential for conflict between the public interest and the patent holder when patents are granted on gene sequences. A decision in favour of Chiron upholding its patent grant would have prevented Murex selling its superior test kit, a kit which could detect additional strains of the Hepatitis C virus. The result would have been a less reliable blood supply, and unnecessary Hepatitis C infections³³ – a cost that could be measured not only in dollars, but also human lives.

g) Gene sequences are not inventions

The law will not grant a patent over a mere discovery. An invention is distinguished from a discovery because it is new and there is a degree of utility.³⁴ It has been argued that because genes are naturally occurring molecules, like oxygen or water, they are not inventions but mere discoveries. Likewise an isolated

²⁸C. Lawson & C. Pickering, "Patent Laws Undermine Access Provisions in the Environmental Protection and Biodiversity Conservation Bill 1998 (Cth)" (1998) 15:6 J.L. & Med 401 at 408.

²⁹C. Lawson, "Under-valuing Australia's Genetic Materials by Accepting Broad Claims in Patenting Genetic Materials Under the Patents Act 1990 (Cth)", submission to the Intellectual Property and Competition Review Committee of Australia at 53.

³⁰*Ibid.* at 10.

³¹Unreported case, Federal Court of Australia (NG380/1996).

³²These strains are prevalent in Australia but not in North America or Europe.

³³This case also illustrates the way in which patents over gene sequences can have a negative effect on scientific research. Following the patent grant to Chiron Corporation for Hepatitis C a number of laboratories discontinued their work on Hepatitis C, fearing they might be in breach of Chiron's patent grant.

³⁴J. Rudolph, *A Study of Issues Relating to the Patentability of Biotechnological Subject Matter* Intellectual Property Policy Directorate of Canada, (January 1996).

or cloned gene sequence is essentially the same as that found in nature,³⁵ and therefore is not an invention. The American College of Clinical Genetics in its position statement on patenting gene sequences states that genes “are naturally occurring substances that should not be patented.”³⁶ Put simply, “no scientist invented the human insulin gene.”³⁷

3. Assessment of Arguments

When assessing whether genes should be patented it is imperative to understand that a patent over a gene sequence does not equate to ownership of that sequence. A patent is a monopoly granted by the state allowing exclusive use of that invention for a set period of time – usually 20 years. It is more akin to a state sanctioned licence rather than an exclusive right of ownership. It is for this reason that statements such as “allowing private companies to own our genome is like allowing companies to own another part of the human body” or that patents over gene sequences “represent the usurpation of the ownership rights of the sovereign of the universe” carry little weight. Likewise the argument that the patenting of gene sequences somehow interferes with one’s privacy is not persuasive. Privacy is the ability to control personal information about oneself.³⁸ The patenting of the gene responsible for prostate cancer, for instance, does not in any way disclose or reveal any personal information about an individual.

There are compelling grounds for concluding that patent grants provide an incentive for investment in biotechnology.³⁹ Indeed many of the advances that humanity has made in the last century have been facilitated by the framework of patent law. Furthermore, the commercial incentive provided by a patent is becoming increasingly important as scientific research is funded more and more by private enterprise. Without patents, it is likely that the genomics industry would be less attractive for potential investors.⁴⁰ However, the argument that patenting encourages dissemination of scientific information has been, in the author’s opinion, overstated. More often than not, it is academic reputation that will spur a

³⁵C. Lawson, “Patenting Genetic Materials: Old Rules May be Restricting the Exploitation of a New Technology” (1999) 6 J.L. & Med 373 at 380; P. Drahos “Biotechnology Patents, Markets and Morality” (1999) 21:9 Euro. Intell. Prop. Rev. 441 at 443; J. Overhauser, “Intellectual Property and Genetic Testing: A Scientist’s Perspective” in M. Frankel & A. Teich, eds., *The Genetic Frontier: Ethics, Law and Policy* (American Association for the Advancement of Science, 1994) 209.

³⁶American College of Medical Genetics, “Position Statement on Gene Patents and Accessibility of Gene Testing,” online: < <http://www.faseb.org/genetics/acmg/pol-34.htm>>.

³⁷Smith & Hopen, “1998 Annual Meeting Debates Human Gene Patents: Promoting Innovation or Strangling Research” (16 November, 1999), online: <http://patent-trademark.net/News/biotechnology_news.htm>. Comment made by Professor King from Massachusetts Institute of Technology>.

³⁸For a discussion on the nature of privacy see M. Powers, “Privacy and the Control of Genetic Information” in Frankel & Teich, eds., *supra* note 35 at 77; T. Huff, “Thinking Clearly About Privacy” (1980) 55 Wash. L.Rev. 777.

³⁹Australian House of Representative Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory* (Canberra: AGPS, 1992) para. 7.113.

⁴⁰Lacy, *supra* note 8 at 803.

scientist to publish his results, which may on occasion even jeopardise a patent application.

