Please find attached a submission to the House of Representatives Standing Committee on Industry, Science and Resources inquiry into Increasing Value-Adding to Australian Raw Materials.

This submission includes materials which have been published by in the following journals:

Lawson CGR (1999) Patenting genetic diversity – old rules may be restricting the exploitation of a new technology, *Journal of Law and Medicine*, 6, in press.

Lawson CGR and Pickering CM (1998) Patent laws will undermine access provisions in the *Environment Protection and Biodiversity Protection Bill* 1998 (Cth), *Environmental and Planning Law Journal*, 15, 401-409.

Lawson CGR (1998) Patenting Genes and Gene Sequences in Australia, *Journal of Law and Medicine*, 5, 364-371.

The remaining materials are from manuscripts in preparation. The Support of Dr Catherine Pickering is acknowledged for both the published materials and the materials in preparation.

Dr Charles Lawson
Visiting Fellow
Research School of Biological Sciences
Australian National University
Canberra ACT 0200

Telephone (02) 6201 7282
Email clawson@act.bglaw.com.au

Increasing value-adding to Australian raw materials

Under-valuing of raw genetic materials imposed by the existing practice of patenting genetic materials under the *Patents Act* 1990 (Cth)

Executive summary

A patent may generally be granted under the Commonwealth *Patents Act* for an invention which is new, not obvious, useful and described in a way that can be followed by others. Patents are granted in Australia for biological processes, organisms and biological molecules. This includes genes and gene sequences, some of the basic and universal elements of biology, as well as a basic elements of a range of economically valuable inventions including diagnostic kits, medicines (veterinary and other) and agriculturally important crops. This submission argues the present patenting scheme for gene and gene sequences has been setting the hurdle for inventiveness (including non obviousness and novelty) and the grant of a patent too low and allowing the scope of the patent to be too broad. Almost any gene or gene sequence identified for the first time can be patented failing to recognise the inherent degeneracy in genetic materials and by allowing these broad patent claims there is very little room left for other inventors to use the genetic materials to be inventive with the effect of undervaluing the potential of genetic materials in Australia. This undermines the purpose of the patenting scheme and the benefits that can be derived from patenting. As a mega-diverse nation there are significant potential benefits which may be derived from Australia's genetic materials. An analysis of the international patenting regime shows Australia only has limited options available and these will rely principally on competition laws.

1. Summary

1.1 Genetic materials, including gene and gene sequences, are the major focus of this submission.

1.2 Genetic materials are valuable, and a resource for future economic development and improving the quality of human lives. Inventions relying on genetic materials have significant potential in agriculture and medicine (including veterinary medicine) through economic development, improved materials, improved practices, etc. This submission acknowledges there are moral and ethical imperative raise by gene technology but does not address these issues.

1.3 A patent may generally be granted under the *Patents Act* 1990 (Cth) for an invention which is new, not obvious, useful and described in a way that can be followed by others. Patents in Australia are granted over genetic materials, including gene and gene sequences.

1.4 Patenting genetic materials is intended to ensure the benefits of the value of these genetic materials are realised - these benefits might include a direct financial return to the inventor, the economic activity related to the commercialisation of the invention (including employment), a reduced need for duplication and an incentive for other inventors to invent and arguably a promotion of the preservation of genetic materials as a resource for future agriculture, medicine, etc. uses.

1.5 This submission questions whether the intentions of the patenting scheme for genetic materials has achieved its goals and concludes there is *no* conclusive evidence to either prove or disprove the benefits of patenting gene and gene sequences.

1.6 A public interest exception exists in the *Patents Act* 1990 (Cth) to disallow patents which would be "contrary to the law or mischievous to the state by raising prices of commodities at home, or hurt trade, or generally inconvenient". This provides an existing mechanism in our laws to deal with patent claims which are against the

public interest, such as patents which would prevent Australians having access to the best diagnostic kits, treatments, etc. An analysis of benefit from gene and gene sequence patenting is questioned in the absence of *any* data, whether financial or otherwise, which justifies the grant a patent.

1.7 This submission argues the present practice of patenting gene and gene sequences has blended the distinction between discovery and invention and an examination of recent cases shows the threshold for invention is contrived and arguably too easily satisfied.

1.8 This submission argues the present patenting practice allows unreasonably broad claims with the arguable effect of reducing the potential for further inventiveness and an undervaluing of Australia's unique genetic materials. This is argued to be a consequence of failing to consistently recognise the inherent degeneracy in genetic materials and the underlying links between different material forms (such as DNA, RNA and protein at the level of genes and gene sequences) of genetic materials which have evolved.

1.9 The arguments for extending patent terms as a measure to deal with long regulatory periods and the high costs of research are questioned, and it is concluded there is presently insufficient evidence to justify either a lengthening or shortening of patent terms.

1.10 An analysis of the international patenting regime finds Australia only has limited options available to amend the existing patenting scheme for genetic materials, principally relying on the regulation of competition.

1.11 The submission concludes Australia's present patenting regime, with respect to gene and gene sequences, is inadequate because the law is unclear, the necessary inventive steps are too small and the breadth or scope of the patent is too large.

2. Underlying assumptions and limitations

2.1 This submission is confined to examining genetic materials[1] and does not consider the issues of non-genetic biological resources represented by species diversity and ecosystem diversity.[2] The major focus of the submission are gene and gene sequences which make up genetic materials and which, in most cases, provide the means by which traits in one organism may be introduced into another organism, or products and processes developed to benefit agriculture, medicine, etc.

2.2 This submission only examines the imposition of Australia's patent laws under the *Patents Act* 1990 (Cth). Other forms of intellectual property may be available and there is some overlap in the protection available. For example, patents may be sought and granted for plant materials which would have been protected as a plant variety under the *Plant Variety Rights Act* 1989 (Cth).[3]

2.3 It is assumed genetic materials are valuable, and a resource for future economic development and improving the quality of human lives.[4] This does not detract from

[1] Article 2 of the *Convention on Biological Diversity* defines the term "genetic material" to mean "any material of plant, animal, microbial or other origin containing functional units of heredity" and the term "genetic resources" to mean "genetic material of actual or potential value"; made at Rio de Janeiro on 5 June 1992, ratified on 18 June 1993 and taking effect generally on 29 June 1993; see Department of Foreign Affairs and Trade, *Convention on Biological Diversity*, Australian Treaty Series 1993 No 32 (AGPS, Canberra, 1995).

[2] See Report of the Senate Rural and Regional Affairs and Transport References Committee, *Commercial utilisation of Australian native wildlife* (Commonwealth of Australia, Canberra, June 1998), at page 12; Prime Minister's Science Council, *Scientific aspects of major environmental issues* (AGPS, Canberra, 1992), at page2; Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-4.

[3] IP Australia Pamphlet, *Australian patents for plants* (IP Australia, Canberra, February 1998), at page 1; it is noteworthy that plant variety rights apply to some materials which would not satisfy the requirements for patenting, such as a naturally occurring variety which has been "discovered", although many patenting issues apply equally to the application of the *Plant Variety Rights Act* 1989 (Cth).

[4] Preamble to the *Convention on Biological Diversity* made at Rio de Janeiro on 5 June 1992 and taking effect generally on 29 June 1993; Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at Chapter 4; see generally T Swanson, *Global Action for Biodiversity* (Earthscan, London, 1997).

the moral and ethical imperative driving biodiversity conservation.[5] Rather, it is a reflection of the economic considerations in international agreement on intellectual property[6] and biodiversity conservation,[7] the need to find commercial justification to persuade political decision makers[8] and as an element in justifying the grant of a patent monopoly over an invention.[9]

2.4 The economic importance of genetic diversity is in the information contained in the genetic materials of organisms which may be applied for the future benefit of our economies: "Biodiversity provides a vast library of genetic material for use now and in the future, for a variety of industries including agriculture, medicine and gene technology".[10] However, "[t]he world is experiencing rapid growth of new industries based on naturally occurring biological materials. These materials provide the building blocks for pharmaceuticals and agents to fight diseases, provide control of pests in agriculture and help develop environmentally friendly

[5] See for example the use of terms such as "beauty", "symbolic value", etc. in the Prime Minister's Science Council, *Scientific aspects of major environmental issues* (AGPS, Canberra, 1992), at pages 9-19; note criticism of this approach: G Meyers and S Temby, "Biodiversity and the law: a review of the Commonwealth Endangered Species Protection Act" (1994) 3 *Griffith Law Review* 39, at pages 55-56.

[6] Agreement on *Trade Related Aspects of Intellectual Property Rights*, 15 April 1994. The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations was ratified by 120 countries, including Australia, at Marrakesh on 15 April 1994.

[7] See for example, the Preamble and Article 11 of the *Convention on Biological Diversity* made at Rio de Janeiro on 5 June 1992 and taking effect generally on 29 June 1993; note A Stretzler, "Biotechnology intellectual property rights as an obstacle to the UNCED convention on biological diversity – it just doesn't matter" (1992) 6 *Transnational Law* 271.

[8] Recognising the economic value to agriculture, medicine, industry, etc.: see Prime Minister's Science Council, *Scientific aspects of major environmental issues* (AGPS, Canberra, 1992), at pages 9-19 see also Australian National Parks and Wildlife Service, *Draft Australian National Strategy for the Conservation of Species and Habitats Threatened with Extinction* (Commonwealth of Australia, Canberra, 1989), at pages 8-9; note the recent Report of the Senate Rural and Regional Affairs and Transport References Committee, *Commercial utilisation of Australian native wildlife* (Commonwealth of Australia, Canberra, June 1998), at Chapter 5, which discusses the economic viability of commercial activities using Australia's native wildlife.

[9] See C Lawson, "Patenting gene and gene sequences in Australia" (1998) 5 *Journal of Law and Medicine* 364.

[10] Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-6; note the discussion in G Meyers and S Temby, "Biodiversity and the law: a review of the Commonwealth Endangered Species Protection Act" (1994) 3 *Griffith Law Review* 39, at page 67.

and sustainable industrial processes. The development of these industries will depend increasingly on the world's biodiversity".[11] These concepts of exploitation are now recognised in Australia[12] and internationally,[13] as a need to regulate access to the world's genetic resources,[14] including the formal protection of genetic materials through patenting.[15]

2.5 This submission has not examined the broader issue of the commercial exploitation of animate objects derived from nature which raises some special problems for patenting[16] - such as the collection of genetic materials from indigenous peoples,[17] the "plundering" of biological resources from developing countries,[18] as well as the concentration of biological intellectual property among a limited number of corporations and nations.[19] These are significant issues for access to gene

[11] Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at page 1.

[12] See Commonwealth Department of the Environment, Sport and Territories, *National Strategy for Ecologically Sustainable Development* (Commonwealth of Australia, December 1992); Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996); *Reform of Commonwealth Environment Legislation Consultation Paper* (Department of the Environment, Canberra, February 1998), at page 40.

[13] See Department of Foreign Affairs and Trade, *Convention on Biological Diversity*, Australian Treaty Series 1993 No 32 (AGPS, Canberra, 1995), at Article 1; see also *The World Charter for Nature*, adopted by the General Assembly of the United Nations on 28 December 1982 which advocates conserving biodiversity.

[14] This is now enshrined in the *Convention on Biological Diversity*: see Department of Foreign Affairs and Trade, *Convention on Biological Diversity*, Australian Treaty Series 1993 No 32 (AGPS, Canberra, 1995), Article 15.

[15] See for example Article 16 of the *Convention on Biological Diversity*: see Department of Foreign Affairs and Trade, *Convention on Biological Diversity*, Australian Treaty Series 1993 No 32 (AGPS, Canberra, 1995.

[16] See for example, *Moore v Regents of the University of California* (1990) 793 P 2d 479; B Burrows, "Second Thoughts about US Patent #4,438,032" (1997) 124 Bull Med Eth 11; note also the model approach suggested in clause 16 of the *Genetic Privacy and Non-discrimination Bill* 1998 (Cth) and reviewed in the Senate Legal and Constitutional Legislation Committee, *Report on the Genetic Privacy and Non-discrimination Bill 1998 (Cth)* (Senate, Canberra, March 1999).

[17] For an Australian perspective see S Gray, "Vampires round the campfire" (1997) 22 AltLJ 60.

[18] For example, pesticides from the neem tree, K Kleiner, "Pesticide tree ends up in court" (1995) *New Scientist* 7, 16 September 1995.

[19] For example, Australia is a net importer of new technology and know-how, while nations such as the United States are net exporters: Organisation for Economic Cooperation and Development, *Basic Science*

technology because they generally reflect the inherent dangers to consumers from monopolies, such as raised prices.

2.6 In the discussion of access to genetic resources in Australia, this submission does not consider access to heritage,[20] sovereignty rights within a territory or Exclusive Economic Zone,[21] rights of private land owners and indigenous rights[22] and jurisdictional differences within the areas affected by Commonwealth laws, etc. even though significant and relevant access issues are involved.

3. Patenting in Australia

3.1 A patent may generally be granted for an invention which is new, not obvious, useful and described in a way that can be followed by others.[23] The basic requirements for patentability are set out in section18 of the *Patent Act* 1990 (Cth), which provides, in part:

> "(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 section 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:

and Technology Statistics (OECD, Paris, 1993); the United States refused to sign the United Nations Conference on Environment and Development Convention 1992 because of the its domination of biotechnology intellectual property: A Stretzler, "Biotechnology Intellectual Property Rights as an Obstacle to the UNCED Convention on Biological Diversity - It Just Doesn't Matter" (1992) 6 Transnat'l Law 271.

[20] For an overview of these issues see Senate Environment, Recreation, Communications and the Arts References Committee, *Access to heritage: user charges in museums, art galleries and national parks* (Senate Printing Unit, Canberra, July 1998).

[21] Note *New South Wales v Commonwealth* (1976) 135 CLR 337; see generally, Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at pages 32-38.

[22] See Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at pages 26-31.

[23] J McKeough and A Stewart, *Intellectual Property in Australia* (Butterworths, Sydney, 1997), Chapters 12 and 15.

(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 by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee`s or nominated person's predecessor in title to the invention."

3.2 The term "inventions" is defined in the *Patents Act* 1990 (Cth), Schedule 1 to mean:

"any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*, and includes an alleged invention;"[24]

3.3 Section 6 of the *Statute of Monopolies* provides, in part, that the declarations of invalidity contained in the preceding provisions of the *Statute of Monopolies*:

"shall not extend to any letters patent and grants of privilege...hereafter to be made of the sole working or making of any manner of new manufacture within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law or mischievous to the state by raising prices of commodities at home, or hurt trade, or generally inconvenient".[25]

3.4 The elements of an "invention" have been carried into the *Patents Act* 1990 (Cth) by the retention of the same definition of "invention" from section 6 of the *Patents Act* 1952 (Cth)[26]. This includes all the requirements of section 6 of the *Statute of Monopolies*[27].

[24] The word "alleged" qualifies the adjective "new" when applied to the phrase "manner of new manufacture": see *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd* (1995) 183 CLR 655, at page 662.

[25] *Halsbury's Statutes of England*, 2nd edition, volume 17 (1950), at page 619 (word spellings updated).

[26] Explanatory Memorandum, *Patents Bill* 1990 (Cth).

[27] Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

3.5 Subsection 18(2) of the *Patents Act* 1990 (Cth) provides that "Human beings, and the biological processes for their generation, are not patentable inventions".[28] Subsection 51(1) of the *Patents Act* 1990 (Cth) provides the Commissioner may refuse to accept a patent request and specification or grant a patent for "an invention the use of which would be contrary to law" and certain other subject matters, including certain foods and medicines.

3.6 The requirements that an invention must be a manner of manufacture, novel and involve an inventive step are not discrete tests. They have a significant heritage in both the common law and statute laws of England and Australia, and the concepts often overlap. The distinctions may be blurred and the concepts have different degrees of importance at different stages of the patenting process (for example, at the stage of application and opposition).

3.7 The Patent Office determines whether the patent application meets the statutory criteria for patentability under the *Patents Act* 1990 (Cth) subject to various challenges set out in the legislation. It is significant that the Patent Office may only reject a patent when "it is practically certain that the letters patent granted on the specification would be held invalid"[29] and where the validity of a patent is uncertain the patent should be granted.[30] Reasons for Patent Office decisions only follow the opposition stages of an application.

4. The public interest and patenting

4.1 The public policy founding the grant of a patent was to provide to the public the details of the invention and how it could be reproduced in return for a limited

[28] However, the Patent Office will accept applications for patents for human genes and gene sequences which have been separated from the human body and manufactured synthetically for re-introduction into the human body for therapeutic purposes: IP Australia Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, February 1998), at page 1.

[29] *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232, at page 244.

[30] *International Business Machines Corporation v Commissioner of Patents* (1991) 22 IPR 417.

monopoly[31] to exploit the invention for profit - to promote the advancement of inventions by reducing duplication of efforts in invention and provide an incentive for inventors to invent.[32] These policy considerations have arguably applied effectively to a range of industrial inventions for a considerable period of time.[33] However, it is not clear whether such policy has been satisfactory in the area of patenting genetic materials, and in particular gene and gene sequences.

4.2 The patent holder may impose considerable social cost by preventing use of the new invention or other inventions based on genes and gene sequences which have been patented. For example, the *Chiron case*[34] in Australia, which was settled out of court, involved a dispute between the Chiron Corporation which had developed and patented in broad terms a diagnostic test (including the gene and nucleotide sequence) for an Hepatitis C strain 1a and Murex Australia which had developed independently a diagnostic test for a range of other Hepatitis C strains not covered by the Chiron test. Murex brought an action against Chiron claiming the Australian patent was invalid and Chiron cross claimed for threat to infringe, infringement or continuing to infringe the Australian patent. The effect of a decision in favor of Chiron would have been to prevent the Murex test being sold in Australia even though it was a test able to identify strains of Hepatitis C the Chiron test could not detect. The Australian blood supply would have been less reliable as there would

[31] The term "monopoly" no longer enjoys favour in some sectors – "It is now accepted that intellectual property laws do not clash with competition laws because they do not create legal or economic monopolies": National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974 - draft report* (National Competition Council, Canberra, November 1998), at page 5. However, for the purposes of this submission the term "monopoly" is used because patents effectively exclude others through exclusive rights (which persist even where there is independent invention) and patents over genetic materials have been used in oligopolist industries (for example, the hepatitis C diagnostic kit in the world wide litigation between Chiron Corporation and others - in Australia this was *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc*., Federal Court, NG380/1996).

