SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

CONTENTS

EXECUTIVE SUMMARY

This is a joint submission from the Department of Innovation, Industry, Science and Research and IP Australia which is a prescribed agency within the Innovation, Industry, Science and Research portfolio. The Department and IP Australia welcome the opportunity to provide comments to the Senate Committee on Community Affairs' Inquiry into gene patents as we welcomed previous inquiries on this and similar topics. [1]

The purpose of this submission is to inform the Committee on: how and why patents are granted in Australia; Australia's obligations under relevant international treaties and agreements; and, possible areas of reform that may increase the inherent quality of patents granted.

Overall, the submission:

- provides information on the patent system in Australia, its objectives and patentability requirements as set out in legislation and case law;
- describes how patent applications claiming isolated gene, nucleic acid[2] or protein sequences derived from DNA are assessed by IP Australia;
- provides some statistical analysis of the number and trends of 'gene patents' filed and granted in Australia;
- proposes improvements to the patent system applicable to all patentable technologies; and
- comments on other matters relevant to the Terms of Reference (ToR) as appropriate.

The purpose of the Australian patent system is to benefit Australia by stimulating industrial innovation and encouraging technology access and transfer. The patent system does this by providing exclusive rights to exploit new technologies, in exchange for diffusing knowledge of new technologies into the public domain. The grant of a patent does not give the owner a guaranteed right to exploit the patented technology in Australia. The use of a patented invention may be regulated by other laws, standards and guidelines, for example laws protecting national security. The grant of a patent only reflects a decision by the Commissioner of Patents that the claimed invention meets the patentability and other requirements set out in the *Patents Act 1990* (Patents Act).

The patentability requirements discussed in the submission include:

- what can be the subject matter of a patent ('manner of manufacture');

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1 See Terms of Reference in the Report by the House of Representatives Standing Committee on Industry, Science and Technology, "Genetic Manipulation: The threat or the glory?", February 1992 and ALRC Report Number 99, "Genes and Ingenuity: Gene patenting and human health", June 2004 ('ALRC 99')

2 See Glossary of Terms in Appendix A.

- whether there has been previous publication or use of the invention ('novelty');

- the level of ingenuity required to be granted a patent ('inventive step');

- the description of the invention in the 'specification' accompanying the patent request ('full description');

- the scope and consistency of the claims with the description of the invention ('fair basis'); and

- whether the results promised by the patentee can be achieved by using the invention ('usefulness').

The courts have decided that patents can be granted for inventions that result in an 'artificially created state of affairs' in a 'field of economic endeavour'. The courts have also recognised that the distinction between discoveries (which under patent law are considered not patentable) and inventions can be extremely fine. If ingenuity has been applied to a discovery to produce a new and useful result then it is an invention and may be patentable.

Australia's current patents law does not give IP Australia any basis in law to refuse to patent genes, nucleic acid or protein sequences defined by their corresponding DNA sequence solely because the patent relates to these areas of technology. As such, IP Australia has granted patents over isolated and purified gene sequences, when other requirements for patentability under the Patents Act are met.

In accordance with international obligations, Australia's patent system is technology neutral. Accordingly, IP Australia assesses all applications according to the same patentability criteria, irrespective of the subject technology.

Considerations by Australian courts of inventive step, full description and fair basis have caused Australia to have lower thresholds compared to other jurisdictions. The absence of Usefulness as a separate ground for examining applications prior to grant in Australia is also different to the practice in other jurisdictions.

IP Australia is progressing a package of reforms to the Australian patent system. The package is comprehensive, covering a range of proposals that would result in increased thresholds for patentability and to bring Australia into alignment with other jurisdictions. It will also include an explicit research exemption in the Patents Act which could help alleviate concerns by researchers regarding lack of freedom to research. These changes would apply across all technologies, not just human gene technology.

Several apparent misunderstandings about patents and genes patents held in the community are addressed in the submission. Patents may be granted for ground-breaking inventions as well as incremental advancements. Patents award inventive ingenuity irrespective of the level of intellectual endeavour or effort exerted to achieve the invention. The validity of a patent cannot be judged on what is well known or routine today, but at the date the patent was assessed—which could be many years in the past. Commercial viability is not relevant to examination of a patent. A patent over a gene sequence does not equate to ownership of that sequence; it is a right to restrain others from using or exploiting the invention without

the patentee's permission. A patent to an isolated gene sequence does not impinge on the freedom of the individual to use their DNA.

IP Australia's data indicates that the number of granted patents that assert rights over an isolated human gene is less than 400 in total to date. The data also indicates that patent applications for methods or processes of using gene sequences are increasing relative to patent applications for isolated gene sequences per se. This indicates that innovation efforts have shifted to downstream applications of gene sequences.

There are solutions proposed in other jurisdictions to address community concerns about gene patents that strike a balance between the need for genetic research, prosperity of the biotechnology industry and access to innovations in health care. Such measures include strong patentability criteria, public education, a research exemption, access to compulsory licensing, and guidelines for the licensing of genetic inventions.

This submission concludes that the ALRC Report 99 and other international reviews have not identified a systemic problem with access to diagnostic genetic tests. Our observation is that the current system appears to be functioning effectively in achieving its concurrent objectives of encouraging innovation, promoting diffusion of information, and encouraging access and transfer of technologies. Existing provisions within the patent system can be used to deal with any impacts associated with the cost of, and access to, gene patents should problems arise. Licensing issues are often resolved through commercial negotiation. Another approach, recommended in the ALRC Report 99, was that Commonwealth granting bodies such as the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) review the *National Principles of Intellectual Property Management for Publicly Funded Research* and associated guidelines, to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[3]

Any proposed changes to Australia's patent system should have regard to, and be consistent with, our obligations under international agreements such as the TRIPS Agreement and Free Trade Agreements, including the requirement for technology neutral assessment of inventions.

That is not to say that Australia's patent system does not need fine-tuning. IP Australia is currently progressing a patent reform package that seeks to strengthen the patentability criteria, and in doing so remove the potential for broad patents to be granted in Australia compared with other international jurisdictions.

[3] ALRC Report 99 (2004), recommendation 11-1

SUBMITTING AGENCIES

Department of Innovation, Industry, Science and Research

1.1. The Department of Innovation, Industry, Science and Research (Innovation Department) has a key role in increasing prosperity for all Australians through encouraging internationally competitive and sustainable business. The Innovation Department operates a number of programs designed to improve the efficiency and competitiveness of Australian industry and seeks to nurture emerging knowledge-based industries.

1.2. The central aim of the Government's innovation and industry policy is to increase prosperity through internationally competitive business and sustainable economic growth. In line with this aim, the Innovation Department believes that Australia's intellectual property (IP) regime should abide by the following principles. It should:

- effectively encourage innovation;
- enhance our competitiveness in a global environment; and
- be consistent with our international obligations.

IP Australia

1.3. IP Australia is the Australian Government agency responsible for:

- assessing and granting intellectual property (IP) rights in patents, trade marks, designs and plant breeder's rights ('registrable IP rights');
- promoting IP awareness;
- developing legislation to support Australia's IP system;
- contributing to bilateral and multilateral negotiations to improve IP protection internationally in accordance with Australia's interests; and
- administering the registration and discipline of patent and trademark attorneys.

1.4. Both the Innovation Department and IP Australia are responsible for providing policy advice to government on registrable IP rights as part of the Innovation, Industry, Science and Research portfolio.

'GENE PATENTS'- DEFINITION

2.1 It is important to note that there is no internationally recognised definition or common understanding of what is a 'gene patent' other than that they are a subset of biotechnology patents.