A question that has caused considerable debate is whether gene sequences are inventions or discoveries. When exactly does a gene sequence transform from a discovery into an invention? This is a difficult question to answer. The law, as we shall see, has drawn a distinction between a sequence in its naturally occurring state and a sequence that is purified and isolated. The former is unpatentable because it is a mere discovery, while the latter, because it is an artificially created state of affairs, may be subject to a patent grant. It is the author's opinion, however, that the mere characterisation of a gene sequence is not sufficient to distinguish it from a discovery. A molecular biologist in determining a gene sequence is simply applying an established method to determine an existing state of affairs. Do I invent a planet simply because I now have a telescope which enables me to view it? In both instances, whether it be looking through a telescope or utilising a method to determine a gene sequence, I think one is doing nothing more than using an established means to uncover a preexisting state of nature, a mere discovery. In some circumstances it may take many years to accurately decode a sequence or characterise its function,⁴¹ or indeed years to locate that unknown planet, but that degree of human effort does not elevate a discovery into an invention. In the same way an astronomer cannot assert property rights over an undiscovered planet, I do not think a molecular biologist should be able to assert property rights over a gene sequence in such circumstances. Of course it is an entirely different matter if, in characterising a sequence, a scientist thinks up a new and non-obvious use for the genetic sequence, such as a diagnostic tool, in which case a sequence *may* represent an invention. Yet, without a specific degree of novel utility it is argued that inventions which comprise gene and amino acid sequences are mere discoveries.

One of the most compelling arguments against the patenting of gene and amino acid sequences is that patenting threatens to inhibit scientific research. Patent grants on the basic tools of molecular biology such as gene sequences, probes, expression sequence tags, expression systems, protein sequences, and transgenic mice inhibit other researchers.⁴² The degeneracy and evolutionary similarity of the genetic code between species broadens the scope of such patents, again serving to constrain research. Given that the one of the primary goals of the patent system is to encourage research and innovation, there are strong arguments for change when this goal is jeopardised.

The ethical concerns that patenting encourages biocolonialism and fails to recognise that genes are a common universal possession are persuasive. The resources of the world are already distributed in a most unequal fashion and the

⁴¹This stance is contrasted with that taken in the English case *Chiron Corporation v. Organon Teknika Ltd.* (No 3) [1994] F.S.R. 202 where a patent over the Hepatitis C virus sequence was upheld because it had taken "30-man years" to achieve and over ten years to identify.

⁴²Fortunately, scientists routinely allow others to use patented research tools on request without payment.

patenting of gene and amino acid sequences may serve to further exaggerate that injustice. It is unfair that a genetic resource that is endemic to a particular country should be exploited by another without recognition or compensation. Likewise, given that all human beings share the same genome and the cooperative spirit of the Human Genome Project, it would be unfair if a small number of companies were vested with the exclusive right to exploit the human genome. Quite clearly there is a need for benefit sharing.⁴³ However, it should not be forgotten that neither industrialised nor developing nations will benefit from research unless there are incentives, which include patent grants, to invest in biotechnology.⁴⁴

The challenge, then, is to encourage research and innovation, reward those who invest their time and money in scientific endeavour producing “inventions”, and facilitate dissemination of scientific research, while discouraging biocolonialism and recognising the common heritage of the human genome. The question is whether our system of patent law has achieved this objective or whether indeed this is an objective that can be achieved at all.

III The Law in Australia

The Australian Patent Office has specified that purified nucleic acids are patentable inventions.⁴⁵ As of March 1997, the Patent Office had received some 8,100 applications for gene or gene sequences and granted some 2,100 patents.⁴⁶ As with all patents an application must comply with section 18 of the *Patents Act* 1990 (Cth). Section 18 provides:

18(1) Subject to subsection (2), a patentable invention is an invention that, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim...

Subsection (2) provides:

⁴³The Human Genome Organisation Ethics Committee, *Genome - Benefit Sharing* (Draft Discussion Paper 1999).

⁴⁴Healy, *supra* note 7 at 666.

⁴⁵IP Australia, *Australian Patents for Microorganisms, Cell Lines, Hybridomas, Related Biological Materials and Their Use, Genetically Manipulated Organisms* (IP Australia: Canberra, 1998) 1.

⁴⁶Australian Senate Question on Notice 449, 24 March 1997.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

There are thus five main requirements that must be satisfied for a patent to be granted: it must (i) be a manner of manufacture, (ii) be novel, (iii) involve an inventive step, (iv) be useful, and (v) not have been secretly used prior to the application of the patent.