[32] Lord Parker in *Attorney General (Commonwealth) v Adelaide Steamship Co.* [1913] AC 781; reviewed in page Loughlan, "Patents: breaking into the loop" (1998) 20 *Sydney Law Review* 553, at pages 567-572.

[33] Looking to the future see K Maskus, *The international regulation of intellectual property*, CIES Seminar Paper 97-11 (University of Adelaide, Adelaide, 1997); although it is interesting that China was able to make significant scientific and innovative advances without any intellectual property rights or customary equivalents: see page Drahos, *A Philosophy of Intellectual Property* (Dartmouth, Sydney, 1997), page 15.

[34] *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc*. (Federal Court, NG380/1996).

have been no test to identify the Hepatitis C strains, other that 1a, such as the prevalent strains 2, 3 and 5. This concern is reinforced by the fact that there is presently no cure for Hepatitis C infection. The cost of unidentified Hepatitis C infection could be considerable in terms of both the personal anguish of those infected and the costs to the community through treatment, public health programs, etc. following infection. This case highlights the conflict between granting a monopoly right to promote innovation and the negative aspects of a monopoly to the community,[35] and the central place of patenting genes and gene sequences in this conflict.

4.3 In a broader context, the greater focus on commercial research and the increasing reliance on patenting to quantify research achievement and capture commercial returns may also be directing research efforts towards those areas suitable for patenting (industrial appropriation) and away from some of the most pressing agricultural, medical, etc. problems, requiring understanding and solution.[36] Further, the practice of "patent blitzkrieg" where big companies apply market power to "consolidate" patents are a relevant social and economic concern which are not exhaustively addressed here, although there is already some evidence of this in gene and gene sequence patents with detrimental consequences for agriculture and medicine.[37]

4.4 The Australian legal system arguably recognises the detriment imposed by monopolies and has limited the application of the *Patents Act* 1990 (Cth) in section 18 by reference to the *Statute of Monopolies*. In *Attorney General (Cth) v Adelaide Steamship Co*.[38] Lord Parker traced the origin of the *Statute of Monopolies* from the strict limits the common law applied to monopolies and identified the requirement at common law that consideration move to the public for the derogation of the right

[35] Elegantly argued in *Darcy v Allen* (1602) 11 Co. Rep. 84; *Attorney General (Commonwealth) v Adelaide Steamship Co.* [1913] AC 781.

[36] See L Evans, "Feeding the ten billion" (Cambridge University Press, Cambridge, 1998), at page 166.

[37] see R Dunford, "Is the development of technology helped or hindered by patent law - can antitrust laws provide a solution?" (1986) 9 UNSWLJ 117; for a recent example: A Thayer, "Monsanto gets all of Calgene" (1997) 75(17) C&EN 11; see discussion in C Arup, *Innovation policy and law* (Cambridge University Press, Cambridge, 1993), at pages 71-75.

[38] [1913] AC 781.

to freedom of trade. In the scheme of patents this was theoretically achieved by disclosure of the details of the invention in exchange for the monopoly rights.

4.5 One of the requirements for patentability is that the subject matter must be an "invention" (subsection 18(1) of the *Patents Act* 1990 (Cth)) and be "a manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*" (paragraph 18(1)(a) of the *Patents Act* 1990 (Cth)). The term "invention" is defined to mean "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*, and includes an alleged invention". The "manner of manufacture" (paragraph 18(1)(a) of the *Patents Act* 1990 (Cth)) was included, although, "[i]t means little more than that an invention must belong to the useful arts rather than the fine arts".[39] These tests maintain the flexibility and judicial interpretation in the English and Australian cases[40] and follow the recommendations of the Industrial Property Advisory Committee.[41] (The various references to "manner of manufacture" and "manner of *new* manufacture" are discussed further below).

4.6 The effect of the existing law in Australia is a recognition that an element within the patent scheme is that a patent should "be not contrary to the law or mischievous to the state by raising prices of commodities at home, or hurt trade, or generally inconvenient" (section 6 of the *Statute of Monopolies*).

4.7 Some commentators[42] and, as noted above, the Patent Office[43] are satisfied that an isolated gene or gene sequence will satisfy the "manner of manufacture" test. This result has not, it is submitted, considered section 6 of the *Statute of Monopolies*. Following the reasoning in *Attorney General (Cth) v Adelaide Steamship Co*.[44] the

[39] Explanatory Memorandum, *Patents Bill* 1990 (Cth).

[40] See for example, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

[41] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 1984).

[42] S Gray, "Vampires round the campfire" (1997) 22 AltLJ, 60-67; D Nicol, "Should human genes be patentable inventions under Australian law?" (1996) 3 JLM 231.

[43] Patent Office Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (Patent Office, Canberra, October 1996).

[44] [1913] AC 781.

common law requirement that consideration move to the public for the derogation of the right to freedom of trade, suggests (i) some economic benefit to the community may be necessary and (ii) the benefits of granting a patent monopoly in Australia must outweigh the detriment of that monopoly in Australia.

4.8 These sentiments have been variously expressed about the patent scheme in Australia:

(i) The Senate Standing Committee on Science and the Environment report:

> "The primary function of patent legislation should be to serve as an instrument of national economic policy aimed at the stimulation of indigenous industrial innovation and not as a means for giving effect to the 'natural rights' of inventors".[45]

(ii) The Industry Property Advisory Committee report (which set out to review the Australian patents system from an economic perspective):

> "The economic significance of patents has at times been obscured by a haze of assumptions about rights and rewards for inventors, special pleading by those directly involved, and a plethora of legal procedures and criteria in the Patents Act. Patents are commonly assumed to confer social benefits arising from greater incentive to industrial innovation and from disclosure of inventions, but there are social costs which may be associated with the monopoly power which patents confer - for example, higher prices and restricted outputs".[46]

(iii) The Dissenting Report of the Industrial Property Advisory Committee by Professor Lamberton may be instructive:

> "The Report is not an imaginative one. It is constrained by the very 'haze of assumptions about rights and rewards for inventors, special pleading by those directly involved, and a plethora of legal procedures and criteria in the Patents Act' that it deplores...A good

[45] Senate Standing Committee on Science and the Environment, *Industrial Research and Development in Australia* (AGPS, Canberra, 1979), at page 129.

[46] Industry Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 1984), at page 11.

> opportunity to adjust an ancient institution to the current needs of the Australian economy has been missed".[47]

4.9 It is arguable there was some recognition of detriment in framing the new *Patents Act* 1990 (Cth): the focus of the *Patents Act* 1990 (Cth) was to maximise social benefit and minimise social cost, [48] the Report of the Industrial Property Advisory Committee, on which the *Patents Act* 1990 (Cth) was based, was directed to "how the patent system can best contribute to the efficiency and progressiveness of the Australian economy",[49] and the conclusion by the Government in a Statement of the Minister of Science and Technology responding to the Industrial Property Advisory Committee stated: "Viewed...from the standpoint of the patentee, a patent is a stick to beat competitors over the head with, if necessary. At the very least, it offers a means of getting and staying that little bit ahead in the field. For the patentee, a patent is not a tool of economic policy, but is potentially a commercial bludgeon",[50] indicate an economic perspective for the granting of patents may be necessary that determines the economic benefit to the Australian community. It may, therefore, be a significant oversight to ignore the possibly detrimental economic effects with respect to gene and gene sequence patents.

4.10 Unfortunately, there is *no* economic data about gene and gene sequence patents. Without evidence to support economic arguments, the economic contentions must rely on theory and assumptions. This partly reflects the difficulty in identifying relevant economic markers. However, an analysis of the available evidence and the various claims leaves open the proposition that the economics of patenting genes

[47] Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (Patent Office, Canberra, 1984).

[48] House of Representatives, *Hansard* 1 June 1989, page 3479 noting the incorporation of this speech into the *Patents Bill 1990* Second Reading Speech at Senate, *Hansard* 29 May 1990, page 1271.

[49] Industrial Property Advisory Committee, *Report on Patents, Innovation and Competition in Australia* (Patent Office, Canberra, 1984).

[50] Statement by the Minister for Science and Technology, Barry Jones MP, responding to the Industrial Property Advisory Committee, *Report on Patents, Innovation and Competition in Australia* (Patent Office, Canberra, 1984).

and gene sequences may not be in the best interests of the Australian community, which lies as the core intention of the *Patents Act* 1990 (Cth).[51]

4.11 In an analysis of the costs of innovation in the pharmaceutical industry, based on data supplied by the Pharmaceutical Manufactures Association (PMA), DiMasi et al.[52] found that a new chemical entity taken to the point of marketing approval cost approximately US$231 million in 1987 dollars. This study made no assessment of the benefits derived from those patents and unfortunately excluded most biological materials.[53] But, this figure is questionable because the out-of-pocket costs of clinical trials for new drug approvals was $21.7 million (or $24.5 million in 1995 dollars), adjusted for the "dry-hole" risks, capital costs and a guesstimate for pre-clinical stage of research to $65.5 million and then adjusted for the opportunity costs of capital to give $231 million.[54] None of this took into account the fact that the US government funds much of the pre-clinical research on drugs and the industry sources of the data have never been disclosed.[55]

4.12 In 1993, the US Office of Technology Assessment published a report on the costs of drug development re-using DiMasi et al.'s data and re-calculated those estimate using new assumptions for the cost of capital for drug development. This report obtained the number of $359 million for the cost of developing a new drug assuming the "upper bound" for the cost of drug development and a 14% real rate of return for the investments in the early pre-clinical research. However, few people understand how this number was developed or what it represents. Further, Office of Technology Assessment wasn't able to obtain its own data on drug development costs and there was no assessment of the contribution of government and university funded research.

[51] House or Representatives, *Hansard* 1 June 1989, page 3479 noting the incorporation of this speech into the *Patents Bill 1990* Second Reading Speech at Senate, *Hansard* 29 May 1990, page 1271.

[52] J DiMasi, R Hansen, H Grabowski and L Lasagna, "Cost of innovation in the pharmaceutical industry" (1991) 10 *Journal of Health Economics* 107.

[53] "new chemical entity" was defined as new molecular compounds not previously tested in humans and excluding biological compounds such as vaccines, antigens, antisera, immunoglobulins, etc.

[54] J Love, "Call for More Reliable Costs Data on Clinical Trials" (1997) 13 *Marketletter* 24.

[55] J Love, "Call for More Reliable Costs Data on Clinical Trials" (1997) 13 *Marketletter* 24.

4.13 In 1997, Love[56] examined the data from the 50 percent tax credit for expenditures on clinical trials for Orphan Drugs under the *US Orphan Drug Act*. Comparisons between the DiMasi et al. data and data from tax credits suggested the following comparisons respectively (in comparable dollars) – $24.5 million v $3.2 million (human-use clinical trials) and $54.8 million v $30.7 million (dry hole risk). Put another way, from 1989 and 1993, $86.6 million in Orphan Drug tax credits were claimed, for an implicit industry cost of clinical trials of $173.2 million. This discrepancy was accounted for as "some unclaimed tax credits, a large role by the government in the development of orphan drugs, and overstating of costs by the industry in the DiMasi et al. study".[57]

4.14 This analysis comparing industry costings against actual figures claimed from government through the tax credit scheme was significant because it highlighted the paucity of data about who pays for the research relied on by private sector and raises the issue of the community subsidising research through public funding and then paying the patent royalties (at least in Australia through the publicly funded Pharmaceutical Benefits Scheme) for many of the benefits of that research.

4.15 In the United States this concern has been recognised and some legislative action proposed. For example, commenting on funding sources for new drug development and innovation in the United States in a Bill proposed to require reporting on research and development expenditures for drugs approved for marketing the accompanying speech noted "of all the cancer drugs developed since the founding of the National Cancer Institute's new drug program in 1955 and approved for marketing by the Food and Drug Administration through 1992, 34 of 37 cancer drugs, or 92 percent, were developed with taxpayer funds".[58]

[56] J Love, "Call for More Reliable Costs Data on Clinical Trials" (1997) 13 *Marketletter* 24.

[57] J Love, "Call for More Reliable Costs Data on Clinical Trials" (1997) 13 *Marketletter* 24; this study also concluded: "The differences also point to the need for disclosure to the public of more reliable data from the industry, so policy makers can better evaluate industry R&D costs". The recent amendment of the *Intellectual Property Laws Amendment Act* 1998 (Cth) required certain clinical trial information to be provided for the extension of patent terms for certain pharmaceuticals. However, the failure to use consistent terminology and detailed mandatory reporting requirements will undermine the proposal.

[58] Section 2, *Sander's Bill* - A Bill to require reporting on research and development expenditures for drugs approved for marketing, and for other purposes (HR 4270, 104th Congress).

4.16 Thus, there may be significant economic returns available to individual patent holders. Monsanto is estimated to collect US$1 to $2 billion in sales of the Roundup Ready soybeans and account for about 15% of United States soybean plantings in 1997[59] and Amgen Inc. was reported to have earned US$587 million in 1993 for erythropoietin.[60] But evidence of significant turnovers (and profits) to individual companies exploiting a monopoly patent right provided by the nation under law *does not* provide evidence that the nation's grant of that monopoly is a good deal for the community. There has been *no* analysis of the benefit to the patent holder in comparable terms to the nation of granting that patent or a comparison of the costs of research with the returns from a monopoly patent, or even the relevant factors in determining that benefit. The Australian Bureau of Statistics has collected data from which estimates have been made of the annual flow of income to a patent holder.[61] The authors acknowledged that these estimates were flawed, because they did not take into account the activities of the higher education sector or the value of patents exploited internally within the company which owned the patent. Similar criticism may be made of other studies,[62] such that there does not seem to be conclusive economic evidence to either support or contradict the community benefit of patenting of genes and gene sequences.

4.17 If there has been no financial benefit, then maybe there has been some other benefit. In a study for the Industry Commission Gruen et al.[63] concluded empirical data from Australia and overseas showed patents had limited commercial importance, had limited effectiveness, delay imitation, fail to provide adequate disclosure and that innovation spill over was limited, and an Industrial Property

[59] A Thayer, "Betting the Transgenic Farm" (1997) 75(14) C&EN 15.

[60] see B Looney, "Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement" (1996) 28 IPLR 101.

[61] N Gruen, G Prior, I Bruse, *Extending patent life: is it in Australia's economic interests?* (Industry Commission Staff Information Paper, Industry Commission, Canberra, 1996).

[62] Relying on very old data - Z Griliches, "Patent statistics as economic indicators: a survey", (1990) 28 J Econ Lit 1661; failing to calculate the commercial gain resulting from the patent - Bureau of Industry Economics, *The Economic of Patents Occasional Paper 18* (AGPS, Canberra, 1994).

[63] N Gruen, G Prior, I Bruse, *Extending patent life: is it in Australia's economic interests*? (Industry Commission Staff Information Paper, Industry Commission, Canberra, 1996).

Advisory Committee[64] investigation into Australian patenting and innovation argued that fine tuning economic policies using the patent scheme was inappropriate and that other measures, such as "tariffs, taxation incentives and other forms of specific selective encouragement or discouragement" should be favored.[65]

4.18 A considerable number of commentators have claimed that researchers will not conduct genetic research without the guarantee of patent protection.[66] This may be a valid argument as an element in a commercial decision whether to fund genetic research under the present regime of patents. However, there is *no* evidence that shows patent protection as the only factor in a commercial decision whether or not to fund research. The research director of the French science agency ISREM is on record suggesting that there is *no* factual basis that patent protection provides an incentive for industry to fund research and suggested that this argument has been put forward to further the cause of patenting.[67] Further, it seems likely that granting a patent in some instances will restrict research, because any development of a patented gene sequence, as an example, which infringes a patent will require the negotiations of royalties with the patent holder thereby reducing the benefit of the development or prolonged litigation in an attempt to limit the scope of the first to patent's claims and establish a presence in the market.[68] This must in some instances be a commercial disincentive to invest money in researching the subject of an existing patent. For example, in *Kirin-Amgen Inc. v. Board of Regents of the University of Washington and Genetics Institute Inc*.[69] the Deputy Commissioner of Patents granted a patent for gene sequences to human and monkey erythropoietin and any DNA sequence coding for a polypeptide analog of naturally occurring

[64] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984).

[65] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984) at page 40.

[66] For example, a number of articles in the "Review: the ethics of patenting genes" (1997) 124 Bull Med Eth 11; T Mandeville, D Lamberton and E Bishop, *Economic Effects of the Australian Patent System* (AGPS, Canberra, 1982).

[67] C Anderson, "NIH Defends Gene Patents as Filing Deadline Approaches" (1992) 375 *Nature* 270.

[68] See for examples the ongoing litigation between Genetics Institute Inc. and Kirin-Amgen Inc. (and the Australian licensee Johnson & Johnson): for example, *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)* [1998] 740 FCA (25 June 1998) and the ongoing decisions.

[69] [1995] 64 AIPO (19 October 1995).

erythropoietin and any DNA sequence that hybridises under stringent conditions. In this instance, Genentech ceased attempts to clone the erythropoietin gene because they believed the gene had been successfully cloned by Amgen,[70] arguably on the basis that once a patent had been granted they would be unable to successfully commercially exploit the gene sequence. Clearly this argument that researchers will not conduct genetic research without the guarantee of patent protection is not as plain as its proponents may suggest.[71] The ongoing litigation between Genetics Institute Inc. and Kirin-Amgen Inc. (and its licensees) in Australia highlights the very limited benefits from later sequencing the same gene, and the possibly huge costs in legal fees trying to limit the wide claims of the first to patent the erythropoietin gene.[72]

4.19 It is also contended in favor of patenting genes, that patenting ensures an efficient allocation of resources.[73] The argument goes that with public disclosure through patents other inventors can obtain the information and save themselves the effort obtaining the same information independently, thus saving time and valuable resources. However, there is evidence to challenge this contention: (i) there are delays in releasing information or information is not released to ensure that the patent application is not harmed,[74] (ii) the Australian experience in the *Chiron case*[75] shows how a patent right was to be used to prevent an arguably superior product from being made available to the community, (iii) the abandonment of

[70] *Kirin-Amgen Inc. v. Board of Regents of the University of Washington and Genetics Institute Inc.* [1995] 64 AIPO (19 October 1995).