2.2 This submission uses the term 'gene patents' broadly to encompass patents that claim a product and/or processes (also known as 'methods') based on genes, nucleic acid or protein sequences[4]. The term encompasses patents over a wide range of biological materials including those listed in the terms of reference (ToR) for the Senate Inquiry. The term would also extend to plant, animal, viral and microbial gene sequences, even though plant and animal genes do not appear to be an intended subject under the ToR.

2.3 The focus of community concern leading up to the inquiry appears to be to the subset of gene patents that assert rights over human DNA sequences and methods of genetic testing using those sequences. This is also reflected in the Committee's Senate hearings and debates.[5] While the submission will address gene patents, it will focus on matters concerning patenting over isolated human genes, nucleic acid or protein sequences derived from DNA. We understand derivatives under the ToR to mean fragments or segments of human genes or therapeutic molecules derived from human gene sequences.

2.4 Figure 1 depicts the typical type of claims that are characteristic of a gene patent. Claims are statements in a patent application that carefully define the exact scope of the monopoly obtained by the patentee. A patentee may seek claims over a product, processes for making a product, or to methods of making or using a product.

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4 Protein sequences falling under 'gene patents' only include those defined by their corresponding DNA sequence. Protein sequences defined by their amino acid sequences are excluded from 'gene patents'.

5 Australia, Senate Standing Committee on Community Affairs, Estimates 2008, Supplementary Budget Estimates, Wednesday 22 October 2008, pp 20-24; Australia, Senate 2008, *Debates* No. 12, 12 November 2008, pp 6702-6706.

Figure 1: Gene Patent

Typical Product Claims

- Isolated gene sequence *per se*
- Isolated protein encoded by the gene sequence
- Vectors harbouring the isolated gene sequence
- Cell lines transformed with the vectors or sequence
- Recombinant protein expressed from the cell lines
- Antibodies produced using the sequence or fragments of the sequence
- Probes comprising the sequences or fragments
- Vaccines and compositions comprising the sequence or protein
- Kits comprising the sequence or specific primers or fragments of the sequence

Typical Method Claims

- Use of the gene or protein sequence to diagnose or prognose disease or disorders associated with the gene
- Use of the sequence and/or protein as a therapeutic to treat a disease or disorder associated with the gene
- Methods of identifying molecules that modulate or interact with the gene wherein the methods are directly based on the use of the sequence
- Gene therapy using the sequence

OBJECTIVES OF THE PATENT SYSTEM

3.1 Australia's patent system, like that of other jurisdictions, seeks to strike a balance between rights and obligations and achieve a number of policy intents. These may be characterised as follows:

Stimulating Innovation

3.2 The main purpose of Australia's patent system is to stimulate industrial innovation:

> "…by granting limited monopoly rights to inventors and by increasing public availability of information on new technology. Patent procedures must achieve a balance among competing interests while remaining administratively workable."[6]

3.3 A fundamental role of the patent system is to provide an incentive to invest in innovation. In providing innovators with exclusive rights to their invention, the system

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6 The Hon David Thomson MP, Minister for Science and Technology, Second Reading Speech, Patents Amendment Bill 1981, House of Representatives, 7 April 1981, p1370

minimises the potential for free-riding and imitation.[7] Exclusive rights for the term of the patent give innovators the opportunity to receive returns from their investment in research and development (R&D).

3.4 The Australian patent system contributes to the development of an environment which enhances the competitiveness of Australian firms both in the domestic and international markets, which in turn supports high value added employment in the Australian market.

3.5 In practice, the patent system has played an important role in spurring innovation in the biotechnology industry. In biotechnology, for example, many start-up companies rely on patent protection as a source of attracting much needed capital in their area.[8] This capital would include foreign direct investments. Similarly, innovations in human genetic research have contributed to new and better healthcare products and services to society, for example:

- the Gardasil® vaccine against cervical cancer,
- monoclonal antibodies for the treatment of specific cancers and arthritic conditions, and
- medicines like Fabyzyme® and Elaprase® for the treatment of rare genetic disorders.

3.6 While a large proportion of health industry activity is not directly related to products which involve gene patents (specific statistics are not available to our knowledge), the Australian pharmaceutical industry employed 40,000 people last year and was Australia's second largest exporter of manufactured goods in 2008 (data based on unpublished Australian Bureau of Statistics (ABS) data; IBIS World 2008 data and Innovation Department estimates and published in the recently released Pharmaceuticals Industry Strategy Group report).[9]

Diffusion of Knowledge

3.7 Diffusion of knowledge to researchers and the public is also encouraged by the patent system. Researchers and the public are informed of the details of the invention through publication of the patent specification. As a result, other researchers can avoid unnecessary duplication of research effort, and this facilitates research in emerging fields.[10] Without patent protection, companies are likely to

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7 K Arrow, 'Economic Welfare and the Allocation of Resources for Inventions', In The *Rate and Direction of Inventive Activity: Economic and Social Factors*, A Report of the National Bureau of Economic Research, , Princeton University Press, Princeton 1962

8 Organisation for Economic Co-operation and Development (OECD), *Patents and Innovation: Trends and Policy Challenges*, 2004, pp5 and 22.

9 Final Report of the Pharmaceuticals Industry Strategy Group, 2009 available at www.innovation.gov.au/Industry/Pharmaceuticals/Pages/PharmaceuticalsIndustryStrategyGroup.aspx

10 D Keays ,'Patenting DNA and Amino Acid Sequences – An Australian Perspective', *Health Law Journal*, vol 7, 1999, p 71; available at http://www.law.ualberta.ca/centres/hli/hl_journal.html#

resort to keeping their knowledge/inventions secret, at least until they are ready to enter the market.[11] The patent system gives the public access to information on new technologies much earlier than would be the case if no protection was available. When a patent ceases or its term expires the invention can be used in an unrestricted fashion to contribute to the public good.

Technology Access and Transfer

3.8 Patents not only provide a framework by which Australian innovators can protect their IP, they encourage overseas innovators to transfer their technology to Australia. However, innovators are reticent to use foreign direct investment or joint ventures in countries with weak IP protection.[12 & 13] Also a well functioning patent system facilitates international research collaborations. In that regard, patents play a pivotal role in both technology protection and technology access for Australian industries and research institutions. Collaborations between patent holders (or their licensees) and other businesses allows diffusion of patented technologies among competitors and other innovating firms. Such business linkages are common where the patented invention is a platform technology, and the patentee cannot use or commercialise all the invention's applications themselves.

3.9 For countries that are a net importer of technology, like Australia, it is advantageous to have patent thresholds set at least as high as thresholds set for countries with which we conduct the majority of our technology trade.[14] Strong and aligned thresholds give Australian innovators confidence that having satisfied those in Australia they are likely to satisfy the requirements in their export markets. Aligned thresholds are also likely to reduce costs for Australian applicants seeking patent protection overseas. Conversely, differences that make Australia's patent law out of step with major jurisdictions may adversely affect Australian businesses wanting to develop their inventions and prosper in a global market place.

Balancing of Rights and Obligations

3.9 The balancing of rights and obligations underpinning the patent system is evidenced by the statement of objectives under *Article 7* of the *World Trade*

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11 Keays, p71.

12 K Maskus 'The role of intellectual property rights in encouraging foreign direct investment and technology transfer', Paper prepared for the conference "Public-private initiatives after TRIPS: Designing a Global Agenda", Brussels, Belgium 16-19/07/1997.

13 K Maskus,, S Doughtery, & A Mertha "Intellectual property rights and economic development in China" in C Fink & K Maskus *Intellectual Property and Development: Lessons from Economic Research*, World Bank, 2005, pp325-327..