a) Manner of manufacture and gene sequences

To generalise, the requirement that an invention be a “manner of manufacture” will be satisfied if a product or process achieved by following the specifications is useful, has some material advantage, has some economic advantage, and there is an industrial application – an innovative idea which provides a practical solution to a technical problem.⁴⁷ In determining whether an invention is a “manner of manufacture,” the law makes an important distinction between discoveries and inventions. Discoveries are excluded from being a manner of manufacture since the observation of certain physical properties, or the finding of a previously unknown, but naturally occurring substance is not something that should be monopolised by any individual or company.⁴⁸ For instance, the laws of physics are not patentable subject matter. However, as was noted in the case of *National Research Development Corporation v. Commissioner of Patents*,⁴⁹ the legal distinction between discovery and invention is not precise. The High Court in that case insisted that the whole process must be looked at, and it was enough that there was one inventive step in this process.⁵⁰ Therefore, although the identification of a naturally occurring gene sequence may be a discovery, the isolation and characterisation of the gene and utilisation of that knowledge to make a synthetic gene and gene products will, at law, inject the requisite degree of inventiveness.⁵¹ This distinction was made in the Australian case of *Kirin-Amgen Inc. v. Board of Regents of the University of Washington*.⁵² The case involved a patent application for the purified or isolated DNA sequence encoding the human protein erythropoietin. The Deputy Commissioner of Patents in this case stated that a claim directed to a naturally occurring DNA sequence would be claiming no more than a discovery per se and not be a manner of manufacture.⁵³ However, because the claim specified a purified and isolated DNA sequence, the claim related to “an artificially created state of affairs,” and thus was a manner of manufacture.⁵⁴

⁴⁷IP Australia, *supra* note 45 at 2.

⁴⁸J. McKeough & A. Stewart, *Intellectual Property in Australia*, 2d ed. (Sydney: Butterworths, 1997) 290.

⁴⁹(1959) 102 C.L.R. 252, 264.

⁵⁰*Ibid.*

⁵¹Nicol, *supra* note 9 at 238.

⁵²(1995) 33 I.P.R. 557.

⁵³*Ibid.* at 569.

⁵⁴*Ibid.*

In addition the definition of “manner of manufacture” incorporates a general public interest test. Section 6 of the *Statute of Monopolies* provides that patents should not be granted where they are “contrary to the law or mischievous to the state by raising prices of commodities at home, or hurt trade, or generally inconvenient.” As of yet this provision has not been applied to restrict patents on DNA or amino acid sequences, but it may provide an avenue whereby the judiciary can introduce public policy or ethical considerations in determining whether DNA and amino acid sequences should be patentable.⁵⁵

b) Novelty and gene sequences

The assessment of novelty basically requires an investigation to establish whether the alleged invention has been anticipated, judged at the time of the patent application. Anticipation may principally occur through prior publication or prior use.⁵⁶ The Australian Patent Office has specified that the requirement of novelty with respect to gene sequences and related biological materials is satisfied if the subject matter is new in the sense of not previously being available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available.⁵⁷

c) Inventiveness and gene sequences

It is not enough that an invention be novel, it must also involve a degree of inventiveness. To establish an inventive step one must ask the question: was it, for practical purposes, obvious to a person skilled in the particular art, armed with all the common general knowledge of his or her art, that he or she could do what the patent proposes?⁵⁸ In most instances this requirement is easily satisfied as there need only be a “scintilla of invention.”⁵⁹ Academic commentators in Australia have argued that the cloning and sequencing of a gene is unlikely to amount to an inventive step because once information about an amino acid sequence is known, then to a person skilled in the art of molecular biology, with common general knowledge, the cloning of a gene is the obvious next step.⁶⁰ Likewise, once a sequence for a specific gene has been isolated in one species, then to a person skilled in the art, it is the next obvious step to develop probes and identify the analogous protein in a different species. However, the Patent Office does not seem

⁵⁵Nicol, *supra* note 9 at 242.

⁵⁶*Griffin v. Isaacs* (1938) 12 A.O.J.P. 739. See also McKeough & Stewart, *supra* note 48 at 297.

⁵⁷IP Australia, *supra* note 45 at 2.

⁵⁸See section 7(2) *Patents Act* 1990 (Cth). This determination is complicated by the fact that a technique used five years ago may not have been obvious then, but today such a technique would be obvious to a person skilled in the art of molecular biology.

⁵⁹*Samuel Parks & Co. Ltd. v. Cocker Bros. Ltd.* (1929) 46 R.P.C. 241 at 248.

⁶⁰Lawson, *supra* note 35 at 379.

to hold this opinion and the requirement of inventiveness has not been a major obstacle to the patenting of DNA or amino acid sequences.⁶¹

d) Utility and gene sequences

The requirement that the invention must be useful does not mean that it must fulfil some worthwhile function. Utility simply means that the result claimed can be achieved by following instructions in the specification.⁶² The Australian Patent Office has specified that the use to which the invention is to be put, for example, for the treatment of human disease such as cancer or multiple sclerosis, must be fully described. This means that there must be an actual use for an invention rather than speculation as to future uses.⁶³ The requirement of utility narrows the scope for patenting gene sequences. For instance random DNA sequences (or expression sequences tags (ESTs))⁶⁴ in the absence of functional information, would not be patentable as diagnostic tools, as there is no actual use, only speculation as to future use.

e) Human beings not patentable

Section 18(2) of the *Patents Act* 1990 (Cth) provides that human beings, and the biological processes for their generation, are not patentable inventions. The Patent Office has stated that the only limitation that this exclusion creates in the area of genetic research is that DNA or genes in the human body are not patentable as such.⁶⁵ This section has deliberately been read very narrowly to allow the patenting of gene sequences.