[71] Further examples, G Poste, D Roberts and S Gentry, "Patents, ethics and improving healthcare" (1997) 124 Bull Med Eth 29; J Kaiser, "Commercial gene kingdom splits up" (1997) 276 *Science* 1959.

[72] See for example, *Genetics Institute Inc. v Kirin-Amgen Inc.* [1999] FCA 9 (6 January 1999).

[73] B Looney, "Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement" (1996) 28 IPLR 101.

[74] J Kaiser, "Commercial gene kingdom splits up" (1997) 276 *Science* 1959; B Burrows, "Second Thoughts about US Patent #4,438,032" (1997) 124 Bull Med Eth 11; D Dickson, "Open access to sequence data will boost hunt for breast cancer gene" (1995) 378 *Nature* 425.

[75] *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc*. (unreported, Federal Court, NG380/1996); M Lawson, "Patent fights over hepatitis C test kit reverberates around the world" (1994) 370 *Nature* 493.

research when a gene sequence was patented,[76] and (iv) the consequences of limiting the use of gene and gene sequence data is not clear.[77]

4.20 For gene and gene sequences the response of the private sector to patenting may be informative. Patenting has not been universally relied on, and doubt must now be cast on the assumption of community economic benefit with the positioning in the United States of pharmaceutical giants SmithKline Becham and Merck. SmithKline Becham has argued strongly for patenting of human gene sequences and has formed a consortium to map, sequence and patent as many human genes as possible, with approximately 200 of the 450 applications for United States patents on human genes[78]. Merck has argued that restricting access to basic structural and descriptive information about the genome through patents will prevent the human genome being extensively exploited[79]. The divergence of these pharmaceutical giants indicates that there is doubt about the benefits to industry of allowing gene and gene sequence patents, and suggests that there may be an argument that the long term financial (and community) benefits may be greater from the application of the gene and gene sequence information.

4.21 A similar approach has been adopted by United States government research institutions. When the National Institute of Health (NIH) attempted to patent partial cDNA sequences with unknown functions (expressed sequence tags or ESTs), the Pharmaceutical Manufacturers Association of America and the Industrial Biotechnology Association of America both urged the NIH not too, because they considered this might interfere with their effective commercial development.[80] This may also have been to prevent the government using its position of power as the owner of the patents to regulate genome-related products. Either way, these examples show patents may restrict technology transfer.

[76] *Kirin-Amgen Inc. v Board of Regents of the University of Washington and Genetics Institute Inc.* [1995] 64 AIPO (19 October 1995).

[77] For example, the patenting of a global regulatory gene(s) might restrict the further development of genetic mechanisms under the control of those gene(s).

[78] G Poste, "The case for genomic patenting" (1995) 378 Nature 534.

[79] D Dickson, "Open access to sequence data will boost hunt for breast cancer gene" (1995) 378 Nature 425.

[80] M Wadman, "NIH is likely to challenge genetic 'probe' patents" (1997) 386 *Nature* 312; M Wadman, "Patent Office replies to fears over ESTs" (1997) 386 *Nature* 747.

4.22 There has also been a reluctance by the private sector to enforce patents over the research tools, such as methods for manipulating DNA, etc. This may be because the remedies for patent infringement are unlikely to stop a competitor in the market and because the costs and administrative burden of combinations of procedures would make development unduly restrictive. However, this illustrates potential detriments from patenting and an unwillingness to use the patenting scheme for every development.

4.23 It is significant to note the present inquiry by the National Competition Council examining the operation of subsection 51(3) of the *Trade Practices Act* 1974 (Cth) Part IV.[81] Subsection 51(3) exempts certain licenses and assignments of patents from the operation of the competition law provisions (sections 45, 45A, 47, 50 and 50A). The draft report by the National Competition Council states: "It is now accepted that intellectual property laws do not clash with competition laws because they do not create legal or economic monopolies. Intellectual property laws create property rights and the goods and services produced using intellectual property compete in the marketplace with other goods and services. Only in particular cases will intellectual property owners be in a position to exert substantial market power or engage in anti-competitive conduct…The Council considers that in some cases the exemption in section 51(3) permits the use of restrictive conditions that are likely to have the effect of substantially lessening competition in a market and therefore impose significant costs on the community. The Council notes that in some circumstances, restrictive conditions in intellectual property licenses can be justified even where they substantially lessen competition. The Council considers that these benefits can be adequately protected through the authorisation and notification provisions in the TPA [Trade Practices Act]. Under these provisions, the ACCC authorises conduct where the benefits of the conduct outweigh the costs".[82] This approach arguably would not impinge on Australia's treaty obligations (TRIPs, discussed further below) which allow Australia to apply

[81] National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974 - draft report* (National Competition Council, Canberra, November 1998).

[82] National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974 - draft report* (National Competition Council, Canberra, November 1998), at pages 5-6.

competition law to restrictive conditions in patent licenses and assignments.[83] This does not affect the application of competition law to other aspects of patenting, which arguably exists under the public interest intentions of the *Statute of Monopolies* reference.

5. Inventiveness, novelty and newness

5.1 The requirement of a "manner of manufacture" includes the body of law which has evolved through the use of this term in the previous legislation (for example, the *Patents Act* 1903 (Cth) and the *Patents Act* 1952 (Cth)) and the flexibility and judicial interpretations in the English and Australian cases, rather than a strict application of the words.[84] To generalise, a "manner of manufacture" will be satisfied for a product or process which may be achieved by following the specifications, it will be useful, it will have some material advantage, there is some economic advantage and there is an industrial application - an innovative idea which provides a practical solution to a technical problem.[85]

5.2 However, the drafting of subsection 18(1) of the *Patents Act* 1990 (Cth) creates some complexity in that the term "invention" is defined in Schedule 1 to mean "any manner of *new* manufacture" while paragraph 18(1)(a) sets out the requirement for a "manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*". In *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd*[86] the High Court split 3-2 on the significance of the word "new" in the definition of "invention" and its absence in paragraph 18(1)(a), in favour of recognising that "[i]f it is apparent on the face of the specification that

[83] National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974 - draft report* (National Competition Council, Canberra, November 1998), at pages 6 and 72.

[84] See *NRDC v Commissioner of Patents* (1959) 102 CLR 252 at 269; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383; Industrial Property Advisory Committee, *Report on Patents, Innovation and Competition in Australia* (Patents Office, Canberra, 1984), at page 40.

[85] IP Australia Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, February 1998), at page 2.

[86] (1995) 183 CLR 655.

the quality of inventiveness necessary for there to be a proper subject of letters patent under the *Statute of Monopolies* is absent, one need go further".[87]

5.3 In this case, the majority found the application was not a "patentable invention", because on its face it was a "new use of an old product". That is, the majority rejected the application because on its face it was not proper subject matter for patenting. This decision is significant because it leaves open to the court to determine what is, in its view, adequate to satisfy the requirement of "newness" or "inventiveness" for a "patentable invention". Until this decision, the High Court was careful to avoid any limitations on inventiveness necessary to meet the requirements of a manner of manufacture,[88] so that the subject matter of an invention was "of such a wide, elastic and amorphous character as to cover almost all newly-created subject matters or processes".[89]

5.4 In contrast, the minority view noted section 18 did not define "invention", but rather specified what was necessary for a patentable invention. They accepted section 18 reflected the draftsman's specific use of the term "new" in the *Statute of Monopolies* "manner of *new* manufacture" and incorporated the requirements in subparagraphs 18(1)(b)(i) and (ii), thus describing a "patentable invention" by requiring a manner of manufacture to show qualities of novelty and inventiveness when compared to the prior art base: "a patentable invention is a manner of manufacture (s 18(1)(a)) which is, amongst other things, new in the sense that, when compared to the prior art base, it is novel and involves an inventive step (paragraphs 18(1)(b)(i), (ii))".[90] This analysis, the minority concluded, was necessary to reflect the particular elements covered by paragraph 18(1)(b) and the comparisons required by section 7, otherwise these matters would be avoided.[91]

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[87] *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd* (1995) 183 CLR 655 at page 664 per Brennan, Deane and Toohey JJ; this approach was then argued to be consistent with the earlier approach in *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at pages 261-262.

[88] *NRDC v Commissioner of Patents* (1959) 102 CLR 252.

[89] J Starke, "The patenting of animal forms with new traits" (1987) 61 ALJ 324, at pages 325-326.

[90] *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd* (1995) 183 CLR 655, at page 670 per Dawson and McHugh JJ.

[91] *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd* (1995) 183 CLR 655, at pages 670-671: in the House of Lords, albeit applying different laws, Lord Hoffman in the

5.5 For genetic materials, the majority approach of quantification of "inventiveness" or "newness" may be a significant consideration. It is not clear how different, varied, advanced, etc. genetic differences must be before this threshold requirement is satisfied. For example, within a population, will a single base difference in a gene in a multi-gene family be sufficient to be a "new" gene? How many different genes will have to be included in an organism to make it a different organism for the purposes of patenting, and what are the criteria for determining how much difference is enough?[92] This may be illustrated by example – in both *In re Deuel*[93] and *In re Bell*[94] the United States Patent and Trade Marks Office examiner rejected claims to the gene and gene sequence as obvious, because the amino acid sequence was known (and the techniques used to clone and sequence the genes were well known and could be applied by those of ordinary skill, etc. – discussed further below). In both cases the court reversed this decision and accepted that degeneracy in the genetic code meant that a number of different nucleotide sequences might code for a specific protein, and this was a basis for accepting the claimed patent (discussed further below).[95] It is arguable on this authority that a single base difference would be sufficient to differentiate between patent applications for proteins with the same function.[96] However, the conflict in this approach is a

Biogen Inc v Medeva plc (1997) 36 IPR 438, at page 449 warned "[o]ne can of course imagine cases in which the alleged subject matter is so obviously not an invention that it is tempting to take an axe to the problem by dismissing the claim without inquiring too closely into which of the conditions has not been satisfied…Judges would therefore be well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth".

[92] With respect to human genes, Senator John Coulter asked the Minister for Industry, Technology and Commerce, Senator John Button: "The Minister has indicated that animals, including animals containing human genes, would be patentable. By what criterion would the Patents Office judge when sufficient human genes were included in that animal to make that animal not patentable?": Senate, *Hansard*, 5 September 1989, at page 943.

[93] *In re Deuel* 51 F 3d 1552 (1995), at pages 1555-1556.

[94] *In re Bell* 51 F 3d 1552 (1993), at page 783.

[95] *In re Deuel* 51 F 3d 1552 (1995), at page 1558; *In re Bell* 51 F 3d 1552 (1993), at page 784.

[96] The disclosed amino acid sequence in *In re Bell* 51 F 3d 1552 (1993) anticipated a genus of corresponding DNA sequences estimated to include 10^{36} members. Following the court's reasoning, a patent would be necessary for almost every unique sequence, so conceivably 10^{36} patents would need to be issued, each claiming a single not obvious sequence. This is theoretically impossible as the resources necessary for such a

recognition of the unique gene or gene sequence in accepting patentability, and then granting a patent claim significantly broader than the claimed gene or gene sequence (such as for a gene with 35% similarity between genes across species and kingdoms[97] or with 65% amino acid homology[98] – discussed further below).

6. Distinguishing discovery and invention

6.1 For a patent to be granted the subject must be an "invention", as mere discoveries are not patentable.[99] Guidance as to the distinction between a discovery and an invention has been provided by the courts, although "[t]he truth is that the distinction between discovery and invention is not precise enough to be other than misleading".[100] In *NRDC v Commissioner of Patents*,[101] the applicant sought a patent for a weed killing method based on known chemicals with well understood properties. The examiner (and Deputy Commissioner) concluded the claims "are not therefore directed to any manner of manufacture in that they are claims to the mere use of known substances – which use also does not result in any vendible product".[102] On appeal, the High Court concluded the chemicals in this instance were being used for a process which involved an inventive step, because it was distinguishable from previously known processes and had a "plainly" inventive step because it was applying chemicals which had not been previously known for this purpose which was (economically) useful.[103] This case did provide some insight into a discovery *without* invention: "There may indeed be a discovery without invention – either because the discovery is of some piece of abstract information

project are not available – an estimated 9.13 x 10^{32} years (if a lodgement takes 8 hours work x 10^{36} times / 24 hours per day / 365.25 days per year), etc.

[97] see as an example Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 7.

[98] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[99] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264.

[100] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264.

[101] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264.

[102] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 261.

[103] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 265; this new use is distinguishable from the new use in *N V Philips Gloeilampenfabrieken and Philips Lighting Pty Ltd v Mirabella International Pty Ltd* (1995) 183 CLR 655 because there the luminescent properties of phosphors were well known at the time whereas the weed killing potential was unknown at the time of the application.

without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of 'manufacture'".[104] The distinction between an unpatentable discovery and a patentable invention may therefore be said to be, at least, a new and useful application of the discovery. In this assessment, it is the whole process which must be considered and the inventor "need not show more than one inventive step in the advance which he has made beyond the prior limits of the relevant art".[105] In the *NRDC case*, the knowledge and experimentation about the functions of the known chemicals would not have been patentable without their ingenious use as a selective weed killer, which was agriculturally useful.[106]

6.2 Applying these principles to genetic materials, it is apparent that any change from a "natural" state may be patentable. In *Ranks Hovis McDougall Ltd's Application*[107] the Patent Office granted a patent for a pure cultured bacterium on the basis that an inventive step has been applied to purify the naturally occurring organism by "producing the variant by some man-controlled microbiological process",[108] while refusing a patent for the isolated strain of the naturally occurring bacteria. The principle established by this case[109] means that potentially any change from a "natural" state may be patentable on the basis that it is an invention, while the "natural" state is a mere discovery. This is consistent with the practice of the Patent Office to grant patents for, and accept as patentable subject matter, an

[104] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264; *General Electric Co Ltd's Application* [1961] RPC 21.

[105] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264; note *Commonwealth Scientific and Industrial Research Organisation et al.* [1995] APO 16 (8 March 1995) where the Deputy Commissioner of Patents considered the inventive component of a collaborative venture in which one group created a cDNA library and identified putative clones and the second group investigated the clones and identified fragments with activity. The Deputy Commissioner found the entitlement to invention was shared because it was a collaboration and it was the whole, rather than the components parts, which was the "invention".

[106] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264.

[107] (1976) 46 AOJP 3915. This decision was made by the Assistant Commissioner and is not binding on the Federal Court, although the decision has been confirmed by a Patent Office Notice (1980) 50 AOJP 1162.

[108] (1976) 46 AOJP 3915, at page 3968.

[109] Precedent US case *Diamond v Chakrabarty* (1980) 484 PTCJ D-1; contrast the decision of the High Court of Ireland in *Ranks Hovis McDougall Ltd v Controller of Patents, Designs and Trade Marks* [1978] FSR 588 which rejected the claim on the basis that micro-organisms cannot be the subject matter of patents.

extensive range of genetic materials, such as, inventions involving non-human organisms, plants, bacteria, fungi, algae, viruses, nucleic acids, amino acids, cell organelles, enzymes, etc.[110]

6.3 Additional elements in determining inventiveness arguably involve novelty and obviousness. In *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[111] the parties accepted the first to isolate a gene or gene sequence satisfied any novelty requirements[112] and in determining obviousness the relevant test was said to be that stated in *Wellcome Foundation Limited v VR Laboratories (Aust) Pty Ltd*:[113] "The test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention whether they be the steps of the inventor or not". This was said to be a substantive test and not an adjectival test such that a skilled worker *would* consider the cloning strategy worth trying rather than *could* be worth trying.[114]

6.4 The patenting of gene and gene sequences illustrates the fine distinctions necessary to sustain differences between discovery and invention when applied to genetic materials – in "nature" the gene is discovered, but outside that "nature" it becomes inventive.[115] Where the gene encodes a protein with known function, there is an issue of whether applying a range of well characterised procedures is in fact inventive. In *Kirin-Amgen Inc. v Board of Regents of the University of*

[110] IP Australia Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, February 1998), at pages 1-2.

[111] [1998] APO (9 September 1998).

[112] In *Genetics Systems Corporation v United Biomedical Inc.* [1993] APO 60 (12 October 1993) a delegate of the Patent's Commissioner considered the novelty requirements applied to an amino acid sequence, applying a reverse infringement test (set out in *Meyers Taylor v Vicarr Industries Ltd* (1977) 137 CLR 228, at page 235) found no documentary disclosure of the sequences (claims 16 to 38 or claims 29, 32 and 34) or parts of sequences (claims 1 to 15) claimed as essential features of the claim so that there was no "clear and unmistakable directions".

[113] (1980) 148 CLR 262, at page 270.

[114] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[115] Similar arguments may apply to other forms of genetic materials, such as organisms. For example, see Patent Application number 70089/81, Cymbidium orchid cultivar, Adelaide Orchids Pty Ltd.