14 Studies that have considered this issue include:

- K Maskus et al (1997) 'Quiet Pioneering: the international economic legacy of Robert Stern, Ann Arbor', University of Michigan press, pp95-118;
- K Maskus (2000) 'Intellectual Property Rights in the Global Economy', Institute for International Economics, Washington D.D.
- Review of Intellectual Property Legislation under the Competition Principles Agreement, 'the Ergas Report', September 2000
- Branstetter et al (2006) Quarterly Journal of Economics 121(1), 321-49

Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Article 7
Objectives

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

3.10 The balance is achieved through a combination of exclusions from patentability, application of relevant patentability thresholds and exclusions from infringement. For example, there are provisions[15] (commonly referred to as 'Crown Use' provisions) in the Patents Act to ensure that the Australian Government is protected from infringement action, should they need to exploit a patent in the public interest. This exception is about balancing the rights of patent owners with the needs for government to provide essential services to the public.

3.11 The patent system rewards inventors with a limited monopoly to exploit their invention, in return for the inventor disclosing their invention to the public. This is often referred to as the '*quid pro quo*' underpinning the patent system. The monopoly is not a positive right for the owner to exploit their invention, as that exploitation may be further regulated by other laws, international standards, guidelines, and practices, for example laws protecting national security. Further, the availability and cost of a drug which is the subject of a patent in Australia will depend on whether it is determined to be safe by the Therapeutic Goods Administration (TGA), and whether it demonstrates cost effectiveness to allow its listing on the Pharmaceutical Benefits Scheme (PBS). The TGA and PBS also have other legislative requirements which a drug may have to meet.

THE AUSTRALIAN PATENT SYSTEM

4.1 A key feature of patent systems worldwide is that they must be technology neutral in compliance with the TRIPS Agreement[16] to which Australia is a signatory. In particular, the TRIPS Agreement requires patents to be made available in all fields of technology without discrimination.[17] IP Australia therefore assesses applications for gene patents by applying the same patentability requirements as for all other applications, irrespective of their technological field. This technology neutral approach contributes to reduced complexity and cost of providing a national patent system and has inherent flexibility to accommodate patenting of new and emerging areas of technology.

4.2 Patent applications may be lodged directly with IP Australia, or may be filed at foreign IP Offices or the World Intellectual Property Organization (WIPO) and transmitted to IP Australia under the provisions of the *Patent Cooperation Treaty*

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15 The Crown use provisions are discussed at paragraph 9.1 of the submission.

16 *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) at Annex 1C to the *Marrakesh Agreement Establishing the World Trade Organisation*.

17 TRIPS Article 27 is included for reference at Appendix B.

(PCT). Applications must be accompanied by a complete patent specification describing in detail how the invention works. This description requirement may be satisfied by deposits of biological samples with 'international depository authorities' under the Budapest Treaty[18] and/or include a separate sequence listing detailing the sequences relevant to the invention. The specification must also contain one or more claims that should carefully define the exact monopoly sought.

4.3 Two types of patents are available in Australia—innovation and standard patents. Innovation patents are a second-tier form of IP protection with a lower inventive threshold criterion than required for standard patents. Innovation patents are a relatively quicker and cheaper protection option with a maximum term of 8 years from filing. Standard patents have a higher inventiveness threshold, but have a longer maximum term of 20 years from filing. This may be extended up to a maximum of 25 years for some pharmaceutical patents. Genetic inventions are normally protected by means of standard patents.

4.4 Publication of patent applications into the public domain is an important step in the application process. This diffusion of knowledge into the public domain alerts researchers and competitors that IP rights are being sought and to plan accordingly. Publication normally occurs 18 months after the priority date of the application. The priority date may be the date of filing in Australia, or the date of the earliest filing in a foreign IP office for the invention (provided it is also filed in Australia within 12 months of that date). A patent application that does not proceed to grant gives the applicant no monopoly over the claimed invention. Consequently, the public benefits from disclosure of the invention in the public domain.

4.5 In Australia, the patent system provides four opportunities to test the validity of a patent:

1. each application is examined by IP Australia before it may be accepted or refused ('examination');[19]

2. each accepted application may be opposed before grant by any party (including the Minister) ('opposition');[20]

3. applications may be re-examined before grant at the discretion of the Commissioner of Patents, and the patent must be re-examined after grant, on request from any person in an approved form (including the Minister) ('re-examination')[21]; and

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18 Australia is a signatory and contracting country to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The treaty provides for the deposits of biological material at international depository authorities to meet requirements of full description. The National Measurement Institute (NMI) is part of DIISR and houses Australia's only facility designated as an international depository authority. NMI is registered to hold limited classes of materials including genetic material of microbial origin, but not human genetic material. Patent applicants are not required to use the authority of their native country and may deposit the material at an authority located overseas in accordance with the regulations under the Budapest Treaty.

19 Examination is dealt with in Chapter 3 of the Patents Act.

20 Opposition is dealt with in Chapter 5 of the Patents Act.

21 Re-examination is dealt with in Chapter 9 of the Patents Act.

4. after grant, the validity of a granted patent can be challenged in the courts by any Party (including the Minister) ('revocation').[22]

4.6 *Section 4* of the Patents Act contains a flow chart setting out what is involved in the application process for a standard patent in Australia.

Patentability Criteria

4.7 Applications are assessed as to a number of matters concerning patentability:[23]

- *Manner of Manufacture*: whether the particular type of matter can be considered an invention and therefore be the subject of patent (i.e. patentable subject matter).
- *Novelty*: whether the invention has been previously publicly used or published.
- *Inventive Step*: whether the invention would be obvious to a 'skilled person' in the field.
- Whether the patent specification complies with specific requirements under section 40 of the Patents Act:[24]
    1. *Full description*: the invention must be described fully to enable a 'skilled person' in the technological field of the subject to work and use the invention.
    2. *Fair basis*: the claim or claims must be fairly based on the matter described in the specification.
- *Usefulness*: whether the results promised by the invention can be achieved or reproduced.

4.8 If an application does not meet one or more of these criteria, the applicant will receive an adverse report from IP Australia[25]. If after various exchanges of examination reports an applicant cannot overcome identified problems with patentability within the prescribed statutory period, their application lapses.

4.9 Currently, different standards of proof apply for different patentability criteria, for example, a higher evidentiary burden is placed on the applicant to prove Novelty

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22 Revocation is dealt with in Chapter 12 of the Patents Act.

23 Not all of the listed criteria are necessarily assessed at each of the four stages identified earlier.

24 There are other requirements with which a specification is required to comply under section 40 of the Patents Act, but these are the most relevant ones for this inquiry.

25 Except in relation to 'usefulness' which is not a stand-alone criteria on which applications are examined. However, 'usefulness' is addressed in part under the Manner of Manufacture requirement.

and Inventive Step than is the case for Full Description or Fair Basis. IP Australia is currently progressing a package of reforms to the Australian patent system. The package will include changes to standardise the standards of proof for all patentability criteria and are the same as those proposed by ALRC Report 99, recommendation 8-12.

4.10 The patentability criteria applied by IP Australia to assess gene patent applications is the same as that applied to all other applications. In this assessment, IP Australia is bound by the legislation as enacted by Parliament and as interpreted by the courts. IP Australia's *Manual of Practice and Procedures* (Manual) is a reference tool for its examiners. It explains IP Australia's application of the law and judicial decisions to examination of applications under the Patents Act and *Patent Regulations 1991*.