f) An experimental use defence

Although there is no provision in the *Patents Act* 1990 (Cth), use of a patented invention for the purpose of carrying out an experiment may not amount to infringement. This common law defence originates from the United Kingdom decision of *Frearson v. Loe*⁶⁶ where it was held that if there is neither using nor vending for profit, but merely bona fide experimentation undertaken with a view of improving an invention, it is not an infringement. This defence has not been applied to gene sequences and, on the rare occasions that it has been raised, it has achieved little success.⁶⁷ It is an extremely narrow defence. If it were to apply to gene sequences, it would have little practical effect. Gene patents normally include

⁶¹See *Synaptic Pharmaceutical Corporations v. Astra Aktiebolag* [1998] A.P.O. (9 September 1998); *Takeda Chemical Industries v. Hoffman-La Roche Aktiengesellschaft* [1996] A.P.O. (18 January 1996).

⁶²McKeough & Stewart, *supra* note 48 at 307.

⁶³IP Australia Pamphlet, *supra* note 45 at 2.

⁶⁴Expression Sequence Tags are segments of DNA of unknown function which are routinely used by researchers in gene discovery.

⁶⁵Nicol, *supra* note 9 at 241.

⁶⁶(1878) 9 Ch. D.48.

⁶⁷*Longworth v. Emerton* (1951) 83 C.L.R. 539; *Re Application of Bruce Lake* (1992) 24 I.P.R. 281.

all foreseeable commercial applications of that sequence. Therefore, another scientist may be permitted to research in the area, but could not commercialise the product. His/her effort would go unrewarded and, as a result, the research is best avoided. It is for this reason that the experimental use defence does not counter concerns that broad gene patents are inhibiting research.⁶⁸

g) Summary of Australian law

In summary a genetic sequence is patentable in Australia so long as:

- it does not encompass the sequence in its natural state, but is limited to the sequence in an “artificially created state of affairs”;
- it is new in the sense of not previously being available;
- it is non-obvious to a person skilled in the art of molecular biology;
- the specification provides for an actual use for the invention rather than speculation as to future uses; and
- it has not been secretly used prior to the patent application.

A patentee is then granted exclusive rights to exploit the invention for a period of twenty years.⁶⁹ These rights include the right to make, sell or import the product, or, where the method is a process, the exclusive right to use that process.⁷⁰

IV. Gene Patenting in Other Countries

1. The Law in the USA

Since the case of *Diamond v. Chakrabarty*,⁷¹ where the United States Supreme Court held that a genetically engineered bacterium capable of breaking down oil was patentable, it has been well settled law that nucleic acid sequences, isolated genes and isolated proteins are patentable in the United States. Since accepting that genetic sequences are patentable subject matter, the United States Patent Office has granted some 12,000 patents on inventions related to DNA sequences.⁷²

Patent law in the United States requires three technical requirements: novelty, utility and non-obviousness.⁷³ Novelty involves a judgement of whether the invention is truly something new and original.⁷⁴ Utility requires that the invention

⁶⁸A similar defence is available in Canada and the United Kingdom. See *Patents Act 1977 (UK)* s 60(5)(b).

⁶⁹*Patents Act 1990 (Australia)* s 13(1).

⁷⁰Schedule 1 of the *Patents Act 1990 (Australia)*.

⁷¹447 U.S. 303 (1980).

⁷²This figure is as of October 1999, determined using IBM Intellectual Property Network database.

⁷³35 U.S.C. §100-112 (1994).

⁷⁴*Ibid.* at § 101-102. With respect to genetic sequences it was held in the case of *Amgen, Inc. v. Chughai Pharmaceutical Co Ltd.*, 927 F.2d (Fed. Cir. 1991) at 1203, that the requirement of novelty is satisfied if the sequences are “purified and isolated”.

have some articulate use.⁷⁵ Non-obviousness requires a hypothetical judgement by a person with ordinary skill in a particular field to determine whether the invention is more than an obvious progression in the field.⁷⁶

a) The utility requirement

The requirement of utility with respect to gene sequences has been the cause of considerable debate in the United States. The grounds required to establish utility were discussed in *Brenner v Manson*.⁷⁷ The Supreme Court stated in that case “unless and until a process is refined and developed to the point of a substantial utility—where a specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”⁷⁸ The court expressly recognised that an invention “which either has no known use or is useful only in the sense that it may be an object of scientific research”⁷⁹ is not patentable. It was because of this requirement that an application by the United States National Institute of Health (NIH) in 1991 for a patent on some 2,000 gene sequences (ESTs) failed. The function of the genes was unknown, and the mere use of the sequences as probes was unacceptable. There was not the requisite degree of specific benefit – they were simply research tools. However, in 1995, the United States Patent Office issued guidelines in assessing utility which are far more generous. According to these guidelines one need only establish a “credible utility.” “Credible utility” is defined as “whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided”.⁸⁰ Academic commentators have argued that this broader test makes a utility rejection highly unlikely.⁸¹ It has been suggested that the guidelines are so broad that the use of ESTs as probes satisfies the utility requirement and they are therefore patentable.⁸² This has been confirmed by the United States Patent Office, who have stated that ESTs, in principle, are patentable.⁸³ This has caused considerable concern amongst researchers who fear that their basic tools might be subject to patent rights.⁸⁴

⁷⁵*Supra* note 73 at § 101.