Washington and Genetics Institute Inc.[116] a patent was sought in Australia for the gene and protein of erythropoietin. The United States District Court in *Amgen Inc. v Chugai Pharmaceuticals Co Ltd*[117] had previously determined that the claim was within the United States patent legislation and a United States patent was upheld. The substance erythropoietin was known, before the gene was cloned, to be involved in the production of red blood cells in bone marrow and as a treatment for kidney failure. Erythropoietin is produced in small quantities and could not be isolated effectively in an active state. With the ability to clone genes it was postulated that through recombinant DNA techniques cell lines could be made to produce recombinant erythropoietin.[118] A number of different and competing groups were involved in trying to clone the erythropoietin gene relying on material and published results from their own and other research groups, and applying similar molecular biology techniques. Amgen finally cloned the gene and lodged an application for an Australian patent. This application was challenged in Australia on the basis that the invention claimed was obvious, it was not novel, the invention was a mere discovery and the claim was not fairly based. The Deputy Commissioner of Patents rejected the challenges and granted the patent in Australia which was upheld on appeal to the Federal Court subject to some amendment.[119]

6.5 This conclusion arguably ignores the accepted dogma that there is a gene that codes for every protein.[120] The erythropoietin protein (and gene) satisfies this dogma, and would have been assumed to satisfy this dogma well before its identification. To a person skilled in the art of molecular biology with the common general knowledge publicly available at the time, cloning the gene would have been the obvious next step. As evidence of this, a number of other research groups were attempting to clone the same gene at the same time in what the Deputy Commissioner of Patents described as "the race to clone erythropoietin".[121] Further, the techniques used to

[116] [1995] 64 AIPO (19 October 1995).

[117] 13 USPQ2d 1737.

[118] Recombinant erythropoietin has certain advantages compared to other erythropoietin isolates: see *Amgen Inc. v Chugai Pharmaceuticals Co Ltd* 13 USPQ2d 1737.

[119] *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)* [1998] 740 FCA (25 June 1998).

[120] Prions may be an exception and it is notable that some genes are transcribed but not translated (that is, there is no protein).

[121] [1995] 64 AIPO (19 October 1995).

clone this gene were common among the research groups in Australia and around the world. To overcome these arguments the Deputy Commissioner of Patents accepted that the amino acid sequence of erythropoietin was unknown in Australia at the relevant time to a sufficient level and that the required knowledge was not obvious in Australia.[122] However, it is difficult to imagine that with sufficient time, resources and the ordinary skills of a molecular biology practitioner, this gene would not have been cloned and sequenced.

6.6 This submission argues the significance attached to the process of isolating a gene or gene sequence should be viewed as a process of discovery of the information from "nature" held in the sequence, which can then be applied for inventive purposes. The approach of characterising the invention as deriving the sequence information from "nature", and then restricting the further exploitation of that information through broad patents is contrived and undermines the policy basis for patenting – the encouraging and rewarding inventiveness. The United States case of *Amgen Inc. v Chuhai Pharmaceutical Co Ltd*[123] exemplifies this contrived distinctions by distinguishing a real gene from an invented gene as a substitute over which the patent was granted even though the gene or gene sequence's function is not substituted, so that it functions similarly to the "real" gene in "nature".[124]

6.7 Courts in the past have grappled with this practice of granting patents of gene and gene sequence claims and in some cases identified something more than a gene sequence as necessary for a patentable invention. For example, in the English *Chiron case*[125] the court upheld the Chiron claim of a patent over the Hepatitis C virus sequence even though its identification was obvious, because it had taken "30-man years" to achieve and over ten years world wide to identify, indicating an

[122] Under the *Patents Act* 1990 (Cth) the prior art base for a standard patent is now worldwide documentation, whereas under the *Patents Act* 1952 (Cth) this was confined to Australia and in this case the patent application preceded the commencement date of the 1990 Act: see *Genetics Institute Inc v Kirin-Amgen Inc. (No 3)* (1998) 740 FCA (25 June 1998).

[123] (1991) 927 F 2d 1200.

[124] see B Looney, "Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement" (1996) 28 IPLR 101.

[125] *Chiron Corp. v Organon Teknika Ltd (No 3)* [1994] FSR 202.

inventive step[126] and arguably in the United States in *Amgen Inc. v Chuhai Pharmaceutical Co Ltd*,[127] the court held the erythropoietin gene was patentable because it was a novel purified and isolated sequence derived from the objects of nature, although noting the DNA screening method used was not obvious suggesting an inventive step.

6.8 Without a challenge to a patent application the present Patent Office practice of patenting gene and gene sequences is likely to continue, granting patents for gene and gene sequences which "have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a defined industrial use".[128]

6.9 A review of Patent Office decisions shows some recognition in the decisions that DNA manipulation techniques (such as cloning, sequencing, etc.) may not be inventive. For example, in *Genetics Institute Inc. v Johnson & Johnson*[129] the Deputy Commissioner of Patents considered the relationship between copy DNA (cDNA) and genomic DNA (gDNA) and stated: "given gDNA, cDNA is deduced by routine procedures normally not involving any invention over and above the derivation of the gDNA. Accordingly, in the absence of some identified problem in deriving the cDNA from the gDNA, I consider that the cDNA corresponding to a gDNA sequence is in fact the same invention as the gDNA".[130]

6.10 However, what constitutes "some identified problem" over and above the routine arguably means an inventive step may *always* be found. Examples of there being something inventive include:

[126] Contrast *Genentech Inc. v Wellcome Foundation Ltd* [1989] RPC 147 where the court found the production of human tissue plasminogen activator (the enzyme that breaks down blood clots) using recombinant DNA techniques was obvious, even though the cloning of the gene had been a long and expensive process.

[127] (1991) 927 F 2d 1200.

[128] The Patent Office has received 8,100 applications for gene and gene sequences and granted 2,100 patents: Senate Question on Notice 449, 24 March 1997; see also IP Australia Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, February 1998).

[129] [1996]APO 56 (19 November 1996).

[130] *Genetics Institute Inc. v Johnson & Johnson* [1996]APO 56 (19 November 1996).

(i) In the recent decision in *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[131] a delegate of the Patents Commissioner considered whether dog cDNA clones (known as RDC4 and isolated using probes based on G protein-coupled receptors, including the 5-HT_{1A} receptor) used to identify a human 5-HT_{1D} receptor gene by standard techniques was obvious – that is, whether it was a routine cloning strategy to screen for (human) cDNA clones using non-homologous (dog) cDNA probe? Before the 5-HT_{1D} receptor gene was cloned a family of proteins known as the 5-HT receptors was known and some of the 5-HT1D receptor protein functions had been characterised. Applying the *Wellcome Foundation Limited v VR Laboratories (Aust) Pty Ltd*:[132] obviousness test (set out above) the delegate determined that despite the isolation of the dog cDNA using a probe based on the 5-HT_{1A} receptor, a skilled worker without further characterising the dog cDNA would not have been led to use this as a probe to isolate a human 5-HT_{1D} receptor gene. Therefore, the invention was not obvious.[133] The decision was allegedly substantiated by a view the dog cDNA clone was only a "tentative" 5-HT receptor with confirmatory functional studies necessary for validation, that a skilled worker intending to clone 5-HT receptors would have used probes based on known receptors and that a skilled worker would not have used a partly characterised clone to screen for a known gene.[134] Submissions showing the routine nature of this cloning strategy were not considered because the first step in choosing the probe was determined to be not obvious. This conclusion is perplexing because the relatedness of this gene family in mammals (including humans and dogs) was known and using non-homologous probes would, with sufficient time, resources and the ordinary skills of a molecular biology practitioner, resulted in the identification and cloning of the target gene. The dog gene may not have been the best choice, but it would with ordinary skill, etc. be expected to identify the human gene.

[131] [1998] APO (9 September 1998).

[132] (1980) 148 CLR 262, at page 270.

[133] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[134] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

(ii) In *Takeda Chemical Industries v Hoffman-La Roche Aktiengesellschaft*[135] where a delegate of the Patent's Commissioner concluded a range of well characterised protein purification techniques, which would have been routine experimentation to a skilled person to apply to the purification of the claimed protein, *did not* confound invention. In finding a skilled worker could not have successfully applied the purification techniques without an inventive step the delegate said: "[The opponent]…provided evidence of a range of well known techniques available to the skilled worker. However, she did not suggest any or all of these techniques would have been expected to successfully purify the protein nor that the skilled worker would have been directly led to try any particular techniques at the priority date which would purify the protein. In my opinion, it is not routine experimentation to try each possible purification technique and combination of techniques to devise a successful purification strategy. Since the opponent has not established that the skilled worker would have selected particular techniques from the myriad available to them, I am not convinced that the skilled worker could have successfully purified recombinant non-glycosylated human interleukin-2 without an inventive step".[136] Protein purification, like manipulating DNA (and RNA), relies on combinations of well established techniques many of them subject to the vagaries of materials suppliers in Australia, availability of equipment, etc. and the preferences of individual skilled persons for particular techniques. The consequence of this, applying the reasoning in this decision, is each skilled worker is arguably likely to be inventive.

6.11 This Patent Office practice is justified because where the validity of the patent is uncertain the patent should be granted,[137] because refusal to accept is final and all the necessary material to make this determination may not be before the Patent

[135] [1996] APO 3 (18 January 1996).

[136] *Takeda Chemical Industries v Hoffman-La Roche Aktiengesellschaft* [1996] APO 3 (18 January 1996).

[137] *International Business Machines Corporation v Commissioner of Patents* (1991) 22 IPR 417.

Office decision maker.[138] This is a matter that can only be resolved in Australia through decisions made in the courts or direct legislative action.

6.12 The Australian courts were scheduled to consider the issue, but the matter was resolved in a settlement between the parties. In *Murex Diagnostics Australia Pty Ltd v Chiron Corp*[139] the Federal Court started to consider whether a patent could be granted for the sequence of the Hepatitis C virus. The Chiron Corporation had developed a test for detecting an Hepatitis C strain 1a. Murex developed independently a diagnostic test for a range of other Hepatitis C strains not covered by the Chiron test. Both test were based on the same Hepatitis C gene sequence. Murex instituted proceedings against Chiron claiming the Australian patent was invalid and Chiron cross claimed. This case would have guided the granting of patents over gene and gene sequences in Australia. Since then the decision in *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[140] considered the issue, but was able to find the probe choice was inventive. Interestingly, the parties challenging a patent claim to the same sequence often fail to raise these issue. For example the Deputy Commissioner of patents stated in *Kirin-Amgen Inc. v Board of Regents of the University of Washington and Genetics Institute Inc*.:[141] "The prime question in this opposition is whether the invention claimed is obvious, although it was not a ground of opposition argued by…[the opponent]". It was also not challenged in the appeal of this matter to the Federal Court.[142] The reasons for this failure are not clear.

6.13 Where a gene or gene sequence encodes a protein with no known function or carries out some other unknown function (for example, where it is transcribed but not translated) the gene or gene sequence will in most instances fail the basic requirements in subsection 18(c) of the *Patents Act* 1990 (Cth), because without a function it will not be useful and therefore not patentable. The exceptions, such as

[138] *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232, at pages 224-225 and cited with approval in *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 740 FCA (25 June 1998).

[139] Federal Court, NG380/1996.

[140] [1998] APO (9 September 1998).

[141] [1995] 64 AIPO (19 October 1995).

[142] *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)* [1998] 740 FCA (25 June 1998).

the proposal to patent expressed sequence tags[143] and single nucleotide polymorphisms[144] are becoming increasingly valuable as tools to identify previously unknown gene and gene sequences and as templates for expressing and characterising proteins for further research. The threshold requirement in these cases is to establish some function for the sequence, and once this is done the same patenting principles will apply. Significantly for this submission, the techniques applied to these sequences in their identification and use are generally well known to those skilled in the art, etc.

6.14 Where a court unable to engineer an invention, it seems likely the Australian courts may follow the United States experience and deal with inventiveness another way. In recent United States cases,[145] the United States Court of Appeals for the Federal Circuit has found gene and gene sequences for proteins of known function are patentable, because the sequence could not have been known without cloning and sequencing, which is sufficient for it to be not obvious.[146] In both *In re Deuel*[147] and *In re Bell*[148] 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 claimed nucleotide sequence was not obvious.[149] This was sufficient for an invention and therefore a patent despite well known and characterised methods for identifying and isolating the claimed sequences.

6.15 In *In re Deuel*[150] (and this is the most recent relevant United States biotechnology authority, following *In re Bell*[151] and *In re Baird*[152]) the heparin-binding growth factor protein from bovine uterine tissue was isolated, partially amino acid

[143] See M Wadman, "NIH is likely to challenge genetic 'probe' patents" (1997) 386 *Nature* 312; M Wadman, "Patent Office replies to fears over ESTs" (1997) 386 *Nature* 747; J Doll, "The patenting of DNA" (1998) 280 *Science* 659.

[144] See J Doll, "The patenting of DNA" (1998) 280 *Science* 659.

[145] *In re Deuel* 51 F 3d 1552 (1995).

[146] *In re Deuel* 51 F 3d 1552 (1995); *In re Bell* 51 F 3d 1552 (1993); *Fiers v Sugano* (1993) 984 F 2d 1164.

[147] *In re Deuel* 51 F 3d 1552 (1995), at pages 1555-1556.

[148] *In re Bell* 51 F 3d 1552 (1993), at page 783.

[149] *In re Deuel* 51 F 3d 1552 (1995), at page 1558; *In re Bell* 51 F 3d 1552 (1993), at page 784.

[150] 51 F 3d 1552 (1995).

[151] 51 F 3d 1552 (1993).

[152] 16 F 3d 380 (1994).

sequenced and probes made from the deduced DNA sequences. Both a human and bovine gene were isolated, sequenced and the full amino acid sequence deduced. The human and bovine DNA sequences, as well as the deduced amino acid sequences were claimed. The Patent and Trade Marks Office examiner rejected the claim based on a finding that the invention was obvious because the partial amino acid sequence for heparin-binding growth factor had previously been published and with this sequence finding the human and bovine sequences and deducing the full amino acid sequence were routine. Following the reasoning applied to chemical inventions the court held the claimed DNA and protein sequences were not obvious on the basis the published amino acid sequences were not DNA sequences and could not render the DNA sequences obvious (because of the wobble between codons and amino acids) and there were so many possible DNA sequences that could potentially code for the protein, a person of ordinary skill in the art could not have determined the DNA sequence without actually doing the experiment. Further the claim was for compounds, and not methods to make compounds, so the fact the methods were already known was irrelevant, following the authority in *In re Bell.*[153]

6.16 However, there was an important departure in reasoning between the *In re Bell*[154] and the *In re Deuel*[155] decisions. In *In re Bell*[156] the claim was for the complete DNA sequences of insulin-like growth factors I and II (IGF I and II). The complete amino acid sequences were known together with a known method for isolating the sequences which suggested short homologous probes derived from the known amino acid sequences be used to identify the DNA sequences. Short probes were constructed, but because of the degeneracy in the genetic code these DNA sequences were not unique (as suggested by the disclosed method), and therefore did not conform to the prior art for cloning. Therefore the cloning of the IGF I and II genes was not obvious. This reasoning considered the invention and found the step of deriving short DNA probes from the known amino acid sequence was inventive because the general method called for short homologous probes and the

[153] 51 F 3d 1552 (1993).

[154] 51 F 3d 1552 (1993).

[155] 51 F 3d 1552 (1995).

[156] 51 F 3d 1552 (1993).

method relied on used short partly homologous probes, because of the wobble in the genetic code, deriving the appropriate DNA sequence for the probes.

6.17 This analysis suggest the broad Australian test set out in the *NRDC case*[157] and the *Wellcome Foundation Limited v VR Laboratories (Aust) Pty Ltd*:[158] obviousness test are likely to accept a gene or gene sequence patent[159] and Australia will most probably evolve into and follow the United States approach which in effect accepts an isolated sequence (which has never before been cloned) as inventive. This approach most likely embraces all gene and gene sequences isolated following standard laboratory procedures, and the "invention" in these circumstances (the advance made beyond the prior limits of the art) is the previously unidentified sequence information itself. The concern with this approach is blending discovery and invention by finding inventiveness in the techniques for manipulating DNA (and RNA) and locking up the sequence information in a monopoly, when that very sequence information is essential for further inventiveness (discussed further below).

6.18 The approach in *In re Deuel*[160] is also defective because a known class of proteins with known sequence can be used to identify specific DNA sequences and the specific DNA sequences can then be relied on to claim broad classes of sequences. The argument that determining a DNA sequence from an amino acid sequence is not obvious because the genetic code from the amino acid to the DNA is not absolutely identifiable overlooks the "information bridge" between amino acids and DNA (and RNA). This is particularly odd because with advancing technology the ability to rapidly synthetically manufacture a DNA sequence from amino acid sequence means an artificial sequence can be generated and a broad claim made to that sequence which would cover the "natural" DNA sequence. This approach also overlooks the additional information held in genetic materials which is the result of evolution, and in Australia's position as a mega diverse nation, it is this additional information which has significant potential (discussed further below).

[157] (1959) 102 CLR 252, at page 264.

[158] (1980) 148 CLR 262, at page 270.

[159] D Nicol, "Should human genes be patentable inventions under Australian patent law?" (1996) 3 JLM 231, at pages 236-237.

[160] 51 F 3d 1552 (1995).

6.19 It is submitted the inventiveness should attached to what the genetic information is to be applied for (invention) rather than how the information was obtained (discovery). This approach is arguably consistent with the *Ranks Hovis McDougall Ltd's Application*[161] decision because the information content is inventive when applied (as with the bacterial variant with a microbiological process) but a discovery when merely collected (as with the isolated naturally occurring bacteria). The effect of this approach would avoid the need to draw fine distinctions presently relied on to justify inventions in the discovery process and the present effect of giant rewards for minimal steps of inventiveness.

7. Broad claims and fair basing

7.1 In the *NRDC Case*[162] the High Court found the weed killing was inventive because the known chemicals were being put to a use which they had not been before, as their weed killing potential was unknown even though the chemicals were themselves well known. In this instance the High Court recognised that these chemicals could be the subject of another patent application, if that application set out a new and ingenious use for the chemicals. However, it is submitted that genetic materials are presently being patented in a way that fails to recognise the potential additional inventiveness – such as the subsequent use of the additional molecular information in the DHK hydroxylating enzyme sequence,[163] the 5-HT_{1D} receptor sequences,[164] erythropoietin sequences,[165] Hepatitis C sequences,[166] etc. – by granting broad claims which include the additional potential of the sequence and other biological processes associated with that sequence.

[161] (1976) 46 AOJP 3915. This decision was made by the Assistant Commissioner and is not binding on the Federal Court, although the decision has been confirmed by a Patent Office Notice (1980) 50 AOJP 1162.

[162] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264.

[163] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd.