Patentable Subject Matter

4.11 The Manner of Manufacture requirement sets the boundary of what can be the subject of a patent. The phrase is defined by reference to *section 6* of the *1624 Statue of Monopolies* (a United Kingdom statue), and has a long history of judicial interpretation. Despite the long judicial history, to date no court decision in Australia has considered specifically whether isolated and purified gene sequences are proper subject-matter for patents. In the absence of Australian precedents, IP Australia has turned for guidance to decisions and practice relating to chemical compounds. The Australian High Court decision in *National Research and Development Corporation v Commissioner of Patents* case[26] (NRDC) is the watershed decision that currently guides examination on Manner of Manufacture aspects of patent applications in Australia. It provides a set of guiding principles, emphasising the broad scope of the expression Manner of Manufacture.

4.12 The NRDC case involved the patentability of a new use of a known chemical, namely to kill weeds. The following principles[27] can be drawn from the decision in the NRDC case:

- The distinction between discovery (which is unpatentable) and invention is very fine and it is not helpful to use terms such as 'work of nature' and 'laws of nature' as everything that happens may be deemed 'the work of nature' and any patentable composite exemplifies in its properties the 'laws of nature'.

- It is the practical application of information to a useful end that takes a discovery into the realm of 'manufacture'.

- Manner of Manufacture should not be rigidly defined: its purpose is to encourage national development in 'excitingly unpredictable fields'.

- An invention is patentable if it gives rise to an '***artificially created state of affairs***' in the ***'field of economic endeavour'***.

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[26] [1959] HCA 67

[27] [1959] HCA 67 at paragraphs 8, 15 and 25

The last bullet point is the key guiding principle employed by IP Australia in applying the Manner of Manufacture criterion.

4.13 Courts have since allowed patenting of products and processes generated in new and emerging fields of technology. Common statements by the courts, both in Australia and the UK, have been:

- The concept of invention has been continually changing by applying the social policy which underlay the *1624 Statute of Monopolies* in the seventeenth century to the changing conditions resulting from advances in technology and the sciences.[28]

- The notion of what is patentable must remain flexible in order for patent law to keep pace with scientific and technological developments.[29]

- The law must move with changing needs and times.[30]

4.14 IP Australia has an accepted practice of granting patents for isolated cells, and chemical compounds isolated from nature. For example in 1949, IP Australia granted a patent for an isolated extract from animal liver that could be used to treat anaemia.[31]

4.15 Given the broad ambit of Manner of Manufacture following the decision in the NRDC case, IP Australia has granted patents over isolated and purified gene sequences, if they meet the other requirements for patentability. The Manual of Patent Practice (the Manual) provides that a biological entity may be patentable if technical intervention (i.e. manufacture) has resulted in an artificial state of affairs (i.e. that does not occur in nature).[32] In 2005, IP Australia published a Fact Sheet relating to *Australian Patents for Biological Inventions* setting out its understanding. The Fact Sheet lists the range of inventions over biological materials which may be patentable, including bacteria, viruses and nucleic acids—but only where the material has been isolated from its natural environment, or has been synthetically or recombinantly produced.[33] Several academics who have considered the law in Australia have reached similar conclusions, namely that isolated and purified DNA sequences are likely to be patentable subject matter in Australia.[34]

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28 *American Cyanamid v Upjohn Co* [1970] 1 W.L.R. 1507 at 1526.

29 *Grant v Commissioner of Patents* [2005] FCA 1100 at paragraph 17.

30 Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065 at paragraph 75

31 Patent number 131,031 'Improvements in or relating to the manufacture of liver extracts'.

32 Patent Manual of Practice and Procedures, 2.9.2.14 (available at http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm).

33 IP Australia Fact Sheet (2005), *Australian Patents for Biological Inventions*, page 2 (available at http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf)

34 D Nicol 'Should Human Genes be Patentable Inventions under Australian Patent Law?', *Journal of Law and Medicine,* vol 31996, 231 at 239 considered isolated and purified DNA sequences are almost always likely to have a material advantage over their naturally occurring counterparts; K Ludlow, 'Genetically Modified Organisms and Their Products as Patentable Subject-matter in Australia' (1999) 21 *European Intellectual Property Review* pp298-312 at 312 said that

4.16 An example of how IP Australia has handled applications for isolated and purified DNA sequences is the decision of a Deputy Commissioner for Patents in *Kiren-Amgen Inc v Board of Regents of the University of Washington*.[35] There the distinction was drawn between:

- naturally occurring DNA, which would be only a discovery and not a Manner of Manufacture; and
- purified and isolated DNA sequences which are patentable as they claim 'an artificially created state of affairs'.

4.17 The international trend, for example in Europe and the US, has been to allow patenting of isolated and purified gene sequences and methods of their use. As of January 15, 2007 all of the 27 European Union member states had implemented a Directive on the legal protection of biotechnological inventions that explicitly provides that biological material isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously occurred in nature.[36]

4.18 The European Patent Office (EPO) has taken a similar approach to that of IP Australia. In 1995, the EPO decided in *Howard Florey/Relaxin*[37] that the gene sequence itself (for H2-relaxin) was patentable because:

- The sequence was new in the absolute sense of having no previously recognised existence.
- It was not a mere finding of something freely occurring in nature, which is not an invention.

4.19 The proprietor claimed the sequence as well as processes for using the sequence. The EPO decided that broad patent protection was warranted because the proprietor:[38]

- had developed a process for obtaining H2-relaxin and the DNA encoding it;
- had characterised these products by their chemical structure and found a use for the protein; and

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Australian courts are likely to accept that human intervention involved in genetic modification [of which isolated gene sequences are a part] is sufficient for the resulting organisms and their products to be patentable subject matter.

35 [1995] APO 61 available at http://www.austlii.edu.au/au/cases/cth/APO/1995/61.html. This decision was appealed to the Federal court on other grounds: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106.

36 Article 3 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998.

37 [1995] EPOR 541 at page 548

38 See note 37.

- had made H2-relaxin available to the public for the first time.

Exclusions from Patentability

4.20 *Section 6* of the *1624 Statue of Monopolies* excludes from patentability any inventions that would be contrary to law or mischievous to the State by raising prices of commodities at home, or hurt of trade or by being 'generally inconvenient'. The Contrary to Law exclusion has been incorporated into section 50(1)(a) of the Patents Act while the courts in recent times have considered Generally Inconvenient in the context of methods of medical treatment for humans.

Contrary to Law

4.21 Section 50(1)(a) of the Patents Act gives the Commissioner the discretion to reject a patent application on the ground that the use of the invention would be contrary to law. This discretionary power is applied only in the clearest of circumstances.[39] In deciding whether to exercise this discretion an examiner (as the delegate of the Commissioner) must have close regard to whether an invention is primarily intended for an unlawful use. Gene patents are generally described to have a lawful use for their invention, thus they have not been excluded on this ground. At the time of writing, no Australian regulation makes the use of gene-related inventions unlawful.

Generally Inconvenient

4.22 General inconvenience has not been subject of judicial consideration in relation to patenting of gene sequences. It has however been considered in the context of methods of treating the human body. Judges in referring to the Generally Inconvenient proviso in recent court decisions have shown a reluctance to rely on it as a ground for refusing patentability.[40] The Manual[41] states that examiners should refrain from raising a Generally Inconvenient objection given the lack of clear guidance from the court decisions as to when it should apply. The Manual also notes that Generally Inconvenient has not been relied on as the primary basis on which to invalidate a patent in any reported cases.[42]

4.23 IP Australia also believes it is inappropriate for it to take ethical or public policy issues into consideration in examination. The Manual states that it is for Parliament, not the courts or the Patent Office to decide whether matters of ethics or social policy are to have any impact on what is patentable. The ALRC Report 99 into

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39 Patent Manual of Practice & Procedures, 2.9.6.

40 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065, Wilcox J at paragraph 11; ALRC also made this observation at page 175 of its report.