⁷⁶*Ibid.* at § 103.

⁷⁷383 U.S. 519 (1966).

⁷⁸*Ibid.* at 534-535.

⁷⁹*Ibid.* at 535.

⁸⁰“PTO Examination Guidelines on Utility Requirements” (1995) 50 Pat. Trademark & Copyright J. 295 at 303.

⁸¹A.T. Kight, “Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of *Brenner*” (1998) 73 Ind. L.J. 997 at 1015.

⁸²*Ibid.* at 1019.

⁸³C. O’Brien, “US Decision ‘Will Not Limit Gene Patents’” (1997) 385 Nature 755.

⁸⁴See American Society of Human Genetics, “Position Paper on Patenting of Expressed Sequence Tags” (November 1991), online: <<http://www.faseb.org/genetics/ashg/policy/pol-08.htm>>

b) The requirement of obviousness

With respect to obviousness, the United States Court of Appeals has, in the cases of *Re Deuel*⁸⁵ and *Re Bell*,⁸⁶ focussed on the obviousness of the sequence rather than the obviousness of the method used to isolate the sequence. In these cases the Court of Appeal found that gene sequences for proteins of known function are patentable, because the sequence would not have been known without cloning and sequencing, which is sufficient for it to be non-obvious. In both cases, the Court accepted that degeneracy in the genetic code meant that a number of different nucleotide sequences might code for a specific protein, and therefore the nucleotide sequence claimed was not obvious.⁸⁷ The existence of a general method for determining DNA sequences was held to be irrelevant. A result of these decisions is that prior disclosure of an amino acid sequence does not necessarily render obvious the DNA molecules which encode the protein, further widening the scope for patenting DNA sequences. It also raises the interesting spectre of a patent being granted for an amino acid sequence, and then another, potentially to a different individual, for the DNA sequence for the same protein. In general, it can be observed that the United States Patent Office has set a low threshold for patenting gene sequences.

2. The Law in Canada

For an invention comprising a gene or amino acid sequence to be patentable in Canada it must meet the requirements set out in the *Patent Act* 1985. The invention must: (1) fall within certain broad categories of subject matter,⁸⁸ (2) be novel,⁸⁹ (3) be objectively nonobvious,⁹⁰ and (4) have some form of utility. As in other jurisdictions, discoveries⁹¹ are excluded from patentability, as are methods of treating living humans or animals by surgery or therapy.⁹² Novelty, as in the United States and Australia, requires an analysis of previous publications to ensure that the invention has not previously been disclosed.⁹³ Similarly, the requirement of

⁸⁵51 F.3d 1552 (Fed. Cir.1995).

⁸⁶991 F. 2d 781 (1993).

⁸⁷*Re Deuel*, *supra* note 85; *Re Bell*, *ibid.* at 784. See also Lawson, *supra* note 35 at 380.

⁸⁸*Patent Act*, R.S.C. 1985, c. P-4, s. 2. An invention is described as any “new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in art process, machine, manufacture or composition of matter”.

⁸⁹*Ibid.* at s. 27.

⁹⁰*Ibid.* at s. 28.3.

⁹¹See *Continental Soya Company Ltd. v. J.R. Short Milling Company* (1943), 2 C.P.R.1; *Reynolds v. Herbet Smith & Company Ltd.* (1902), 20 R.P.C. 123 (Ch D).

⁹²Canadian Patent Office, *Manual of Patent Office Practice* (Ottawa: Supply and Services Canada, 1989) 12.03.01; R. Marusyk & A. Athanassiadis, “Patenting of Human Genetic Sequences in Canada” in B. Knoppers, *supra* note 26, 343 at 345. However, “methods of use” claims are commonly accepted by the Canadian Patent Office if they are appropriately worded. See Intellectual Property Directorate of Canada, *supra* note 34 at 37.

⁹³Canada allows for a grace period of one year in which an inventor may disclose an invention without invalidating the novelty requirement. This is unique to Canadian intellectual property law. See *Patent Act*, *supra* note 88.

objective non-obviousness requires determination of whether a person skilled in the relevant art of science would consider the invention obvious.⁹⁴ All that is required to satisfy the element of utility is that the invention be useful for solving a practical problem or have commercial value.⁹⁵

Provided that these criteria are met, the Canadian Patent Office will accept a patent for a gene sequence. The Canadian Patent Office will not accept claims to a natural occurring sequence in itself. Nor will the Patent Office accept claims to a product which is a mere laboratory curiosity, such as a genetic sequence for research only. There must be a defined utility. Provided that the patent details a sequence which has been isolated, in addition to a new and inventive use for the sequence, it will be acceptable.⁹⁶ This stance is similar to that adopted in Australia.