[164] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO 49 (9 September 1998).

[165] *Kirin-Amgen Inc. v Board of Regents of Washington and Genetics Institute Inc.* [1995] 64 AIPO (19 October 1995).

[166] *Chiron Corp. v Organon Teknika Ltd (No 3)* [1994] FSR 202.

7.2 Put another way, the concern is some genetic materials are highly conserved across a wide range of organisms - a DNA (or RNA) sequence in one organism can have the same or a similar DNA (or RNA) sequence in another organism, even if distantly related, such that the identification of a sequence in one organism means the same (or similar) sequence (or a functional part of that sequence) is most likely present in another organism.[167] Together with the similarities in genetic materials, there are also the subtle variations and differences. For example, variation in sequence, which are identifiable at various levels or patterns of diversity. The genetic composition (and population structures) of individuals, communities, population, species, etc. are important in determining the amount (richness and evenness) of diversity as well as structural barriers to gene flows (such as breeding systems) and added to this the molecular diversity which occurs as ploidy with single gene, multi-gene family, hypervariable (minisatellite and microsatellite) sequence and organellar (mitochondria and chloroplast) genome levels of complexity. The subtle variations and differences are the source of significant potential benefit from (bio)technology and reflect the value of Australia's genetic resources as a mega-diverse nation. Significantly, these levels and patterns of diversity are reflected in the DNA (and RNA) sequences, although an individual sequence *may not* give any indication of the levels or patterns of diversity.

7.3 Examples of patent claims over genetic materials accepted by the Patent Office which illustrate the breadth of accepted claims include:

(i) gene and gene sequences - an application for a "nucleic acid isolate comprising a sequence of nucleotides encoding, or complementary to a sequence encoding, a dihydrokaempferol (DHK) hydroxylating enzyme or a functional derivative or part of the enzyme",[168] which was isolated using standard molecular genetic techniques for cloning and sequencing.[169]

[167] See Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-37.

[168] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd.

[169] Other reported examples include DNA encoding 5-HT_{1D} receptors, *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998); DNA encoding erythropoietin, *Kirin-Amgen Inc v Board of Regents of the University of Washington and Genetics Institute Inc* [1995] 64 AIPO (19 October

(ii) organisms – an application for a new cymbidium orchid cultivar developed using conventional hybridising techniques.[170] The description of the invention claims that 10,000 or more hybrids need to be examined to identify one of interest and that a period of at least 4 years of cultivation was necessary to determine the hybrids worth (although it is not clear from this application that this was in fact the process undertaken) – "[a]ccordingly it is a substantially valuable discovery taking much skill in selection of correct parents and then having substantial luck together with careful controls to result in a meritorious cymbidium orchid cultivar".[171] It is assumed the new orchid was a vendible product. The new cultivar was obtained using known techniques and a lot of work, with some luck,[172] and the inventiveness was arguably confined to the selection of parental cultivars.

(iii) biological processes – an application for the expression of (any) DNA which significantly disturbs the metabolism, functioning and/or development of stamen cells causing male sterility.[173]

7.4 In the settled case of *Murex Diagnostics Australia Pty Ltd v Chiron Corp*[174] the Federal Court started to consider whether a patent could be granted for the sequence of the Hepatitis C virus. The Chiron test (including the gene/nucleotide sequence) detected a Hepatitis C strain 1a. Murex's independently developed test identified a range of additional strains based on the Hepatitis C gene sequence. A decision in favour of Chiron would have prevented the Murex test being sold in Australia even though it was a test able to identify strains of Hepatitis C the Chiron test could not detect, and would have arguably limited the making of any other tests

1995); DNA encoding Taq DNA polymerase, *Hoffman-La Roche AG v Bresagen Lth and New England Biolabs* [1997] APO 57 (12 November 1997).

[170] Patent Application number 70089/81, Cymbidium orchid cultivar, Adelaide Orchids Pty Ltd.

[171] Patent Application number 70089/81, Cymbidium orchid cultivar, Adelaide Orchids Pty Ltd, at page 1.

[172] Patent Application number 70089/81, Cymbidium orchid cultivar, Adelaide Orchids Pty Ltd, at page 2.

[173] Patent Application 52245/96, Plants with modified stamen cells, Plant Genetic Systems NV, at page 51.

[174] Federal Court, NG380/1996; procedural dispute reported in *Murex Diagnostics Australia Pty Ltd v Chiron Corp* (1995) 30 IPR 277.

based on the Hepatitis C sequence, including other strains not identified by the Murex test. Therefore, a patent over the Hepatitis C gene sequence as part of a diagnostic kit fails to recognise the additional serotype information which distinguished the Chiron and Murex tests.

7.5 Since then the Federal Court has provided some indication of the limits to patented genes and gene sequences. In *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)*[175] Justice Heerey found a claim to DNA sequences from human and monkey erythropoietins and the erythropoietins in other mammals was fairly based[176] applying a test of "whether the specification provided a real and reasonably clear disclosure of the invention".[177] This claim was fair because the specification disclosed the boundaries to the coding regions, intron/exon sites, protein sequence confirmation, a full range of biological activity tested and 5' and 3' untranslated regions that described a wide population of cDNAs. Therefore a skilled person would have relied on the information as disclosing the claimed human cDNA sequence and the claim to human and monkey erythropoietin genes and the erythropoietin genes in other mammals was valid. However, the issue of whether a claim to "DNA sequences which hybridise under stringent conditions" to the specified sequences was not addressed.

7.6 Other limits have been suggested by decisions of the Patent Office:

(i) In *Genetics Systems Corporation v United Biomedical Inc*.[178] a delegate of the Patent's Commissioner concluded sequence claims (and in this instance it was claims for amino acid sequences and polypeptides) relying on combinations of sequences within a sequence which was already known had

[175] [1998] 740 FCA (25 June 1998).

[176] Section 40 of the *Patents Act* 1952 (Cth) was applied because the validity of the patent commenced prior to the commencement date of the *Patents Act* 1990 (Cth), although the parties agreed the relevant provision in each Act was of the same effect despite some drafting differences.

[177] Justice Heerey distinguishes the House of Lords decision in *Biogen Inc v Medeva plc* [1997] RPC 1 in that the present matter disclosed a sequence, and so "discloses a 'principle capable of general application' and discloses a beneficial property which is common to the class. It cannot be said of it that it 'discloses no principle which would enable other products [of the class] to be made'".

[178] [1993] APO 60 (12 October 1993).

to clearly define and describe the sequence of amino acids and the combinations of peptide sequences. In this case competitive epitopic binding sites (amino acids in a sequence) for the already sequenced LAV/HTLP-III virus were claimed by listing peptides and claiming sequences of amino acids (the binding site) within those combinations (of at least one) of peptides. These claims were found not to comply with section 40 of the *Patents Act* 1952 (Cth) and time was allowed to make amendment to the claim so that it did comply – claims to amino acid from particular regions are fairly based if they specify the sequence.

(ii) In *Commonwealth Scientific and Industrial Research Organisation et al.*[179] the Deputy Commissioner of Patents considered the addition of start and stop codons to a clone, together with the conservative substitution of two amino acids outside the catalytic domain through polymerase chain reaction (PCR) cloning was something a person skilled in the art, etc. would do and therefore was not sufficiently inventive. Significantly, the PCR primers used were not claimed and the conservative substitutions were not detailed suggesting they were of no consequence and thus a "colorful variation". However, if these primers had been detailed, as they had been in other accepted patent claims, the decision may have arguably been different because there would have been a basis to conclude inventiveness.

(iii) Before the Deputy Commissioner of Patents in *Kirin-Amgen Inc v Board of Regents of the University of Washington and Genetics Institute Inc*[180] it was argued the sequence claims should be limited to the specific sequences set out in the specification and to any variants of those sequences specifically defined. This was rejected by the Deputy Commissioner who accepted the sequences in the specification together with "DNA sequences which hybridise under stringent conditions" to the specified sequences and said "the discovery of a natural DNA sequence is tantamount to the discovery of a class of compounds – which class would be readily understood by a person skilled in the art. Accordingly I am satisfied that there is sufficient

[179] [1995] APO 16 (8 March 1995).

[180] [1995] 64 AIPO (19 October 1995).

teaching to provide a fair basis to claims to erythropoietin unlimited either by species or specific structure". The Deputy Commissioner also stated, "And I would observe that if it was subsequently found that a particular variation of the sequence gave rise to new and surprising results, the law of selection would apply". However, these statement should now be read in the context of Justice Heerey's decision in *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)*[181] in the Federal Court which stated the test to be "whether the specification provided a 'real and reasonably clear' disclosure of the invention", and the test for novelty in a future claim would be the reverse infringement test of "whether the alleged anticipation would, if the patent were valid, constitute an infringement".[182] It seems hard to imagine a clearly stated claim and specification for homologues and hybridisation would not cover future sequence variations, irrespective of "new and surprising results".[183]

(iv) In *Hoffmann-La Roche AG v Bresagen Ltd and New England Bioloabs*[184] a "recombinant DNA comprising at least a sequence encoding all or part of a thermostable DNA polymerase" was claimed. A delegate of the Patent's Commissioner concluded the claim did not define an invention because there was "no size or functional limitation in the claimed 'part'",[185] suggesting a claim must have a size or functional limitation to the seqeunce. The decision in *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)*[186] probably illutrates what is necessary – the Federal Court determined the claim (to erythropoietin genes) was fair because the specification disclosed the boundaries to the coding regions, intron/exon sites, protein sequence

[181] [1998] 740 FCA (25 June 1998).

[182] *Meyers Taylor v Vicarr Industries Ltd* (1977) 137 CLR 228, at page 235 and applied to amino acid sequences in *Genetics Systems Corporation v United Biomedical Inc.* [1993] APO 60 (12 October 1993).

[183] Note also Justice Heerey in *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)* [1998] 740 FCA (25 June 1998) rejected the "radical transformation" argument of Justices Stephen and Mason in *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 14 ALR 149, at page 172.

[184] [1997] APO 57 (12 November 1997).

[185] *Hoffmann-La Roche AG v Bresagen Ltd and New England Bioloabs* [1997] APO 57 (12 November 1997).

[186] [1998] 740 FCA (25 June 1998).

confirmation, a full range of biological activity tested and 5' and 3' untranslated regions that described a wide population of cDNAs.

(v) In *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[187] a delegate of the Patents Commissioner considered a claim for sequence encoding the human 5-HT_{1D} receptor gene and by a definition in the specification included genes of the 5-HT receptor family which exhibit 65% or higher homology at the amino acid level. In this case it was argued the claimed sequences should be limited to only those disclosed in the patent application because the specification only provided substantive details of 2 members of a sub-family (5-$HT_{1D\text{-}1}$ and 5-$HT_{1D\text{-}2}$) and not all family members (the 5-HT_{1D} receptor family). The decision accepted as a matter of interpretation a person skilled in the art would understand this to be limited to sequences "isolated from nature" and excluded sequences created artificially (such as *in vitro* techniques like site directed mutagenesis).[188] Further this decision found the claimed sequences provided "a principle of general application and demostrated a beneficial property common to the class of compounds" and concluded "that while the technical contribution made by the applicant was to isolate and sequence to human 5-HT_{1D} receptor genes, the inventive concept of the current specification resides in the isolation and sequencing of the whole class of human 5-HT_{1D} receptors (as defined in the specification)".[189] The claim to all the 5-HT receptor genes was allowed.

(vi) In *Genetics Institute Inc v Johnson & Johnson*[190] the Deputy Commissioner of Patents considered competing claims for a method for the production of erythropoietin. The prior claiming provisions relevant to this decision were under the *Patents Act* 1952 (Cth) which were changed in the *Patents Act* 1990 (Cth) to a "whole of contents" novelty. Significantly, the patent being challenged by Johnson & Johnson in this case was the same patent challenged by Genetics Institute Inc. in the decision *Kirin-Amgen Inc. v.*

[187] [1998] APO (9 September 1998).

[188] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[189] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[190] [1996] APO 56 (19 November 1996).

Board of Regents of the University of Washington and Genetics Institute Inc.[191] (that is, Johnson & Johnson is the Australian licensee of the Kirin-Amgen Inc. patent for erythropoietin sequences). Johnson & Johnson challenged Genetics Institute's claimed patent over the same coding region of DNA sequence (despite some small differences, which were not contested as it was accepted both claimed the same gene). Genetics Institute contended it had sequenced the whole gene with introns while Johnson & Johnson had not completely sequenced the introns. The Deputy Commissioner found there would not have been a new invention just because the sequences were different and further characterisation of the gene did not change the invention. Genetics Institute also argued its further sequencing of the flanking regions of cDNAs was important for stability, expression rates and glycosylation and because their flanking regions were different to the Johnson & Johnson regions there was a new invention. This was rejected by the Deputy Commissioner because the specifications did not make this claim, although left open whether this would be significant had the specification identified a function for these regions. The Deputy Commissioner also suggested a distinction between a substance versus method claim – "a claim to a substance which requires the steps set out in the claim to a method of producing the substance, prior claims the method claimed" while the converse is not true.

7.7 The acceptance by the Patent Office of very broad claims is likely to limit the potential for others to claim inventions relying on these levels and patterns of diversity within genetic materials. For example, the decision in *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[192] also considered claims based on a sequence which "telescope or microscope". This invention (isolating the human 5-HT_{1D} receptor genes) covered nucleic acid molecules encoding the human 5-HT_{1D} receptor, anti-sense oligonucleotides of the human 5-HT_{1D} receptor genes, human 5-HT_{1D} receptor proteins, methods for ligand binding, antibodies directed to the human 5-HT_{1D} receptor and methods of diagnosing a pre-disposition to a

[191] [1995] 64 AIPO (19 October 1995).

[192] [1998] APO (9 September 1998).

human 5-HT_{1D} receptor disorder.[193] The decision found, relying on authority in *Olin Corporation v Super Cartridge Co Pty Ltd*[194] that a claim "must be referable to the invention disclosed and cannot extend to cases where the result represents or may represent a different invention"[195] and *Montecatini Edison SpA v Eastman Kodak*[196] that a patentee is entitled to a claim which "embodies his inventive idea but not for an article which, while capable of being used to carry his inventive idea into effect, is described in terms which cover things quite unrelated to his inventive idea, and which do not embody it at all",[197] that claims set out above were within the scope of the invention (isolating the human 5-HT_{1D} receptor genes) because the subject matter of the claim was "linked in such a way to the inventive concept as to be limited by it",[198] while claims outside this scope included methods to detect ligands (merely identify properties of known products) and methods not limited to the involvement of an isolated human 5-HT_{1D} receptor.[199] This decision also suggested antibody claims are limited to those raised against the isolated protein product.[200] The claims limited to the inventive concept were allowed while the others were rejected on the basis they were not fairly based.[201]

7.8 The consequence of this is to under value the potentially wide benefits of Australia's genetic resources and the inventions relying on Australia's unique genetic materials. For example, the Patent Office has accepted a claim for the DHK hydroxylating enzyme sequence.[202] Breaking down this claim illustrates the breadth of genetic materials which may be included in this claim, and the limits this

[193] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[194] (1977) 14 ALR 149.

[195] *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 14 ALR 149.

[196] (1971) 45 ALJR 593.

[197] *Montecatini Edison SpA v Eastman Kodak* (1971) 45 ALJR 593.

[198] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[199] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[200] *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO (9 September 1998).

[201] Section 40 of the *Patents Act* 1990 (Cth).

[202] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd.

may place of further exploitation of a genetic resource.[203] The DHK hydroxylating enzyme claim includes:

(i) The 3',5'-hydroxylase gene (for the DHK hydroxylating enzyme) from all plant sources as well as other nucleic acids (and amino acid) sequences having at least 35% similarity[204] - this includes every sequence from any source which has at least 35% sequence homology irrespective of the function of the particular sequence.

(ii) Other nucleic acid molecules which hybridise under low, medium and high stringency conditions[205] - this includes every sequence from any source which has sufficient homology irrespective of the function of the particular hybridising gene or sequence.

(iii) To a "nucleic acid isolate comprising a sequence of nucleotides encoding, or complementary to a sequence encoding, a…[DHK hydroxylating enzyme]…or a functional derivative or part of the enzyme"[206] – this includes the sequence from any source which has a function similar to a function of the DHK hydroxylating enzyme or part of the DHK hydroxylating enzyme and might include the active site coding sequence in every gene from any source which has a similar function to DHK hydroxylating enzyme or a part of the enzyme, which could include catalytic sites, membrane binding, channels, secondary/tertiary motifs, etc.

(iv) As well as a claim for any nucleic acid isolate from petunia, verbena, delphinium, grape, iris, freesia, hydrangea, cyclamen, potato, pansy or egg

[203] The alternative argument is the acceptance of very broad patents exposes any future claim either prosecuting or defending a claim at some considerable expense.

[204] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 7.

[205] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 7; see also *Kirin-Amgen Inc v Board of Regents of the University of Washington and Genetics Institute Inc* [1995] 64 AIPO (19 October 1995).

[206] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 59.

plant origin which is at least 40% similar to all or part of the presented gene sequence, as well as any derivative or part of the recombinant enzyme – all of the above in relation to the specified plants.

7.9 This claim may cover all the genes in a multi-gene family,[207] molecular polymorphisms,[208] as well as (highly) conserved genes and gene sequences across species[209] and in some instances across Kingdoms.[210] Further, the DHK hydroxylating enzyme in this instance undertakes the function of 3',5'-hydroxylase and is a member of the cytochrome P450 class of enzymes.[211] These P450 class enzymes occur in a wide variety of organisms and may be grouped into families, each family having greater than 40% sequence homology,[212] and characterised by a ten residue (cysteine heme-iron ligand) signature specific to P450 enzymes. Therefore, this patent application may cover a range of other P450 enzymes in the claimed plants and in a range of other organisms, and arguably *every* P450 enzyme or functional part of an enzyme. An analysis in the following table of the claimed DHK hydroxylating enzyme sequences with other gene sequences confirms the broad scope of this patent application, including sequences which presently have no known function.