41 Patent Manual of Practice & Procedures, 2.9.3.

42 See note 41.

gene patenting also commented that patent offices and examiners have no special authority in philosophical or moral matters.[43]

Excluded Subject Matter

4.24 In addition to the above, certain subject matter is excluded from patentability under the Patents Act. These express exclusions operate to narrow the broader field of patentable subject matter under the Manner of Manufacture requirement. Human beings and biological processes for their generation are excluded from patentability. The exclusion was introduced by Parliament on ethical grounds in response to concerns expressed in the Senate on the issue of patentability of human beings.[44]

4.25 The courts have said that it is the role of Parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable, not the courts.[45] There have been two attempts to amend the Patents Act to exclude genes and naturally occurring gene sequences.[46] On both occasions these proposals have not been supported by Parliament.

4.26 The Advisory Council on Intellectual Property (ACIP) is currently considering issues regarding the scope of patentable subject matter in Australia including whether, for example, Manner of Manufacture is still meeting Australia's needs.[47] ACIP received thirty-seven submissions in response to its issues paper, and will be seeking further public input later in 2009.

Discovery versus Invention

4.27 Much debate underpins the question of whether isolated and purified materials are actually discoveries and therefore are not patentable subject matter. The reality is, and the courts concede this, that the distinction between a discovery and what is an invention can be extremely fine. The decision in the NRDC case recognised that discoveries can enter into the realm of an invention where ingenuity is applied to the discovery to produce a useful result.[48] This is consistent with the approach in older English cases where, for there to be an invention, a person must have used knowledge and ingenuity to produce either a new and useful thing or result.[49]

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43 ALRC Report 99 (2004) Chapter 7 Exclusions from Patentability at paragraph 7.82.

44 ACIP Issue paper on Patentable Subject Matter, July 2008, page 29.

45 Wilcox J in [1994] FCA 1065 at paragraph 11.

46 See the ALRC Report 99 discussion of this in Chapter 7 at page 170.

47 Advisory Council in Intellectual Property, Review of Patentable Subject Matter, Issues paper (July 2008) can be found at http://www.acip.gov.au/reviews.html##subject

48 [1959] HCA 67 at paragraph 8.

49 *Lane-Fox v Kensington & Knightsbridge Electric Lighting Co (Ltd)* (1892) 9 RPC 413 at 416.

4.28 IP Australia only grants patents that claim isolated and purified gene sequences where the patentee has disclosed a practical use for the sequence. It does not matter whether the gene has been identified and isolated from a natural source or synthesised artificially. If no practical use for the gene sequence is disclosed in the specification the sequence will be considered to be a discovery and unpatentable. Gene patents usually disclose a biological function for the gene and/or its association with a particular disease, along with evidence that the isolated sequence has a diagnostic or therapeutic use, thereby meeting the requirement of invention.

4.29 The European Patent Office has a passage that usefully encapsulates the distinction:

> Discoveries, which do not extend human ability, but only human knowledge, are by their very nature not patentable…It is different however if a DNA sequence is released from its natural surroundings by means of a technical procedure and is made available for the first time to a commercial application. Here there is a step taken from knowing to being able.[50]

4.30 Interestingly, the US patents legislation does not preclude discoveries from being patentable. It explicitly allows for patentability of both discoveries and inventions providing they meet other patentability requirements, such as being a new and useful improvement.[51]

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4.31 In practice, gene patents usually meet the Manner of Manufacture requirement. In contrast, the Novelty and Inventive Step criteria tend to determine whether gene patents are granted or not.

Novelty Requirement

4.32 A fundamental requirement of the patent system is that patents are only granted for things that have not been done or disclosed before. This is assessed under a requirement termed Novelty by looking to see if the invention has been publicly used or published before.

4.33 In terms of gene patents, gene sequences and any isolated and purified biological material not previously published or used will usually satisfy the Novelty test. If the sequence of a gene is already known, a person cannot claim a monopoly to the sequence itself. However, if the claimed invention discloses an *unknown* use, function or property of the gene (such as a new association with a particular disease), Novelty may be satisfied. In that case, claims could be directed to use of the known gene as a diagnostic for the newly identified disease. Where the known gene sequence is patented, cross-licensing with the patent holder of the gene sequence may be necessary. This is not unique to gene patents, and is common to patents concerning chemistry, medical engineering, medical devices, drugs and

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50 See *Legal protection of biotechnological inventions: Frequently Asked Questions on scope and objective of the EU Directive (98/44)* 3 July 2000, available through http://ec.europa.eu/internal_market/indprop/invent/index_en.htm.

51 See Chapter 35 of the *United States Code (U.S.C.) 101*available through http://www.uspto.gov/web/offices/pac/mpep/documents/appxl.htm

software, particularly when businesses wish to make use of patented pioneer or platform technology.

4.34 Generally, Australian practice is consistent with other major international jurisdictions like the EPO and the US on this patentability criterion.

Inventive Step Requirement

4.35 Inventive Step requires that patents are only granted for inventions that advance technology beyond what is routine or obvious. The statutory basis for the Inventive Step test is contained under section 7(2) and 7(3) of the Patents Act. Inventive Step is a complex patentability criterion.

4.36 What is routine or obvious is assessed from the perspective of an unimaginative but 'person skilled in the art' or technological field (Skilled Person). The assessment of what is obvious requires an objective comparison by the Skilled Person of the invention claimed against the existing knowledge base. That knowledge base comprises both the 'common general knowledge' (CGK) and the kinds of information permitted for consideration under the Patents Act (referred to statutorily as the 'prior art base').[52] The CGK involves:

> "…the use of that which is known or used by those in the relevant trade. It forms the background knowledge and experience which is available to all in the trade in considering the making of new products, or the making of improvements in old, and it must be treated as being used by an individual as a general body of knowledge".[53]

4.37 A Skilled Person can consider one, two or more sources of information in the prior art base that they could reasonably have been expected to have ascertained, understood, regard as relevant and combine where multiple sources are involved.

4.38 The most relevant judicial consideration of Inventive Step in the context of medical technology and chemical compounds is *Aktiebolaget Hassle v Alphapharm Pty Ltd* (Alphapharm).[54] The decision in Alphapharm concerned the inventiveness of a particular oral preparation containing omeprazole as the active ingredient. Omeprazole is used to treat gastric and duodenal[55] ulcers.

4.39 Alphapharm set out the relevant question as:

> "Would the notional research group at the relevant date, in all the circumstances, which include knowledge of all the relevant prior art and of the facts…directly be led as a matter of course to try the [experiment] in the expectation that it might well produce [the desired result?][56]

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52 Subsections 7(2) and (3) of the Patents Act.

53 *Minnesota Mining and Manufacturing Co and 3M Australia Pty Ltd* v *Beiersdorf (Aust) Ltd* [1980] HCA 9, Aickin J at paragraph 115.

54 *Aktiebolaget Hassle v Alphapharm Pty Ltd* [2002] HCA 59.

55 Duodenal relates to the first portion of the small intestine, from the stomach to the middle portion of the small intestine (jejunum).

56 [2002] HCA 59 at paragraph 53.

4.40 IP Australia has applied this test to its practice of assessing gene patent applications. The result is that Inventive Step is considered to be satisfied in the case of a novel gene sequence, if the function of the gene was not predictable or non-obvious. In the case of a known gene, claims to uses or applications of the gene may be inventive if a new and non-obvious or unpredictable function is demonstrated for the gene. For example:

- *Inventive Step met*: The prior art teaches that a particular protein encoded by a known gene is expressed in cancerous prostate tissue. Subsequent inventors might claim a patent over the *us*e of the gene or protein in methods for diagnosing another type of cancer, say renal cancer, if this is not predictable from the existing knowledge base.