3. The Law in Europe

Patent law in Europe is governed largely by the European Patent Convention. Article 52 of this Convention provides that for an invention to be patentable it must be: (1) an invention, (2) be novel, (3) present an inventive activity, and (4) have an industrial application. Within the European Union dispute arose as to the patentability of gene sequences. In response the European Parliament and European Commission passed a directive on the legal protection of biotechnological inventions in order to remove uncertainty in this area of the law.

This directive in its preamble recognises that biotechnological inventions are playing an increasingly important role in a broad range of industries,⁹⁷ and that research and development in the field of genetic engineering are high risk investments and therefore require adequate legal protection.⁹⁸ It also recognises that patent law should be applied so as to respect the fundamental principles safeguarding the dignity and integrity of a person, and thus the human body and its

⁹⁴*Ibid.* at s. 28.3. The classic test for non-obviousness in Canada was formulated by Justice Hugessen in *Beloit Canada Ltd. v. Valmet Oy* (1986), 7 C.I.P.R. 205 at 211. He stated that:

The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art of common knowledge as at the claim date of the invention, have come directly and without difficulty to the solution taught by the patent.

⁹⁵There is no formal obligation on the patentee to establish utility as there is a *prima facie* presumption that inventions are useful. See *Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd.* (1972), 8 C.P.R. (2d) 6.

⁹⁶E. McMahon, "Nucleic Acid Sequences and Other Naturally Occurring Products: Are They Patentable in Canada?" 10 Can. Intell. Prop. Rev. 11 at 18; Marusyk & Athanassiadis, *supra* note 92 at 349.

⁹⁷European Parliament, *Directive of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions* (Commission of the European Communities: 1998) recital 1.

⁹⁸*Ibid.* recital 2.

elements are unpatentable in their natural state.⁹⁹ The directive clearly makes provision for the patenting of DNA sequences. Article 3 states that inventions which are new, which involve an inventive step, and which are susceptible of industrial application shall be patentable even if they concern a product consisting of biological material. It specifically provides in Article 5 that an element isolated from the human body, including the sequence of a gene, may constitute a patentable invention.¹⁰⁰ However, a mere DNA sequence without indication of a function is not a patentable invention.¹⁰¹ The two key requirements are an isolated gene sequence and knowledge of the gene's function.

An additional limiting factor is that inventions must not be contrary to *ordre public* or morality. Article 6 provides that such inventions are unpatentable.¹⁰² The directive specifies that the cloning of human beings and the use of human embryos for industrial or commercial purposes fall within this category.¹⁰³ It can be observed that the European Union, while recognising the patentability of gene sequences, has taken a more conservative stance than the United States.

4. Recent Recommendations and Proposals for Change

The challenge for the law has been to encourage research and innovation while discouraging biocolonialism and respecting the human genome. The law is not meeting this objective. The growing trend across the globe is to recognise the patentability of genetic sequences, increasingly with less scrutiny and with no regard to ethical or policy considerations. This trend is being led by the United States, which, as the leader in biotechnology, has the most to gain from granting monopolies on gene sequences. Patent grants on gene and amino acid sequences have been permitted despite the compelling legal arguments that gene sequences are not inventions, but rather mere discoveries. This important distinction exists to encourage invention by driving a discoverer into the realm of practical application and workmanship.¹⁰⁴ It is contended that the patent system in its current form is not effectively regulating the exploitation of genetic resources. A number of proposals have been made at the national and international levels as alternatives. These will be briefly explained and assessed.

⁹⁹*Ibid.* recital 16.

¹⁰⁰*Ibid.* article 5(2).

¹⁰¹*Ibid.* recital 23, article 5(1).

¹⁰²*Ibid.* article 6(1).

¹⁰³*Ibid.* article 6(2).

¹⁰⁴Drahos, *supra* note 35 at 443.

a) A ban on gene patents

Two attempts to ban patents on gene sequences have been made in Australia. The first attempt in September 1990, by Democrat¹⁰⁵ Senator John Coulter, proposed an amendment to Australia's patent legislation specifying that a patentable invention does not include "[a] gene or genes, whether derived from cells or chemically synthesised, or a genome either complete or one which has had genetic material added or deleted."¹⁰⁶ This amendment failed to win support. The second attempt, by Democrat Senator Stott Despoja in 1996, was also unsuccessful. Senator Stott Despoja proposed that the *Patents Act* 1990 (Cth) should be amended preventing patent grants on "naturally occurring genes, naturally occurring gene sequences, and descriptions of the base sequence of a naturally occurring gene or naturally occurring gene sequence."¹⁰⁷

A ban on patenting naturally occurring DNA sequences would immediately solve many ethical concerns. The human genome would not become the exclusive domain of large corporations and biocolonialism would not manifest itself in the form of patents on gene sequences. Furthermore, from a practical perspective, scientific researchers would not be deterred from researching specific areas so as to avoid potential patent infringement. The law would be injected with a much needed clarity, and the courts would no longer need to jump through hoops to justify the inclusion of genetic sequences as inventions.