7.10 A comparison of the DHK hydroxylating enzyme sequence with other sequences illustrates the breadth of similarity and scope of this claim.[213] The displayed

[207] Sequences grouped by the function of the resulting protein which occur at different loci and may have some sequence variation: see for example, C Lawson, M Djordjevic, J Weinman, B Rolfe, "*Rhizobium* inoculation and physical wounding results in the rapid induction of the same chalcone synthase copy in *Trifolium subterraneum*" (1994) 7 *Molecular Plant Microbe Interactions* 498, and references therein.

[208] Such as hypervariable minisatellites and microsatellite sequences, organellar genomic sequences (mitochondrial and chloroplast), etc.

[209] For example, the (leg)-haemoglobin genes.

[210] For example, the ubiquitin genes.

[211] T Holton, F Brugliera, D Lester, et al., "Cloning and expression of cytochrome P450 genes controlling flower colour" (1993) 366 *Nature* 276.

[212] See D Nelson, T Kamataki, D Waxman, F Guengerich, et al., "The P450 superfamily: update on new sequences, gene mapping, accession numbers, early trivial names of enzymes and nomenclature" (1993) 12 DNA Cell Biol 1; K Degtyarenko and I Archakov, "Molecular evolution of P450 superfamily and P450-containing mono-oxygenase systems" (1993) 332 FEBS Lett 1.

[213] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at Figure 9; Basic BLAST of non-redundant

analysis is a selection of the 315 sequences identified which had greater than 45% nucleotide matching for the gene sequence or part of the gene sequence.

Organism	Sequence name/ Function	Similarity		Accession number	Comparison analysis				Reference
		Nucleotides compared (similar/total compared)	%		High score	Expected	Smallest sum probability P(N)	N	
P. hybrida	Flavonoid-3',5'-hydroxylase	1922/1922	100	Z22544	-	-	-	-	Holton et al. (1993) 366 *Nature* 276.
P. hybrida	Flavonoid-3',5'-hydroxylase	1915/1922	99	Z22545	9183	0.0	0.0	1	Holton et al. *Nature* 276.
P. hybrida	Flavonoid-3',5'-hydroxylase	1838/1845	99	D14588	6752	0.0	0.0	1	Ohbayashi et al., Unpublished.
P. hybrida	P450 hydroxylase	1319/1326	99	X71130	6588	0.0	0.0	1	Toguri (1993) 94 *Plant Sci* 119.
S. melongena	P450 hydroxylase	1162/1424	81	X70824	4783	0.0	0.0	1	Toguri et al. *Plant Mol Biol* 933.
E. russellianum	flavonoid 3',5'-hydroxylase	1031/1423	72	D14589	3608	$3.3x10^{-289}$	$3.3x10^{-289}$	1	Ohbayashi Unpublished.
E. grandiflorum	flavonoid 3'5'-hydroxylase	1031/1423	72	U72654	3599	$1.9x10^{-288}$	$1.9x10^{-288}$	1	Nielsen and Podivinsky, Unpublished.
G. triflora	flavonoid 3',5'-hydroxylase	732/1031	70	D85184	2485	$3.3x10^{-264}$	$3.3x10^{-264}$	3	Tanaka et al. (1996) 37 *Plant Cell Physiol* 711.
C. medium	flavonoid 3',5'-hydroxylase	310/471	65	D14590	927	$1.2x10^{-234}$	$1.2x10^{-234}$	3	Ohbayashi, Unpublished.
H. tuberosus	7-ethoxy-coumarin O-deethylase	228/395	57	Y10098	472	$6.3x10^{-42}$	$6.3x10^{-42}$	2	Batard et al., Unpublished.
H. tuberosus	7-ethoxy-coumarin O-deethylase	228/395	57	Y09920	472	$6.3x10^{-42}$	$6.3x10^{-42}$	2	Batard et al., Unpublished.
A. thaliana	chromosome 4, BAC clone F10N7	280/498	56	AL021636	528	$5.2x10^{-33}$	$5.2x10^{-33}$	1	Bevan, Unpublished.
G. max	cytochrome P450 monooxygenase	215/381	56	AF022459	411	$1.5x10^{-32}$	$5.4x10^{-31}$	2	Siminszky, Unpublished.
B. stolonifera	cytochrome P450	219/382	57	U09610	443	$5.4x10^{-31}$	5.4e-31	2	Kraus et al. (1995) 92 *Proc. Natl Acad Sci USA* 2071.
G. echinata	cytochrome P450	144/223	64	AB001380 D89433	404	$1.1x10^{-22}$	$1.1x10^{-22}$	1	Akashi et al. (1997) 115 *Plant Physiol* 1288.
M. piperita	cytochrome P450 oxidase	201/373	53	Z33875	317	1.910^{-15}	1.910^{-15}	1	Kang and Choi, Unpublished.
N. tabacum	Cytochrome P450	70/11	63	X95342	186	$1.5x10^{-4}$	$1.5x10^{-4}$	1	Czernic et al. (1996) 31 *Plant Mol Biol* 255.
H. Sapiens	Chromosome X clone bWXD501	37/46	80	AC004677	149	$1.6x10^{-1}$	$1.8x10^{-1}$	1	Chen et al., Unpublished.
E. californica	(S)-N-methyl-coclaurine 3'-hydroxylase	74/131	56	AF014802	142	$6.7x10^{-1}$	$4.9x10^{-1}$	1	Pauli and Kutchan (1998) 13 *Plant J* 793.
C. elegans	cosmid T09D3	61/102	59	U64835	141	$8.1x10^{-1}$	$5.6x10^{-1}$	1	Wilson et al. (1994) 368 *Nature* 32.

7.11 Taking examples from the table above to illustrate further the possible breadth of the claim. The observed homology is arguably sufficient for a person skilled in the art, etc. to speculate the identified regions have some functionality:

GenBank+AMBL+DDBJ+PDB sequences and selecting high scoring segment pairs; see

(i) A *Solanum melongena* hydroxylase[214] show 66% similarity over a region of sequence, and would arguably fall within the breadth of the DHK hydroxylating enzyme claim because it is an eggplant sequence which is "at least 40% similar to all or part of the [DHK hydroxylating enzyme] sequence" [215] set out in the application. The analysis[216] shows 74 of the 111 bases compared to be matched (that is, 66%) between bases 1208 and 1318 of the DHK hydroxylating enzyme sequence and bases 1271 and 1381 of the *Solanum melongena* hydroxylase sequence (analysis, high score = 222, expected = $1.5x10^{-7}$, smallest sum probability P(1) = $1.5x10^{-7}$, where N = 1).

Plus Strand HSPs:
Score = 222 (61.3 bits), Expect = 1.5e-07, P = 1.5e-07
Identities = 74/111 (66%), Positives = 74/111 (66%), Strand = Plus / Plus

```
Query:1271 TTATTACATACCAAAAAACACTAGGCTTAGTGTTAACATATGGGCAATTGGAAGAGATCC
           |||| |||||||    |  |||  |   | | ||||    ||||| || |||||||| ||
Sbjct:1208 TTATCACATACCTGCTAGAACTCAGGCCATTATTAATGCTTGGGCGATAGGAAGAGACCC

Query:1331 CCAAGTTTGGGAAAATCCACTAGAGTTTAATCCCGAAAGATTCTTGAGTGG 1381
           |  |   ||||||||||||  |||||   | || || |||||||| | | |
Sbjct:1268 CTTATCATGGGAAAATCCAGAAGAGTACCAGCCTGAGAGATTCTTAAATAG 1318
```

(ii) A *Homo sapiens* Chromosome X clone bWXD501[217] show 80% similarity over a region of sequence, and could arguably fall within the breadth of the DHK hydroxylating enzyme claim if it is "a functional derivative or part of

http://www.ncbi.nlm.nih.gov/BLAST/.

[214] N Umemoto, O Kobayashi, O Ishizaki-Nishizawa, T Toguri, "cDNAs sequences encoding cytochrome P450 (CYP71 family) from eggplant seedlings" (1993) 330 FEBS Lett 169.

[215] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 59.

[216] A comparison of the DHK hydroxylating enzyme (Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at Figure 9; "Query") with a *Solanum melongena* hydroxylase (X71654; N Umemoto, O Kobayashi, O Ishizaki-Nishizawa, T Toguri, "cDNAs sequences encoding cytochrome P450 (CYP71 family) from eggplant seedlings" (1993) 330 FEBS Lett 169; "Sbjct"), with Basic BLAST of non-redundant GenBank+AMBL+DDBJ+PDB sequences and selecting high scoring segment pairs (see http://www.ncbi.nlm.nih.gov/BLAST/).

[217] E Chen B Brownstein D States D Schlessinger R Mazzarella (1997) Unpublished, Accession number AC004677.

the enzyme"[218] as set out in the claim. The analysis[219] shows 37 of the 46 bases compared to be matched (that is, 80%) between bases 1095 and 1140 of the DHK hydroxylating enzyme sequence and bases 43130 and 43175 of the *Homo sapiens* Chromosome X clone bWXD501 sequence (analysis, high score = 149, expected = $1.8x10^{-1}$, smallest sum probability P(1) = $1.6x10^{-1}$, where N = 1).

Plus Strand HSPs:
Score = 149 (41.2 bits), Expect = 0.18, P = 0.16
Identities = 37/46 (80%), Positives = 37/46 (80%), Strand = Plus / Plus

```
Query:1095  TTGAAAAAAGCACAAGCAGAAATGGATCAAGTCATTGGAAGAAATA 1140
            |||||||||| ||||||||||     ||||||||  |||| |||
Sbjct:43130 TTGAAAAAAGTACAAGCAGAAATAAGCAAAGTCATTAAAAGATATA 43175
```

7.12 The concern is key aspects of genetic materials will be subjected to patent restrictions and prevent further inventiveness, such as the development of a different means of male sterility, albeit relying on the metabolism, functioning and/or development of stamen cells.[220] Similar arguments apply to genes, organisms and processes. This is a valid concern and has been illustrated in the ongoing litigation between Genetics Institute Inc. and the patent holder of the erythropoietin gene Kirin-Amgen Inc. (and its Australian licensee Johnson & Johnson). Kirin-Amgen established its patent over the erythropoietin gene sequence[221] with 56 claims and Genetics Institute successfully sequences the erythropoietin gene some 12 months later and claimed a patent over the gene sequence with 33 claims.[222] Genetics Institute sought to establish further

[218] Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at page 59; it is likely this sequence is "a functional derivative or part of the enzyme" because it shows high homology and could be part of an active site, etc.

[219] A comparison of the DHK hydroxylating enzyme (Patent Application number 19530/92, Genetic sequences encoding flavonoid pathway enzymes and uses therefor, International Flower Developments Pty Ltd, at Figure 9; "Query") with *Homo sapiens* Chromosome X clone bWXD501 (AC004677; E Chen, B Brownstein, D States, D Schlessinger, R Mazzarella (1997) Unpublished; "Sbjct") with Basic BLAST of non-redundant GenBank+AMBL+DDBJ+PDB sequences and selecting high scoring segment pairs (see http://www.ncbi.nlm.nih.gov/BLAST/).

[220] Patent Application 52245/96, Plants with modified stamen cells, Plant Genetic Systems NV, at page 51.

[221] *Kirin-Amgen Inc. v Board of Regents of the University of Washington and Genetics Institute Inc.* [1995] 64 AIPO (19 October 1995).

[222] *Genetics Institute Inc. v Johnson & Johnson* [1996] APO 56 (19 November 1996).

inventiveness beyond the existing sequence, such as putting the sequence in particular host cells, using specific promotors, identifying different cDNA sources as well as identifying and further characterising the sequence (5', 3' and introns). The Deputy Commissioner in comparing the claims[223] found further characterisations of the sequence were not a new invention (although attaching a demonstrated purpose may have been different), cDNA from gDNA without some identified problem was not inventive and new promotors, vectors, cell lines and culture conditions without selection or new features failed invention, further elaboration of glycosylation (and presumably methylation) failed invention. The only claim allowed as a new invention was a method isolating the gene from a new tissue source. The Deputy Commissioner's drew up a detailed comparison of the claims showing the scope of the Kirin-Amgen claims and illustrates the difficulty with which another inventor in the same field has to establish inventiveness once a sequence has been patented. It is significant that a claim of a sequence does not need to demonstrate the claim and only developments outside what a skilled person in the art would do are possible inventions – given broad claiming the potential for new inventiveness is likely to be very narrow.

7.13 A theoretical example starkly illustrates the concern and highlights the additional information in genetic materials which may be limited by the existing practice of broad claiming. The importance of methylation of sequences is best illustrated by genomic imprinting and the Prader-Willi and Angelman syndromes in humans. These syndromes exhibit different characteristics and yet both are the result of deletion from the same segment of chromosome 15.[224] An individual with paternal inheritance of the deletion will have Prader-Willi syndrome, while maternal inheritance will show Angelman syndrome. The Prader-Willi gene(s) and the Angelman gene(s) are different, but the syndromes share the same break point. This phenomena is believed to be the result of genomic imprinting where the particular allele has an effect depending on the parental source, and has been

[223] Noting the prior claiming provisions relevant to this decision were under the *Patents Act* 1952 (Cth), which were changed in the *Patents Act* 1990 (Cth) to a "whole of contents" novelty.

[224] See generally S Cassidy, "Syndrome of the month: Prader-Willi syndrome" (1997) 34 J Med Genet 917; J Conroy, T Grebe, L Baker, et al., "Balanced translocation 46,XY,t(2;15)(q37.2;q11.2) associated with atypical Prader-Willi syndrome" (1997) 61 Am J Hum Genet 388.

ascribed to methylation of nucleotides at specific loci on the chromosome.[225] If a patent were granted for the sequence of the break point mechanism (say the Prader-Willi syndrome), and later research found the same break point mechanism (say the Angelman syndrome), a patent over the sequence would arguably affect the patenting (and commercialisation) of the latter research.[226]

7.14 The following table illustrates the breadth of claims based on a gene or gene sequence made up from issues discussed in reported cases and where the claim has been accepted. It is notable the specifications are much wider than the scope set out here, and the specifications listed here are generally at the bounds of what might be claimed (generally amendment of the claim was allowed to further broaden the scope of the claim).

Specification	Erythropoietin *Genetics Institute v Kirin-Amgen Inc (No 3)* [1998] 740 FCA (25 June 1998)	Taq DNA Polymerase *Hoffmann-La Roche AG v Bresagen Limited and NE Biolabs* [1997] APO 57 (12 November 1997)	Serotonin receptor *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1988] APO 49 (9 September 1998)
DNA sequence (including parts of sequence)	✕	✕	✕
Related sequences - Homology: Hybridisation: Codons: Other:	✕ ✕ ✕	✕	✕
Vectors containing claimed sequence	✕	✕	✕
Expression system	✕	✕	
Method for using DNA sequence		✕	✕
Protein	✕	✕	✕
Amino acid sequence	✕		
Related sequence – Analogues: Variants: Substitutions:	✕ ✕ ✕	✕	
Glycoproteins	✕		
Antibodies	✕		✕
Functions of protein	✕	✕	

[225] See C Glenn, D Driscoll, T Yang, R Nicholls, "Genomic imprinting: potential function and mechanism revealed by the Prader-Willi and Angelman syndromes" (1997) 3 *Molecular Human Reproduction* 321.

[226] See C Glenn, D Driscoll, T Yang, R Nicholls, "Genomic imprinting: potential function and mechanism revealed by the Prader-Willi and Angelman syndromes" (1997) 3 *Molecular Human Reproduction* 321.

Characteristics of protein (properties)	✕	✕	
Methods for using protein		✕	✕
Other inventions relying on sequences	✕	✕	✕
Methods for treating humans			✕

7.15 Perhaps most concerning is the characterisation of genetic material patenting in the United States following *In re Deuel*[227] where the court accepted an unpublished sequence could not have been known without cloning and sequencing, because of the degeneracy in the genetic code, which is sufficient for it to be not obvious. Almost every sequence will be patentable because the focus is on the novelty of the sequence and not the invention in obtaining it (discussed above). However, there are still some limits in the United States, and any sequence will still be required to meet the statutory patenting requirements of patentable subject matter, usefulness, novelty and non-obviousness. For sequences the significant hurdle will be utility. However, this may be easily satisfied – the Federal Circuit has held that "[w]hen a properly claimed invention meets at least one stated objective, utility under Section 101[228] is clearly shown"[229] and "To violate Section 101 the claimed device must be totally incapable of achieving a useful result".[230] The useful result may only be that it is a probe and will hybridise to DNA (or RNA). Further, the claim may not have to be tested as a correlation need only be reasonable,[231] and so long as the sequence is unpublished it will be novel.[232]

7.16 Genetic materials reflect the accumulation of evolutionary changes in the genome between and across individuals and distinct species. Therefore, a gene sequence in one organism generally has the same or a similar gene sequence in another

[227] 51 F 3d 1552 (1995).

[228] "Whoever patents and discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title": 35 USC 101.

[229] *Raytheon v Roper* 724 F 2d 951 (1983), at page 958.

[230] *Brooktree Corporation v Advanced Micro Devices Inc.* 977 F.2d 1555 (1992), at page 1571.

[231] See *Fujikawa v Wattanasin* 93 F 3d 1559 (1996).

[232] See *In re Bond* 910 F 2d 831 (1992).

individual or organism, so that its identification in one organism means the same (or similar) gene is present in another individual or organism.[233] Further, the examples set out above illustrate the broad application of accepted patents and the limits this might imposes on subsequent patentable subject matters. It is submitted the accepted patents for genetic materials may be beyond the understood scope of the patent at the time of acceptance, and this reflects a failure to take into account the difference between traditional patentable subject matter and the inherent degeneracy in genetic materials. For the purposes of genetic materials, this arguably means that under the existing regime for determining inventiveness there may be a failure to value the potentially wide benefits of genetic materials by granting broad monopolies.