- *Inventive Step not met*: The identification of a polymorphism or mutation within a known gene may be inventive if a novel and non-obvious function can be ascribed to the mutation, for example, a relationship between the mutation and susceptibility to a particular disease. In contrast, if the existing knowledge base reveals that other mutations in the same gene are known to predispose to the same disease then the new mutation would be considered obvious and lacking an Inventive Step.

4.41 The concept of Inventive Step has been subject of much judicial consideration. As a result of a number of recent court decisions, IP Australia's view is that the Inventive Step threshold is lower in Australia than other countries.

4.42 IP Australia is proposing a number of changes to the Patents Act to increase the Inventive Step threshold to at least that applicable in other jurisdictions. The reforms would apply across all technologies, including gene patents.

Usefulness Requirement

4.43 To satisfy the patentability criteria an invention must be useful. This does not mean the invention has some usefulness to society or that it is commercially viable or successful. Rather Usefulness under patent law requires that the claimed invention be capable of achieving the result(s) that the patentee promises it can achieve.[57]

4.44 In any case, IP Australia is proposing a number of changes to the Usefulness requirement under the Patents Act with a view to aligning it with other international jurisdictions. Under the proposals, Usefulness would become a ground for consideration in examination and it would be clarified that the claimed invention would have to demonstrate 'specific, substantial and credible utility' similar to requirements in the United States. These changes are the same as those proposed by ALRC Report 99, recommendations 6-3 (a) – (c).

[57] Lahore, J. & Dufty, A., *Patents, Trade Marks and Related Rights*, Butterworths (2006) at [12,970].

Full Description and Fair Basis

4.45 Full Description and Fair Basis are two tests that form the quid pro quo underpinning the patent system. The quid pro quo refers to the exchange between the inventor and the public; the inventor is rewarded with the monopoly while the information required to make and work the invention is disseminated to the public.

4.46 Both these tests are used to ensure an appropriate balance between the invention disclosed and the monopoly claimed. Full Description ensures the published patent provides sufficient information for the Skilled Person to understand how to make and use the invention, without the need for any further inventions or additions or prolonged studies.[58] Where sufficient instructions are provided for a Skilled Person to reproduce the genetic materials and use them in methods claimed, Full Description is usually met. The Full Description requirement may be met through deposition of a biological sample at a designated facility in accordance with the Budapest Treaty.

4.47 Fair Basis ensures the scope of the granted patent is consistent with what the description as a whole describes as the invention. This requirement ensures the scope of monopoly claimed is consistent with what is described in the body of the patent specification. For example, Fair Basis is not met:

- if the claims extend the use of the gene to diagnose Alzheimer's disease, when the specification teaches the use of the gene to diagnose cancer and only contains examples for cancer;

  or

- if the specification teaches one particular gene sequence that is a genetic marker for breast cancer but claims any and all possible gene sequences that are markers of breast cancer including those yet to be identified as markers of breast cancer.

4.48 Recently Australian court decisions have interpreted the existing law as providing a relatively low threshold for Full Description and Fair Basis in Australia. IP Australia is proposing changes to raise the thresholds in Australia to align more closely with other international jurisdictions and minimise claims that are not fully supported by their accompanying description. These proposed reforms would apply across all technologies not only to gene patents.

Some Common Misunderstandings About Patents

5.1 A number of misunderstandings about patents and gene patents appear to exist in the community through miscomprehensions of the topic. We have chosen to address a few of these in this submission.

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[58] For a recent consideration of the full description requirement see *Kimberly Clark v Arico* [2001] HCA 8 at paragraph 25.

Only Ground-breaking Inventions are Patentable

5.2 This misunderstanding is most often voiced by researchers. That belief is inconsistent with recent High Court authority which affirms that only the smallest level of inventiveness (i.e. a scintilla of inventiveness) is needed for the grant of a patent.[59] Inventions as defined by patent law can be, and often are, incremental advancements over what has been done before.

Patents are the Result of Enormous Intellectual Endeavour or Effort

5.3 Another apparent misunderstanding is that inventions should only be granted a patent if they are the result of enormous intellectual endeavour or effort. The patent system was not designed to reward effort, it rewards inventive ingenuity. This ingenuity may be as a result of no more than serendipity, or relying on little intellectual endeavour or effort. A patent may also be granted irrespective of whether once the invention is made, it is possible for a Skilled Person to conceive of the steps the inventor has taken to arrive at the invention. It may sometimes be easy to reverse engineer an invention after the fact. The risk of bringing hindsight into the picture in assessing obviousness can be high, such that the courts often warn experts giving evidence before it to avoid application of hindsight when assessing questions of patentability.

Isolating Gene Sequences and Determining Their Functions Is Not Inventive

5.4 Some researchers query the validity of patents for isolating and determining the function of particular genes, as techniques to accomplish this are now quite routine and well-known. However, a misconception can arise from the application of hindsight and taking into account the knowledge base that exists now compared to when the patent application was assessed. Although isolating the gene sequence might be routine *now*, Inventive Step is assessed as at the 'priority date' of the patent claims, which could be many years in the past.

Patented Inventions Must be Commercially Viable

5.5 Patents are granted on the basis of the criteria outlined in the previous section. Commercial viability is not one of the criteria. In fact on filing an application for a patent, the applicant may not know the commercial value of the invention. This may not be able to be determined until many years after lodging an application. If an invention lacks market appeal or is difficult to commercialise, the applicant may withdraw their application or allow it to lapse. Alternatively, they may decide not to renew[60] the patent once it has been granted.

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59 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* [2007] HCA 21 at paragraph 52.

60 Granted patents must be renewed annually to stay in force upon payment of the requisite renewal fee.

5.6 Regardless of the fate of the patent, once the information contained in the patent specification has been published, it remains in the public domain. Members of the public are free to use the information and teachings available to them in the published specification, provided they do not commercially exploit or deal with the patented invention in a way that is infringement under the Patents Act. However, introduction of an 'experimental use exemption' may be useful in providing more clarity to researchers and the public as to their freedom to research. IP Australia is currently progressing a proposal for an explicit 'experimental use exemption' in the Patents Act.

Confusing gene patents with ownership of genes

5.7 A patent over a gene sequence does not equate to ownership of that sequence. A patent is a right to restrain others from using or exploiting the claimed invention without the patentee's permission; it does not confer ownership of the physical material as it exists in the body. A patent on an isolated gene sequence does not impinge on the freedom of the individual to use their own DNA.

5.8 The arguments that patenting of gene sequences somehow interferes with one's privacy is not persuasive.[61] Privacy is the ability to control personal information about oneself which is a separate issue to patenting of sequences and diagnostic tests. Issues regarding the use of DNA samples obtained from patients by clinical test providers were considered by the ALRC Report 96[62] and the Government's response[63] to that report.

5.9 IP Australia considers that these misunderstandings point to the need for further public education on the topic of gene technologies and gene patents.

Obligations Under International Treaties

6.1 Consideration of introducing exclusions and criteria for specific technologies needs to be considered in light of Australia's obligations under various international treaties and bilateral and multilateral trade agreements. The international treaties and agreements most relevant to the issue of gene patents are TRIPS and the Australia-United States Free Trade Agreement (AUSFTA).

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61 Keays, p75.