There are, however, several difficulties with this proposal. A blanket ban on patenting gene sequences assumes that the concept of inventiveness and patenting gene sequences are mutually exclusive. What though, of a scientist who creates a new gene sequence? Likewise difficulties would arise with respect to an individual who has conceived a novel and inventive use for a pre-existing gene sequence, such as a diagnostic tool or use in gene therapy. Furthermore, it would be illogical if DNA sequences were excluded from patent grants but amino acid sequences were permitted. Perhaps these objections could be countered by a carefully worded provision which applies exclusively to naturally occurring gene and amino acid sequences. Regrettably, there are even greater obstacles. Had Australia adopted the proposed law banning patents on DNA sequences, it is likely that such a law would breach the *Trade Related Aspects of Intellectual Property Rights* (TRIPS) agreement,¹⁰⁸ to which Australia is a signatory. Article 27(1) of this agreement

¹⁰⁵The Democrats are a small political party, holding a number of seats in Australia's Upper House the Senate.

¹⁰⁶Australia, Senate, *Hansard* (17 September 1990, P.2478).

¹⁰⁷*Patents Amendment Bill* 1996, Schedule 1. See also Australia, Senate, *Hansard* (27 June 1996, P.2332). "Naturally occurring" sequence was not defined in the proposed Bill, however the second reading speech indicates that it is intended to apply to all gene sequences.

¹⁰⁸Final Act Embodying the Results of the Uruguay Round of the Multilateral Negotiations, Marrakesh Agreement Establishing the World Trade Organization, signed at Marrakesh (Morocco), April 15, 1994, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPS],

provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. Given the economic interests underlying the World Trade Organisation it is likely that a dispute at an international level would find that isolated gene sequences are in fact inventions.

A ban on patenting DNA and amino acid sequences would only be effective if done at a global level. Clearly the world is moving away from this option, as illustrated by the recent European Directive on the legal protection of biotechnological inventions allowing patents on gene sequences. Developed countries such as the United States, the United Kingdom and Japan, whose patent systems serve to drive the development of science and technology, and with it their economies, have little to gain by voluntarily revoking monopolies on gene sequences. A more pragmatic approach is required.

b) Creation of a Human Genome Trust

A number of academics have proposed the creation of a world genome trust.¹⁰⁹ Such a trust would oversee human genome research, holding gene sequences in trust for humanity. A board which would preside over the trust would have the ability to grant licences to researchers to protect rights prior to the development of patentable inventions.¹¹⁰ Additionally the board would have the capacity to check unethical development, alleviating some of the fear and mistrust associated with genetic research.¹¹¹ Advocates of the Human Genome trust argue that it recognises the ethical reasons not to patent genes, but preserves the economic incentive of a patent system, finding a compromise between the competing ethical positions of the gene patenting controversy.¹¹² It has been argued that a Human Genome trust reflects the increasing globalisation of science.¹¹³ However, creation of a Human Genome trust would require a major collaborative effort on an international level. Widespread cooperation would be required by all major developed countries, along with considerable financial support. Furthermore, one is likely to encounter political tension, imbalances of power and bureaucratic waste.¹¹⁴ There is also the potential for dispute in issuing licences, especially with respect to pre-existing patent holders. The idea is a good concept but there are better alternatives.

GATT, Doc.MTN/FA/Add.1 (15 December 1993); reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations - The Legal Text*, vol. 31 (GATT Secretariat, ed., 1994) 365-403; 33 I.L.M. 1197, 1200; 25 I.L.C. 209. The TRIPS Agreement came into effect on January 1, 1995. Note, however, that article 27(3) provides that member states exclude from patentability diagnostic, therapeutic and surgical methods of treatment, and plants, animals and other micro-organisms.

¹⁰⁹Looney, *supra* note 8; Lacy, *supra* note 8.

¹¹⁰Looney, *ibid.* at 268.

¹¹¹*Ibid.* at 270.

¹¹²*Ibid.* at 272.

¹¹³Lacy, *supra* note 8 at 804.

¹¹⁴Looney, *supra* note 8 at 269.

c) The Human Genome and the Common Heritage Principle

The Common Heritage Principle is an international legal concept which conveys equal property interests to all people.¹¹⁵ It has been traditionally applied to deep seabeds,¹¹⁶ Antarctica,¹¹⁷ the Moon, and certain historic sites.¹¹⁸ It has been argued that since the human genome is literally the blueprint of humankind's Common Heritage, it is a perfect candidate for the Common Heritage Principle. An international treaty would be the best way to recognise the human genome as falling within the Common Heritage Principle. Such a treaty would vest all rights in the human genome in humanity as a whole and provide that all of humanity should benefit from its exploration and exploitation.¹¹⁹ The role of protecting the status of the human genome would thus fall upon the shoulders of the Human Genome Organisation. One of the key advantages of this proposal is that it effectively addresses many ethical concerns associated with patenting human genetic sequences. Such a proposal is, however, likely to be opposed by developed countries as it effectively redistributes resources to less developed countries.¹²⁰ Opposition is also likely to be encountered from pre-existing patent holders who may feel that their legal rights are being stripped from them. Regrettably, the proposal is limited to only one species while there are thousands of organisms whose genomes are subject to patent grants. Broad patents for other animal and plant sequences will continue to be granted. In addition, one would need to ensure that the treaty would not be stymied by the patenting of amino acid sequences. Recognition of the human genome as falling within the Common Heritage Principle will not, alone, provide an effective solution.