7.17 The law relating to selection patents and combination patents may have some limited application. Selection patents may be granted where an invention applies only to a limited number of members of a known class - the criteria for a selection patent are the selected members will provide some substantial advantage and all the selected members possess the advantage.[234] Combination patents may be granted for a new combination of known components or integers which have some "substantial exercise of the inventive faculty".[235] The potential of these branches of patenting is presently unclear, although the requirements are the same for all patents,[236] the inventiveness being applied to the new combination or new selection. However, this is unlikely to overcome problems of broad claiming based of gene and gene sequences which overlook the degeneracy in genetic materials.[237]

[233] See Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-37

[234] See *IG Farben Industrie's Patents* (1930) 47 RPC 289.

[235] *Willman v Peterson* (1904) 2 CLR 1, at page 21.

[236] See *Shell's Refining and Marketing Co's Patent* [1960] RPC 35.

[237] See for example the limiting effect of broad claims to the erythropoietin gene on later claims to sequence in the regulatory regions (5' and 3') of the gene affecting expression rates, stability and glycosylation patterns: *Genetics Institute Inc. v Johnson & Johnson* [1996] APO 56 (19 November 1996).

8. Access to genetic resources

8.1 Australia has considerable biodiversity to conserve, including genetic materials. Australia is one of the Earth's twelve mega diverse nations,[238] with some 85% of Australia's flowering plants, 84% of mammals, 89% of reptiles, 93% of frogs, and 85% of inshore fin fish are found nowhere else in the world.[239] This high number of endemic species is a result of the independent evolution of the Australia flora and fauna during the long period of isolation. During this time, Australia's plants and animals, bacteria and fungi have accumulated many distinct and unique genetic sequences, contributing to the high levels of genetic diversity, as well as species biodiversity.[240]

8.2 By granting broad patents many of Australia's unique genetic materials will be subsumed into the patent monopolies, with the effect of undermining both the policy objectives of the patents scheme (encouraging and rewarding inventiveness) and the value of Australia's genetic resources. Many of the benefits of access to these resources depends on a patent scheme which effectively encourages inventiveness and rewards that inventiveness equitably.

8.3 Access to biological materials are covered by Conventions and other international agreements to which Australia is a party. These obligations set the framework within which our present laws operate and how they may be changed to better suit our needs.

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[238] Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-30.

[239] Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-4; see also the Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996), at Appendix 1.

[240] Commonwealth Department of the Environment, *Australia: State of the Environment 1996* (Commonwealth of Australia, 1996), at page 4-6; Commonwealth Department of the Environment, Sport and Territories, *Biodiversity and its value*, Biodiversity Series, Paper No 1 (Commonwealth of Australia, 1993), at Part 2.2.

8.4 The *Convention on Biological Diversity* [241] at Article 1 makes specific recognition of a need to make available genetic resources: "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, including appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies".

8.5 Article 15 recognises the "sovereign rights of States over their natural resources" so that "access to genetic resources rests with the national governments and is subject to national legislation". However, Article 16 specifically restricts this access providing: "In the case of [(bio)]technology subject to patents and other intellectual property rights, such access…shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights". The term "biotechnology" is defined in Article 2 to mean "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

8.6 Access may include access to information about the existence of the genetic material, access to the physical location of the genetic material, access to the scientific and technical information about the genetic material access to the financial and other returns from exploitation of the genetic material.[242] Existing Australian laws regulate aspects of access through a range of Commonwealth laws[243] and various State and Territory laws.[244] The *Environment Protection and*

[241] Made at Rio de Janeiro on 5 June 1992, ratified on 18 June 1993 and taking effect generally on 29 June 1993; see Department of Foreign Affairs and Trade, *Convention on Biological Diversity*, Australian Treaty Series 1993 No 32 (AGPS, Canberra, 1995).

[242] See Environment Australia, *Discussion Paper: Managing Access to Australia's Biological Resources* (Environment Australia, Canberra 1996), at pages 13-14.

[243] For example, *Wildlife Protection (Regulation of Export and Import) Act* 1982 (Cth), *Customs (Prohibited Exports) Regulations* (Cth), *Patents Act* 1990 (Cth), etc.

[244] For example, *National Parks and Wildlife Act* 1974 (NSW), *National Parks Act* 1975 (Vic), *Nature Conservation Act* 1992 (Qld), *Conservation and Land Management Act* 1984 (WA), *National Parks and Wildlife Act* 1972 (SA), *National Parks and Wildlife Act* 1970 (Tas), *Territory Parks and Wildlife Conservation Act* 1988 (NT), *Nature Conservation Act* 1980 (ACT).

Biodiversity Conservation Bill 1998 (Cth) now proposes a new (and limited) scheme for access.[245]

8.7 The *National Strategy for the Conservation of Australia's Biological Diversity* states: "All Australians rely on industries that use biological resources to maintain and enhance their standard of living. These industries provide employment for many Australians, support secondary industries, and contribute significantly to the economy".[246] The Strategy examined the issue of access to genetic resources and stated an objective to "[e]nsure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia".[247] This report noted the recognition in the *Convention on Biological Diversity* of a nation's right to determine access to its genetic resources and suggested "[i]t is in Australia's interests to control access to our genetic resources and obtain an appropriate return for any permitted access".[248] The report recommended a Commonwealth/State Working Group be established to investigate and report on matters relating to access to Australia's genetic resources with a view to providing effective controls (legislation, incentives, etc.) which ensure Australia's participation in research and development and the benefits from genetic resources.[249] Significantly, this report noted the role of plant variety rights and patent legislation should be investigated to ensure the benefits of access flowed to

[245] Introduced into the Senate on 2 July 1998 (Senate, *Hansard*, 2 July 1998, at page 4087) and referred to the Senate Environment, Communications and the Arts Legislation Committee (Senate, *Hansard*, 8 July 1998, at page 4401), but prorogued due to the Federal Election on 3 October 1998, reintroduced in 12 November 1998 (Senate, *Hansard*, 12 November 1998, at page 143), referred to the Environment, Communications, Information Technology and the Arts Committee: Senate Environment, Communications, Information Technology and the Arts Legislation Committee *Environment Protection and Biodiversity Conservation Bill 1998 & Environmental Reform (Consequential Provisions) Bill 1998* (Senate, Canberra, April 1999); for review of access provisions see C Lawson and C Pickering, "Patent laws will undermine access provisions in the *Environment Protection and Biodiversity Protection Bill* 1998 (Cth) (1998) 15 *Environmental and Planning Law Journal* 401.

[246] Commonwealth Department of the Environment, National Strategy for the Conservation of Australia's Biological Diversity (Commonwealth of Australia, Canberra, June 1996), at Chapter 2.

[247] Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996), at Chapter 2.8.

[248] Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996), at Chapter 2.8.

[249] Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996), at Chapter 2.8.

Australia.[250] These benefits might include a direct financial return to the inventor, the economic activity related to the commercialisation of the invention (including employment), a reduced need for duplication and an incentive for other inventors to invent and promote the preservation of genetic materials as a resource.[251]

8.8 Access issues have also been addressed by the Australian and New Zealand Environment and Conservation Council Task Force examining the implementation of the *Convention on Biological Diversity*,[252] the Commonwealth Government's Coordination Committee on Science and Technology[253] and the Commonwealth State Working Group on Access to Australia's Biological Resources.[254] Each of these reports identifies intellectual property, and in particular patenting, as an element in deriving (economic) benefits from access.[255]

8.9 The practice in Australia of granting very broad patent claims over genetic material arguably undermines the benefit of access by restricting the potential economic benefits which might flow from Australia's genetic resources through patenting. Without recognising the current patenting practices in Australia, the potential of Australia's considerable and unique genetic materials (characterised by a store of unique genetic solutions to environmental challenges) will be undermined. Patent

[250] Commonwealth Department of the Environment, *National Strategy for the Conservation of Australia's Biological Diversity* (Commonwealth of Australia, Canberra, June 1996), at Chapter 2.8.5; see also Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at page 36.

[251] See generally the Second Reading, *Environment Protection and Biodiversity Conservation Bill* 1998 (Cth), Senate, *Hansard*, 2 July 1998, at page 4087; Industrial Property Advisory Committee, *Report on Patents, Innovation and Competition in Australia* (Patents Office, Canberra, 1984), at page 11; incentive policy reviewed in page Loughlan, "Patents: breaking into the loop" (1998) 20 *Sydney Law Review* 553, at pages 567-572.

[252] See Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at page 7.

[253] Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994).

[254] See Environment Australia, *Discussion Paper: Managing Access to Australia's Biological Resources* (Environment Australia, Canberra 1996).

[255] For example, Environment Australia, *Discussion Paper: Managing Access to Australia's Biological Resources* (Environment Australia, Canberra 1996), at page 23; Department of Prime Minister and Cabinet, *Access to Australia's Biological Resources* (AGPS, Canberra, 1994), at page 36.

laws should promote the useful exploitation of genetic materials and derive the maximum benefit from our genetic resources by *at least* limiting the breadth of patent claims over genetic materials.

9. Human treatment and patents

9.1 Some analysis of the public policy (and ethical) requirements for patentability were undertaken in *Anaesthetic Supplies Pty Ltd v Rescare Ltd.*[256] In that case, it was argued that section 6 of the *Statute of Monopolies* should apply to prevent the patenting of manners of new manufacture which are generally inconvenient in the context of human treatments. This was rejected by Lockhart and Wilcox JJ, who determined this case on the issue of "fair basing", while accepting patents could be granted for new properties and new uses of known chemicals with an economic utility. Sheppard J also accepted the claim was not fairly based, but went on to consider the granting of patents for methods of treatment for humans. In Sheppard J's analysis, he accepted the argument that human treatment methods were "generally inconvenient" and therefore unpatentable.[257] However, he did not consider the economic benefit or detriment to the Australian community as a part of his analysis. Both Lockhart and Wilcox JJ noted there had been no statutory provisions enacted by Parliament in the *Patents Act* 1990 (Cth) when an opportunity had been available to present the relevant policy arguments against patenting, and Wilcox J clearly stated that he did not consider the courts should determine matters of ethical and social policy, but that the matter should be determined by Parliament.[258] Similar comments have been made in the United States by the majority in *Diamond v Chakrabarty*.[259] These comments and the different

[256] (1994) 28 IPR 383.

[257] Cooke, Mullin and Somers JJ in *Commissioner of Patents v. The Welcome Foundation Ltd* (1983) NZLR 385, 2 IPR 156 of the New Zealand Court of Appeal set out reasoning which Sheppard J cited with approval. However, the High Court refused to grant leave to appeal in this case.

[258] (1994) 28 IPR 383 at paragraph 13 of Wilcox J's judgement; contrast approach of the House of Lords in *R v Brown* [1992] QB 491 (CA); Sheppard J considered the "matter is best left to Parliament" and that "It seems not unlikely that, in the light of the recent TRIPS agreement, this whole question will now be taken from the courts by legislation", at paragraph 59.

[259] (1980) 447 US 303.

approaches of the Federal Court in applying the patentability requirements of the *Statute of Monopolies* suggests some legislative guidance may be necessary.[260]

9.2 More recently Justice Heerey in *Bristol-Meyers Squibb Company v FH Faulding & Co Ltd*[261] found claims defining a method of administering an anti-cancer drug in humans was generally inconvenient and unpatentable because they were not a manner of manufacture. However, a delegate of the Commissioner of Patents in *Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[262] considered Justice Heerey's comments were *obita dicta* and non-binding, favouring the majority view in *Anaesthetic Supplies Pty Ltd v Rescare Ltd.*[263]

10. Legislative action in Australia

10.1 The *Patents Act* 1990 (Cth) does not specifically refer to genes or gene sequences. However, amendments have been proposed which could exclude gene and gene sequences from patentability. Senator John Coulter proposed amending section 18 of the *Patents Bill* 1990 (Cth)[264] so that "a patentable invention does not include a thing that consists of or includes: (a) gene or genes, whether derived from cells or chemically synthesised".[265] The term "gene" was defined to include "genetic material" and "genetic engineering" which would have incorporated gene and gene sequences. These amendments failed to gain Senate support.

10.2 More recently, Senator Natasha Stott Despoja introduced into the Senate the *Patents Amendment Bill* 1996 (Cth) to amend section 18 of the *Patents Act* 1990 (Cth).[266] This Bill has been read a second time[267] and remains on the Notice Paper awaiting further debate. The *Patents Amendment Bill* 1996 (Cth) proposes an amendment to

[260] I Freckelton, "Patenting therapeutic treatments and methods" (1994) 2 JLM 87.

[261] [1988] 80 FCA (22 July 1998).

[262] [1998] APO 49 (9 September 1998).

[263] (1994) 28 IPR 383.

[264] Senate, *Hansard* 22 August 1990, page 1910, 17 September 1990 page 2478 and 20 September 1990 page 2653.

[265] Senate, *Hansard* 22 August 1990, page 1910, 17 September 1990 page 2478.

[266] Senate, *Hansard* 27 June 1996, page 2332.

[267] Senate, *Hansard* 27 June 1996, page 2332.

section 18 of the *Patents Act* 1990 (Cth) by preventing the *Patents Act* 1990 (Cth) from applying to "naturally occurring genes", "naturally occurring gene sequences" and "descriptions of the base sequence of a naturally occurring gene or a naturally occurring gene sequence".[268] This amendment has attracted criticism for the legal reasoning and the philosophy,[269] although the Second Reading speech sets out a clear intention that the words used should exclude all gene and gene sequences from patentability.[270] The future of this Bill is presently unclear.

10.3 The only other limit on patenting organisms and process has been the acceptance by the Government of amendments proposed to section 18 during the passage of the *Patents Bill* 1990 (Cth) through the Senate: "Human beings, and the biological processes for their generation, are not patentable inventions". However, the Patent Office will accept applications for patents for human genes and gene sequences which have been separated from the human body and manufactured synthetically for re-introduction into the human body for therapeutic purposes.[271] The line between what is and is not patentable remains uncertain, although the recent application in the United States for a human/animal chimera (where human cells are fused with animal cells and visa versa) may provide some useful directions.[272]

11. Extending patent terms

11.1 The effect of TRIPs was to require Australia to implement minimum standard patent laws.[273] This has been achieved by the *Patents (World Trade Organisation Amendment) Act* 1994 (Cth),[274] although Australia's patent laws were already close

[268] Schedule 1, *Patents Amendment Bill* 1996 (Cth).

[269] Report of criticism, see J McKeough, "Patenting genetic material: what are people concerned about?" (1997) IPF 12; the details of this criticism are unclear.

[270] Senate, *Hansard* 27 June 1996, page 2332.

[271] IP Australia Pamphlet, *Australian Patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, February 1998), at page 1.

[272] See report in "Legal fight looms over patent bid on human/animal chimeras" (1998) 392 *Nature* 423.

[273] Article 1(1).

[274] *Patents (World Trade Organisation Amendment) Act* 1994 (Cth) amended the *Patents Act* 1990 (Cth) to be consistent with TRIPs by extending the patent term to 20 years, onus requirements for infringement proceedings, compulsory licences and Commonwealth and State use of a patent.

to the minimum standards.[275] Section 67 of the *Patents Act* 1990 (Cth) provides for a standard patent term of 20 years. The *Intellectual Property Laws Amendment Act* 1998 (Cth) extended the patent term for some pharmaceuticals to 25 years.[276] The issue is whether Australia should extend patent terms. Reducing patent terms is unlikely because of the sanctions Australia would suffer under the World Trade Organisation rules (discussed further below).

11.2 There may be arguments for patent extensions. This was illustrated by the recent *Intellectual Property Laws Amendment Act* 1998 (Cth), which extended the patent term for certain pharmaceuticals to 25 years subject to some condition (such as "spring boarding", reporting, etc.) The second reading speech stated:

> "The development of a new drug is a long process. A new chemical entity, from which a pharmaceutical is derived, is patented early in the process. However, considerable research and testing is still required before the product can enter the market.
>
> This long development time, combined with the considerable regulatory processes to register and market a new product, means that companies usually have considerably fewer years under patent in which to gain a return on their investment.
>
> This becomes significant to the industry as companies rely heavily on patents to generate the substantial cash flows necessary to finance the development of new drugs".[277]

11.3 This incentive based justification of patenting means a patent term, at least in theory, should be a balance between promoting the number of inventions against the harm caused to society by the distortion in the allocation of resources by the monopoly behavior. Loughlin argues the definitive patent term cannot be justified either economically or scientifically:

> "The patent term is a social construct…like an other, and not a matter for scientific or economic 'proof'. It therefore is and must remain the result of a balance struck by the political process between

[275] Second Reading Speech, *Patents (World Trade Organisation Amendment) Bill* 1994 (Cth), House Hansard, 18 October 1994, at page 2185.

[276] House of Representatives, *Hansard* 26 November 1997, at page 11274.

[277] House of Representatives, *Hansard* 26 November 1997, at page 11274.

public and private interests, a matter about which people can contend using arguments which in part at least reflect their broader conceptions of society and its issues".[278]

11.4 However, these assertion of benefit from increased patent terms are questions by:

(i) The Prices Surveillance's Authority states:

> "The PSA is concerned that monopolies granted as a result of intellectual property rights may unnecessarily diminish competition in the Australian market. Also, given that Australia's principal exports are farm products, minerals and tourism, while its imports are technologically-intensive goods…enhanced intellectual property rights can only adversely effect our terms of trade. It is therefore by no means certain that Australia should always seek to align itself with the first world countries of Europe, North America and Japan, which clearly have a vested interest in strengthening intellectual property rights on a global basis."[279]

(ii) The Industry Commission[280] investigated the effects of extending the patent term on Australia's economy and concluded there would be a net cost to Australians, 2/3 or more of this will result from the extension to existing patents, there is no economic justification for extending existing patents and this will be a windfall gain to the patent holders, because Australia is a net importer of intellectual property it is unlikely to be in Australia's interests to go beyond what international agreements require and the extension to 25 years will have a very minor effect on incentives to invest.

(iii) The Bureau of Industry Economics[281] argue that the extended patent period is unlikely to provide significant benefit to the patent holder, but is likely to extract significant detriment from the community through retarded competition and technical improvement.

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[278] P Loughlan, "Patents: breaking into the loop" (1998) 20 *Sydney Law Review* 553, at page 562.

[279] Prices Surveillance's Authority, Report No 49, 23 August 1993, at page 141.