62 ALRC Report Number 96, 'Essentially Yours: The Protection of Human Genetic Information in Australia', 2003 ('ALRC Report 96')

63 The Australian Government response to the ALRC Report 96 was released in December 2005 and can be found at http://www.alrc.gov.au/inquiries/title/alrc96/agd.htm

TRIPS

6.2 Australia has been a member of the World Trade Organisation (WTO) since 1 January 1995. As such, Australia is required to apply the WTO's TRIPS Agreement. In particular, the TRIPS Agreement requires patents to be made available to all fields of technologies without discrimination.[64] IP Australia assesses applications for gene patents by applying the same patentability requirements as for all other applications, irrespective of their technological field. Introducing a limited term of protection, higher thresholds of patentability or a general exclusion specifically for gene technologies may breach obligations under the TRIPS agreement.

6.3 Article 27 of TRIPS provides some limited exclusions from patentability. These include:

- *Article 27(2)* permits an exemption to protect public order or morality as a result of commercial exploitation in a member's territory.
    - The European Union has a provision to this effect; however, the exemption has been narrowly interpreted and would not in practice be able to be used to limit patentability of genetic material.

- *Article 27(3)(a)* provides exclusion from patentability all methods of diagnostic, therapeutic and surgical treatment of humans. Australia does not currently use this exclusion.
    - Changes to Australian patent law to implement this exclusion would require careful consideration of the full impact on innovation in Australia, trade with overseas countries, and transfer and access to medical technologies.

AUSFTA

6.4 AUSFTA is a major bilateral trade agreement with the United States that Australia entered into in 2004. *Chapter 17* of the AUSFTA deals with IP rights, including patents.

6.5 AUSFTA does not expand the exclusions from patentability allowed under the TRIPS Agreement.[65] The agreement does require both parties to seek to reduce differences in law and practices between their respective systems and participate in international patent harmonisation efforts.[66] There is flexibility to implement the agreement in a way that reflects the interests of our domestic interest groups and

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64 See Article 27 of the TRIPS Agreement.

65 In contrast it actually removes an exclusion permitted under TRIPS relating to plants and animals, and biological processes for their generation. But this is not directly relevant to gene sequences.

66 See Article 14 of Chapter 14 Intellectual Property Rights of the Australia-United States Free Trade Agreement

Australia's legal and regulatory environment.[67] Any changes to Australian patent law would require consideration of Australia's obligations under AUSFTA, and an assessment of:

- the full impact on Australia's exports to the US;
- inward technology transfer from the US, and
- trade with the US more generally.

Statistics on Gene Patents in Australia

Patent Classification System

7.1 Before considering the results of the data analysis, it is necessary to explain how the International Patent Classification (IPC) system[68] applies to patent applications and patents pertaining to gene patents.

7.2 At filing, all patent applications are classified according to the technical matter with which the invention is most concerned using the IPC system. The IPC system is a means for standardising the way in which patent technical information is catalogued by patent offices. Many offices worldwide use the IPC system, but some also have developed their own classification system. Any one invention can be accorded more than one IPC mark. A primary mark is allocated for the core invention, and an additional mark(s) is allocated to capture peripheral aspects of the invention.

7.3 The Organisation for Economic Co-operation and Development (OECD) has identified 15 IPC marks as capturing all biotechnology patent applications.[69] Of these 15, two subclasses; C12N and C12Q, are relevant to gene patents as they cover most inventions relating to genes and genetic engineering. The scope of coverage includes:

- **C12N** and more particularly the C12N15/12 to C12N15/28 subgroup will most likely contain applications that **claim a human gene sequence per se,** derivatives of the sequence such as probes and primers, and their use in diagnostic or therapeutic methods.

- **C12Q** is more likely to contain applications directed to **processes and methods that use gene sequences**, rather than claiming the gene sequence per se (e.g. improved methods of diagnosing a genetic disorder based on the use of a known gene sequence would be categorised into the C12Q1/68 subgroup).

7.4 IPC subgroups C12N15/12 to C12N15/28 are a good but not absolute indicator of patents that claim a human gene sequence. This limitation stems from the fact that the IPC system does not include a discrete mark for sequences of

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67 Department of Foreign Affairs and Trade's Fact Sheet 8 Intellectual Property, http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/08_intellectual_property.html

68 An explanation of the hierarchical structure of the IPC is in **Appendix C**.

69 OECD, *Compendium of Patent Statistics*, 2008, page 18.

human origin and in many cases the claim to a human gene sequence is presented as a mammalian gene sequence.

7.5 This limitation, namely the inability to separate applications covering human DNA instead of animal DNA, is not unique to IP Australia. Our understanding is that the Korean Patent Office, for example, is involved in an initiative to construct a database of all sequences filed with the Korean Patent Office and analyse the association of the sequences with biological function and genes. The patent classification system developed by the US Patent and Trade Marks Office (while it is more comprehensive than the IPC system in its categorisation of genetic technology) also does not enable separation of human gene patents from animal gene patents.

7.6 Although there is no discrete IPC mark for human genes, patents that claim a human gene sequence per se would most likely be categorised into one of the marks from C12N15/12 to C12N 15/28 subgroups. Patents that disclose inventions which focus on methods of using nucleic acid sequences rather than claim the sequence itself would be classified into the C12Q1/68 subgroup. However, most inventions that relate to genes and genetic technologies have more than one IPC mark. For example, a patent disclosing a novel human gene sequence and its use as a diagnostic would have C12N15/12 as it primary mark and C12Q1/68 as its additional mark.

7.7 Patents relating to proteins defined by their amino acid sequences, as distinct from the corresponding DNA sequence, fall within the C07K subclass.

7.8 An analysis of IP Australia's filing records reveal that C12N and C12Q subclasses comprise about 60% of all biotechnology patent applications filed in Australia from 1990 to 2008. The C12N subclass does, however, include main groups and subgroups for classifying other inventions that are not directly related to genetic technologies (eg. media for culturing cells and micro-organisms, methods of purifying virus particles).

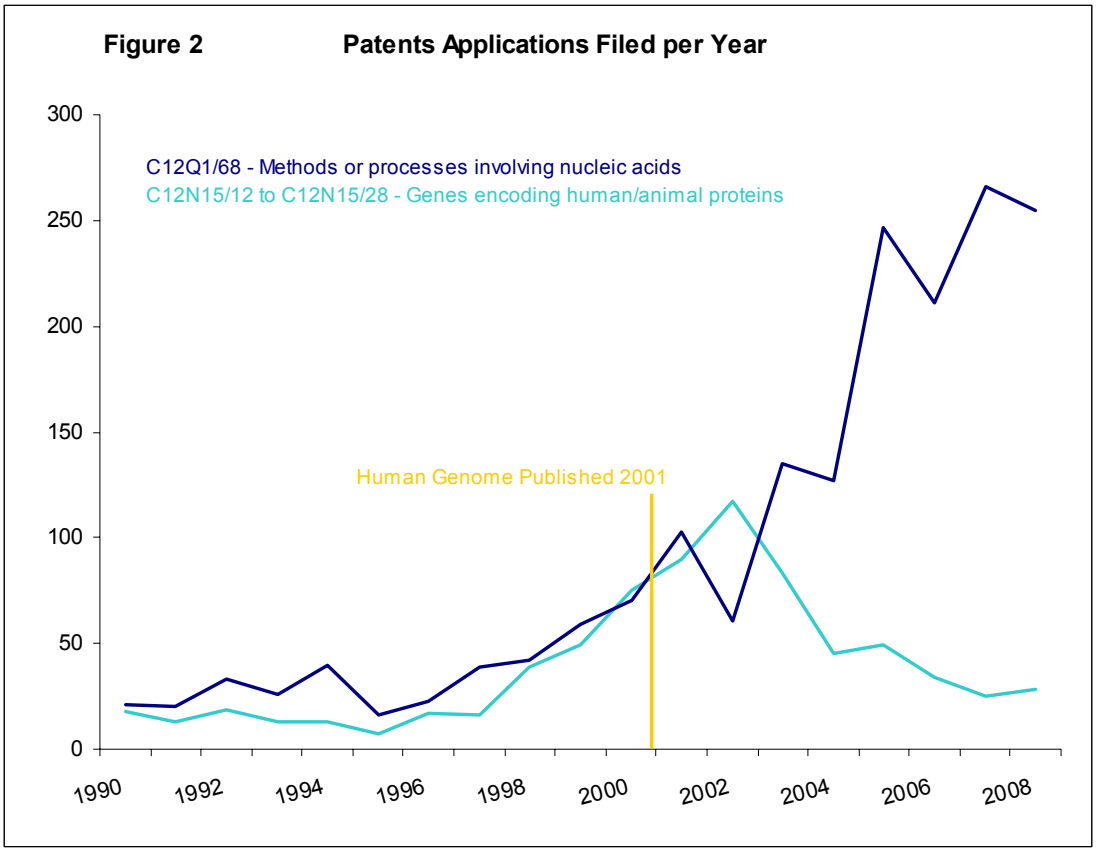
7.9 For a listing of the subset of IPC marks most relevant to genetic sequences and genetic technologies refer to **Appendix D**.