d) More Stringent Patent Grants

A recent report prepared by an independent working group for the Prime Minister's Science, Engineering and Innovation Council (PMSEIC) expressed its concern that broader than necessary patent protection had been given, particularly in the case of naturally occurring genes.¹²¹ The group recommended a change in the international patent system to be far less supportive of monopolies in genetics.¹²² The group noted that if Australia took this initiative, then it would probably adversely affect the biotechnology industry in Australia. The group thus proposed establishing an international initiative to influence World Trade Organisation

¹¹⁵M. Sturges, *supra* note 13 at 245.

¹¹⁶M. Harry, "The Deep Seabed: The Common Heritage of Mankind or Arena for Unilateral Exploitation?" (1992) 40 *Naval L. Rev.* 207.

¹¹⁷E. Tenenbaum, "A World Park in Antarctica: The Common Heritage of Mankind" (1990) 10 *Va. Env. L.J.* 109.

¹¹⁸Sturges, *supra* note 13 at 247.

¹¹⁹*Ibid.* at 254, 256, Articles 1 and 2.

¹²⁰*Ibid.* at 246-247.

¹²¹"Profiting From the Biotechnology Revolution" Prime Minister's Science Engineering and Innovation Council (29 May 1998) at 8.

¹²²*Ibid.*

forums, such as the TRIPS agreement, to narrow the scope of patents for naturally occurring genes. This could be achieved by focusing on the utility requirement when considering a patent application involving a gene sequence.¹²³ By limiting patent protection to instances when a specific useful purpose is indicated,¹²⁴ one avoids monopolisation of basic research tools, broad nonspecific patent grants¹²⁵ and the patenting of mere discoveries. In essence this would be a narrowing of the patent grant by focusing on the utility requirement. Patents could be further narrowed by limiting the monopoly to specific species. The advantage of this option is that it maintains this existing patent framework,¹²⁶ and does not invalidate all pre-existing patent grants. To be effective in its implementation global guidelines would be required, preferably issued by the World Trade Organisation. The best solution would be to couple such guidelines with recognition of the human genome as falling within the Common Heritage Principle. Such an approach would address the most significant concerns raised by patenting DNA and amino acid sequences.

V. Conclusion

Patent law in Australia, the United States, Canada and Europe has recognised that DNA and amino acid sequences are patentable inventions. To satisfy patenting requirements the law in these countries requires that the sequence be isolated, new, non-obvious, and that it possess some degree of utility. However, there are compelling grounds for concluding that the determination of gene sequences are mere discoveries, and their characterisation involves processes, more often than not, obvious to a person skilled in the art of molecular biology. Patents on genes also raise serious ethical and policy concerns. One of the most significant concerns is that the patents on gene sequences are inhibiting scientific research. The primary strength of the patent system has always been that it has encouraged research and innovation. This strength and fundamental tenet is being undermined by the grant of broad patents on gene sequences. Scientific research, which was once stimulated by patent law, is now being threatened by it. This will undoubtedly become more evident when the dust of the gene rush settles and the litigation begins. An international response is required if these concerns are to be met. International guidelines, which limit gene patents based on utility in conjunction with the recognition of the human genome as falling within the Common Heritage Principle, are the most appropriate way of regulating genetic exploitation in the future. The first tentative step in this direction have recently been made. It has been reported that the United States and the United Kingdom are negotiating an agreement to publish human gene sequences within 24 hours of discovery, thus preventing them

¹²³See Austin & Tribble, *supra* note 26 at 382.

¹²⁴Lacy, *supra* note 8 at 806.

¹²⁵See J. Miller, "Patent Law and Human Genomics" (1997) 26 Cap. U. L. Rev. 893 at 921.

¹²⁶A further limitation that has been suggested is that the term for gene patents be reduced to five years, *ibid.*

from being the subject of patent grants.¹²⁷ In addition, the United States Patent Office has just released proposed utility guidelines which are narrower in scope.¹²⁸ However, if the human genome is to be respected, and if the patent law is to continue as an engine for scientific research, these first promising steps will have to be followed by many more.

¹²⁷D. Hencke, R. Evans & T. Radford, "Blair and Clinton Push to Stop Gene Patents" *Guardian* (20 September 1999), online: < <http://www.mannvernd.is/english/news/guardian.UKUS.deal.e.html>>.

¹²⁸V. Slind-Flor, "PTO's New Guide to DNA Info" *Nat. L. J.* (2000) Jan. B06. The proposed guidelines require patent examiners to look for a "specific and substantial" utility, as opposed to a mere "credible utility". These guidelines are available through the United States Patent Office website at <<http://www.uspto.gov/>>.