[280] N Gruen, G Prior, I Bruse, *Extending patent life: is it in Australia's economic interests?* (Industry Commission Staff Information Paper, Industry Commission, Canberra, 1996).

[281] Bureau of Industry Economics, "The economics of patents - Occasional Paper 18" (AGPS, Canberra, 1994), at page 44.

(iv) The Industrial Property Advisory Committee[282] investigation into patenting concluded that patent terms should not be increased because there was *no* case made out for a longer term and arguments favoring international trends towards longer patent terms were unconvincing because the trend was confined to developed nations. The Committee expressly rejected extending pharmaceutical patent terms on the basis of uncertain regulatory approval times saying there were a range of other regulatory delays and it would be illogical to single out federal legislation.

(v) The Industrial Property Advisory Committee[283] investigation into patents and innovation rejected the argument that investment decisions were made on the basis of long patent term extensions saying, "in the absence of contrary empirical evidence, it strains credulity to contemplate that research or innovation investment decisions, made early in the life of the invention, could ever be materially influenced by the prospective availability of an extension after expiration of the initial 16 year term to compensate for inadequate remuneration, particularly when allowance is made for discounting".[284]

(vi) The Industrial Property Advisory Committee[285] investigation patenting and innovation argued that fine tuning economic policies using the patent scheme was inappropriate and that other measures, such as "tariffs, taxation incentives and other forms of specific selective encouragement or discouragement" should be favored.

(vii) Patent extension have been granted for certain pharmaceuticals under the *Intellectual Property Laws Amendment Act* 1998 (Cth), while other intellectual property rights argued to promote Australian industries have

[282] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984).

[283] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984).

[284] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984), at pages 38-39.

[285] Industrial Property Advisory Committee, *Patents, innovation and competition in Australia* (AGPS, Canberra, 29 August 1984), at page 40.

been removed, such as the parallel import restrictions on packaging and labeling (*Copyright Amendment Act* 1997 (Cth)) and sound recordings (*Copyright Amendment Act (No 2)* 1997 (Cth)).[286] However, there is no explanation for why pharmaceuticals are a special case which do not apply equally to other industries. For example, small businesses have severely limited resources to effectively market an invention and as a result it may take longer to effectively bring their invention to market - why should they not receive the same benefit as proposed for the pharmaceutical industry? Further, many of the pricing issues important to the pharmaceutical industry are in fact issues of concern about the Pharmaceutical Benefits Scheme (the PBS) - these are not patent issues and they should arguably be dealt with separately.

(viii) The Productivity Commission[287] reviewing the policy implications of TRIPs suggested:

> "Given the strong international orientation of…[intellectual property right]…protection, the analysis presented in this paper suggests that generally, Australia's best approach from an economic point of view seems to be to provide…[intellectual property right]…that complies with the minimum protection standards. Compliance with the minimum standards of TRIPs is advisable in order to avoid political and trade retaliation and disciplinary action under the WTO. On the other hand, providing protection beyond the minimum standards might hamper competition in the domestic market and provide additional income to foreign…[intellectual property right]…holders at the expense of Australian consumers. Without reciprocal agreements with our major trading partners, providing protection above the minimum international standard does not help our exporters".

11.5 There is no requirement to extend beyond this 20 year term. The Bureau of Industry Economics[288] state:

[286] See Senate Legal and Constitutional Legislation Committee, *Report on Copyright Amendment Bill 1997 (Cth)* (Senate, Canberra, 1997); Senate Legal and Constitutional Legislation Committee, *Report on Copyright Amendment Bill (No 2) 1997 (Cth)* (Senate, Canberra, 1998) noting especially an analysis of the data presented to the Committee as being old and inconsistent.

[287] J Revesz, *Trade Related Aspects of Intellectual Property Rights - Productivity Commission Staff Research Paper* (AGPS, Canberra, 1999), at page xiv.

> "...given Australia's heavy dependence on overseas trade and technology imports, it does not appear to be in the broad national interest to alter the [patent] system in any way that contravenes international conventions and agreements and thus may lead to curtailment of technology transfer from abroad or result in trade or political retaliations. On the other hand, neither is it in Australia's national interests to pursue the protection of patent rights beyond accepted international norms".[289]

11.6 However, the Bureau of Industry Economics[290] also suggest game theory promotes self-interest when pursuing short term goals which results in sub-optimal outcomes for some players, but that cooperation with the group interests is beneficial for repeated games. Thus, in the long term it may be better for Australia to cooperate with the international community which in the OECD is extending patents for pharmaceuticals to 25 years.

11.7 The Productivity Commission[291] suggests because Australia has a strong biotechnology industry "it might be economically advantageous for Australia to support international agreement that would strengthen the worldwide…[intellectual property right]…protection of biological innovations".

11.8 Loughlan states the case:

> "The political process by which the decision on patent term is actually made is, however, skewed by the fact…that patent decisions are not widely seen as political decisions involving winner and losers and possible conflicts between the public interests, but rather as technical, economic decisions suitable to be made by experts. The process is further skewed by the related fact that, as Manderville[292] pointed out, those who would benefit from a strengthening of the patents system such as an extension of the patent term, 'are concentrated, powerful and active defenders of their interests.

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[288] Bureau of Industry Economics. *The economics of patents - Occasional Paper 18* (AGPS, Canberra, 1994).

[289] Bureau of Industry Economics. *The economics of patents - Occasional Paper 18* (AGPS, Canberra, 1994), at page ix.

[290] Bureau of Industry Economics. *The economics of patents - Occasional Paper 18* (AGPS, Canberra, 1994), at page 50.

[291] J Revesz, *Trade Related Aspects of Intellectual Property Rights - Productivity Commission Staff Research Paper* (AGPS, Canberra, 1999), at page xv.

[292] T Manderville, D Lamberton, E Bishop, *Economic effects of the Australian Patent System* (AGPS, Canberra, 1982), at page 213.

In contrast, those who would gain by patent reform are diffuse and hardly aware of their interests in the matter'".[293]

12. International constraints

12.1 If it is accepted that our existing system for patenting genetic materials is not entirely satisfactory, it is not certain that Australia may, by itself, implement reforms or changes from the existing international norms. Australia is bound by the TRIPs[294] which was negotiated in the Uruguay Round of Multilateral Trade Negotiations (GATT).[295] The negotiation of an intellectual property agreement (TRIPs) in the forum of trade negotiations (GATT) created the mechanisms necessary for agreement and enforcement under the World Trade Organisation (WTO).[296] This had been unsuccessful at the World Intellectual Property Organisation (WIPO)[297] and the reasons for a successful TRIPs agreement at GATT reflected the peculiarities of that forum and the strategy of the United States in the negotiations.[298]

12.2 The effect of TRIPs was to require Australia to implement minimum standard patent laws.[299] This has been achieved by the *Patents (World Trade Organisation Amendment) Act* 1994 (Cth),[300] although Australia's patent laws were already close to the minimum standards.[301] TRIPs Article 27(1) provides "patents shall be

[293] P Loughlan, "Patents: breaking into the loop" (1998) 20 *Sydney Law Review* 553, at page 562.

[294] Agreement on *Trade Related Aspects of Intellectual Property Rights*, 15 April 1994.

[295] The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations was ratified by 120 countries, including Australia, at Marrakesh on 15 April 1994.

[296] Agreement Establishing the World Trade Organisation, 15 April 1994 (and established on 1 January 1995).

[297] P Drahos, "Global property right in information: the story of TRIPs at the GATT" (1995) 13 *Prometheus* 6, at page 14.

[298] P Drahos, "Global property right in information: the story of TRIPs at the GATT" (1995) 13 *Prometheus* 6, at pages 12-13

[299] Article 1(1).

[300] *Patents (World Trade Organisation Amendment) Act* 1994 (Cth) amended the *Patents Act* 1990 (Cth) to be consistent with TRIPs by extending the patent term to 20 years, onus requirements for infringement proceedings, compulsory licenses and Commonwealth and State use of a patent.

[301] Second Reading Speech, *Patents (World Trade Organisation Amendment) Bill* 1994 (Cth), House of Representatives *Hansard*, 18 October 1994, at page 2185.

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".[302] The distinction between a discovery and an invention is enshrined in the TRIPs, and in any dispute under the WTO would be required to determine an "invention". However, under the GATT/WTO, all member states are bond by the Understanding on Rules and Procedures Governing the Settlement of Disputes.[303] The effect of this agreement is to force compliance with decisions of the WTO through stipulated enforceable rules and remedies, which includes compensation and retaliation.[304] This in effect requires an international consensus and this is likely to encounter significant obstacles based predominantly on the different economic interests of nations.[305] For example, the United States Trade Representative in 1998 identified 32 trading partners (including Australia, on the Special 301 'Watch List'[306]) as failing to provide adequate intellectual property protection for United States companies,[307] and this process would be unlikely to overlook any changes to Australia broad test for "invention", because Special 301 have effect to "obtain increased foreign market access for US goods, to provide more equitable conditions for US investment abroad, and to obtain more effective protection worldwide for US intellectual property".[308]

[302] The only exceptions to this is where it is "necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law" (Article 27.2), diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)) and plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes, so long as there is an effective *sui generis* system of protection (Article 27.3(b)).

[303] Reprinted at (1994) 33 ILM 1, at page 112.

[304] Reviewed in A Lowenfeld, "Remedies along with rights: institutional reform in the new GATT (1994) 88 *American Journal of International Law* 477, at pages 481-487.

[305] J Kirby, "Challenges of the genome" (1997) 20 UNSWLJ 537, at page 547 for comments on achieving international cooperation for the regulation of genome research.

[306] Section 301 *Trade Act* 1974 (US) enables the United States to take action to enforce United States rights under bilateral and multilateral trade agreements and as a response to unreasonable, unjustified and discriminatory foreign government practices which may be detrimental to United States commerce.

[307] United States Trade Representative, *US announces results of special 301 annual review*, Press Release, 1 May 1998.

[308] See United States Trade Representative, *1997 Annual Report* (US Government, Washington, 1998), at page 238.

12.3 It is also notable that national patent laws are being reinterpreted to reflect the interests of the particular nations. Terms such as "invention" are being broadened to increase the scope of what may be patented, and in particular the breadth of genetic materials which may be patented. The United States provides a good illustration of this approach. Ananda Chakrabarty lodged an application for a genetically engineered micro-organism capable of breaking up ocean oil spills. This application was rejected by the Patents and Trade Marks Office because living materials were not believed to be patentable subject matter.[309] This was appealed and the decision reversed in favour (3-2) of Chakrabarty on the basis that the micro-organism was "more akin to inanimate chemical composition such as reactants, reagents and catalysts, that to horses and honey bees or raspberries or roses".[310] On appeal to the Supreme Court this decision was upheld (5-4) for Chakrabarty.[311] The Chief Justice (in the majority) said the distinction was not between living and inanimate, but rather whether the micro-organism was a human made invention.

12.4 This decision cleared the way for the commodification of genetic materials, and in response to this decision the Patent and Trade Marks Office issued a ruling in 1987 making potentially every genetically engineered organism patentable.[312] Since then, the decision in *In re Bell*,[313] *In re Baird*[314] and *In re Deuel*[315] have effectively expanded invention in the United States to include (almost) every gene or gene sequence which is isolated and which has not been isolated before.

[309] Application No 477,766, 10 June 1974.

[310] Judge Rich *In re Bergy* (1977) 563 F 2d 1031, at page 1038; he also said "As for the Board's fear that our holding [allowing the micro-organism patent] will of necessity, or 'logically' make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched" (at page 1038) and Judge Kashiwa said "I read the majority opinion as setting forth an extremely limited holding…While the PTO and the dissenting opinion raise the spectre of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition" (at page 1039).

[311] *Diamond v Chakrabarty* (1980) 447 US 303.

[312] US Patent and Trade Marks Office, *Animals – patentability* (Washington DC, US Government Printer, 7 April 1987).

[313] 51 F 3d 1552 (1993).

[314] 16 F 3d 380 (1994).

[315] *In re Deuel* 51 F 3d 1552 (1995), at pages 1555-1556.

12.5 The effect of these decisions has been to expand the meaning of "invention" to include genetic materials, contrary to the previous Patent and Trade Marks Office, legislative and court decisions.[316] This arguably reflects the interests of the United States as the leading nation in biotechnology.[317] Similar examples exist in Australia, with the same effect of extending the subject matter which may be patented.[318]

12.6 An alternative approach to reform may be to rely on Australia's competition laws. The TRIPs agreement expressly recognises the role of competition laws and the possibility intellectual property laws may in some instances fail to promote innovation and the dissemination of technology.[319] Article 8 suggests "appropriate measures" consistent with TRIPs are contemplated where intellectual property rights holders abuse their rights or resort to practices which "unreasonably restrain trade or adversely affect the international transfer of technology". Article 40 accepts some practices or conditions may restrict competition and together with Article 8 it is arguable Australian competition laws might be applied in particular cases to at least address market abuse.[320] The scope of these competition laws as they appear in the *Trade Practices Act* 1974 (Cth) is not addressed in this submission other than to suggest this might provide a solution to the grant of overly broad patents or the use of patents to abuse market power. It is however, notable,

[316] Note in the United States, legislation (35 USC, Chapter 15, sections 161-164) was specifically enacted to reward agriculturalists and horticulturalists because patents were not considered to be available: see Judge Miller in *In re Bergy* (1977) 563 F 2d 1031, at page 1039.

[317] See A Stretzler, "Biotechnology Intellectual Property Rights as an obstacle to the UNCED Convention on Biological Diversity – It just doesn't matter" (1992) 6 *Transnational Law* 271; R Subramanian, "Putting some numbers on the TRIPS pharmaceutical debate" (1995) 10 Int J Tech Management 252.

[318] *NRDC v Commissioner of Patents* (1959) 102 CLR 252, at page 264 the majority overruled the practice of the Patents Office to reject applications for agricultural and horticultural processes; see *Re Rau Gesellschaft's Application* (1935) 52 RPC 362; and argued in this submission the tortured distinction between "discovery" and "invention" in decisions under the *Patents Act* 1990 (Cth), such as *Synaptic Pharmaceutical Corporation v Astra Aktiebolag* [1998] APO 49 (9 September 1998).

[319] See Article 7.

[320] For example, where a patent over a gene sequence unreasonably limits further inventiveness or prevents market access to a superior product: see *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc*. (Federal Court, NG380/1996). However, this outcome is by no means a certain or a complete solution.

the threshold requirement of establishing "market power" may be difficult and the consequences on innovation of competition law may not all be favourable.

12.7 A pro-competitive approach may be to implement the minimum standards set by TRIPs. Maskus[321] suggests adopting the highest minimum standards for non-obviousness and the judicious use of non-exclusive compulsory licenses (with adequate compensation).

13. Conclusions

13.1 In *Genetics Institute Inc. v Kirin-Amgen Inc. (No3)*[322] Justice Heerey explains the case (for allowing a patent over a gene sequence) by analogy: "Counsel for Genetics likened the Amgen case to that of a treasure hunter who discovers a map giving directions to buried treasure on a desert island. Counsel said that Amgen were trying to prevent anyone else from obtaining the treasure, even by a route different from the one shown on the map. However a more apt analogy in my view is that of treasure in a castle. The castle has many gates, each with a combination lock (this being a modern castle). The combination for each lock is the same. Anyone who knows the combination can enter the castle. Finding the treasure may require some further time and trouble but this will merely be a matter of carefully searching through every room and cupboard in the castle. The critical knowledge is the combination of the locks. Without that, it is impossible to enter the castle. Once you have that, entry can be obtained through any gate. With reasonable time and effort the treasure will be discovered".

13.2 Extending this analogy, this submission has argued that in accepting privileges that go with the combination to enter the castle (the patent), combinations have been given away to enter *other* castles, with access to all their treasures *as well*.

13.3 The argued breadth of gene and gene sequence patents, illustrated by the examples provided in this submission, are arguably limiting the potential of further

[321] K Maskus, *The international regulation of intellectual property*, CIES Seminar Paper 97-11 (University of Adelaide, Adelaide, 1997), at page 14.

[322] [1998] 740 FCA (25 June 1998).

inventiveness. For a mega-diverse nation like Australia this means we are allowing our genetic materials to be subsumed by patent claims which probably never contemplated their potential or even steering potential research effort away from the possible benefits derived from Australian genetic materials.

13.4 If the existing practices of the Patent Office under the *Patents Act* 1990 (Cth) are failing to distinguish the limits of gene and gene sequence claims, then it is for the Parliament to enact legislation setting those limits. If this is not possible, then it is for the government through clearly stated, enacted and enforced competition laws to ensure the grant of patents reflects the inherent degeneracy of genetic materials and that overly broad patents are not granted.

13.5 Perhaps it is also notable that the costs of enforcing a patent or challenging a patent are significant, and in many cases impossible except for large corporations. The grant of a broad patent requiring a further inventor to make a challenge to an existing broad patent is likely to add significantly to the costs of any invention.

13.6 This submission has also argued the existing patenting scheme needs to be remodeled to meet modern day requirements. Examples of failings in our present intellectual property scheme include empirical data from Australia and overseas which show patents have limited commercial importance, have limited effectiveness, to delay imitation to a limited extent, to fail to provide adequate disclosure and that innovation spill over is limited.[323]

13.7 The same message may also coming from the business sector. For example, Thurow states:

> "Fundamental shifts in technology and in the economic landscape are rapidly making the current system of intellectual property rights unworkable and ineffective. Designed more than 100 years ago to meet the simpler needs of an industrial era, it is an undifferentiated, one-size-fits-all system. Although treating all advances in knowledge in the same way may have worked when most patents

[323] Industry Commission, N Gruen, G Prior, I Bruse, *Extending patent life: is it in Australia's economic interests?* (Industry Commission Staff Information Paper, Industry Commission, Canberra, 1996), at pages 16-40.

were granted for new mechanical devices, today's brain power industries pose challenges that are far more complex".[324]

[324] L Thurow, Needed: a new system of intellectual property rights (1997) 75 *Harvard Business Review* 95, at page 95.