Patent Filings for Gene Sequences or Derivatives

7.10 Figure 2 shows that post publication of the Human Genome Project in 2001[70], filing numbers for methods or processes (i.e. downstream applications – dark blue line) have surged relative to the filings over the product patents for gene sequences per se (light blue line). This is not surprising because the increase in knowledge of the human genome would have meant patentability requirements for Inventive Step and Novelty became more difficult to satisfy. This trend also indicates that innovation efforts have shifted to downstream applications of gene sequences. It is reiterated that there is no discrete IPC mark for human gene sequences and the data is inclusive of animal genes, but IP Australia's experience is that the majority of gene sequences will relate to humans. Figure 3 shows a similar although less pronounced surge in C12Q1/68 gene patents granted (as distinct from filed) annually in Australia.

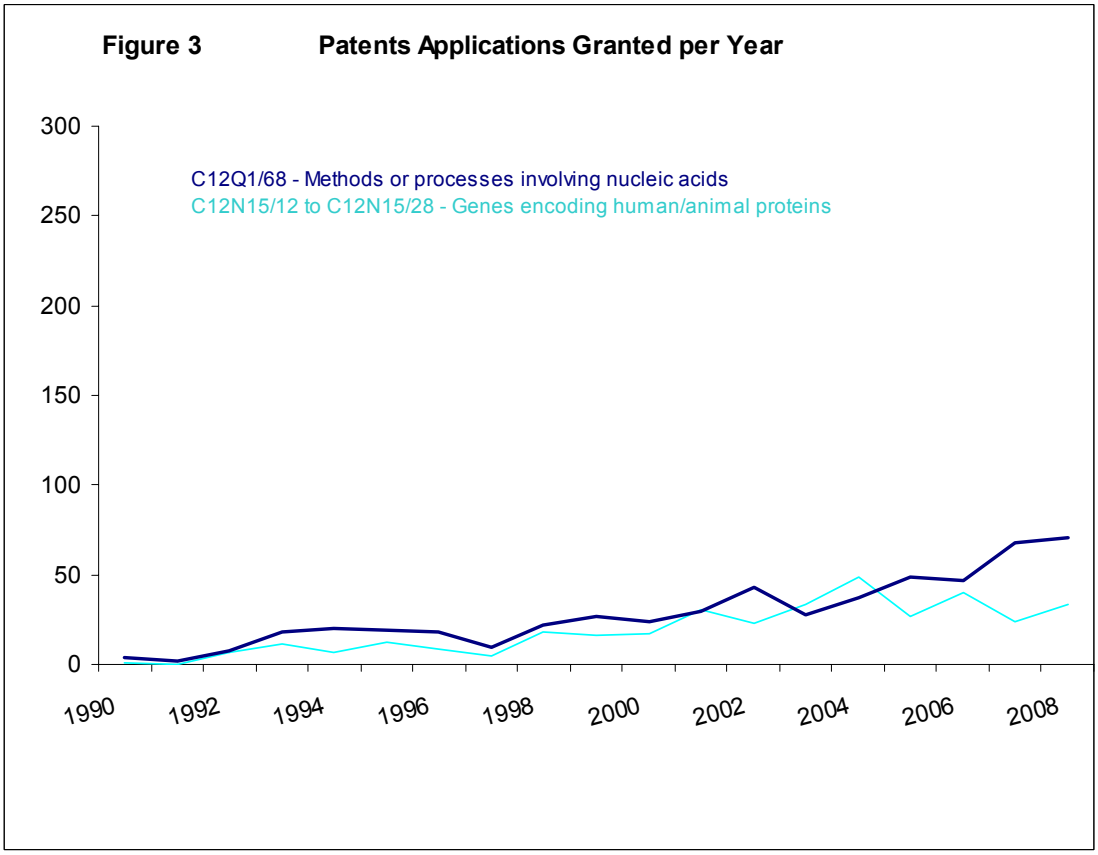
[70] The Human Genome Project was an international consortium that participated in sequencing the complete human genome. A draft sequence was published in 2001 and the project was completed in 2003 (see genomics.energy.gov).

Figure 2 Patents Applications Filed per Year



Data Source: IP Australia patent databases

Figure 3 Patents Applications Granted per Year



Data Source: IP Australia patent databases

7.11 Contrasting Figure 2 and 3 in terms of patent filings versus patents granted, it is informative that while annual filings may be in the hundreds (the highest peak about 260), actual patent applications granted over these materials are in the tens (the highest peak 70) in Australia.

7.12 In summary, it is difficult to accurately distinguish the number of granted patents that claim a human gene product from those that claim a process based on a human gene product. However, our records indicate that the number of granted patents that assert rights over an isolated human gene itself is less than 400. Patents granted to proteins of the C07K subclass over the 1983-2008 period number 1315.

IMPACTS OF GENE PATENTS

8.1 The ALRC's inquiry into Gene Patenting and Human Health in 2004 (ALRC Report 99) reviewed the impacts of gene patents. Significantly it concludes that there is little evidence that gene patents have had any significant adverse effect to date on the conduct of genetic research in Australia.[71] The ALRC referred to international empirical studies suggesting that the research and biotechnology sectors are capable of developing robust combination of working solutions for dealing with problems that emerge. The ALRC in agreeing with these studies said that:

> 'while these solutions sometimes take time to work out, and may not be optimal, but research generally moves forward.'

A statutory 'experimental use exemption' may help expedite this process.

8.2 Reviews in other countries have also contained cautionary notes regarding perceived impacts on healthcare and impacts of gene patents more generally.

8.3 In 2006, the University of Sussex in the UK conducted a study to analyse key trends in filing, granting and exploitation of patents claiming human DNA sequences in Europe, Japan and the USA. Some of its policy conclusions were that:

> "Moreover, with the number of patent applications in decline, more stringent examination procedures, and the likely restriction of the scope of granted patents by case law, suggest that the negative impact of DNA patenting may turn out to be more limited than some had feared."[72]

8.4 In 2002, the provincial government of Ontario in Canada produced a report on genetic patenting and the growing importance of genetic medicine for healthcare: *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Ontario Report). Before making a number of recommendations, the Ontario Report recognised that in some ways it was too early to fully outline the possible consequences for healthcare of gene patenting.

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71 See ALRC 99 Report, Chapter 12 Patents and Human Genetic Research.

72 Science and Technology Policy Research, University of Sussex, UK, 'The Patenting of Human DNA: Global Trends in Public and Private Sector Activity' (The PATGEN Project), 2006 at page ix.

8.5 However, the report did recommend a number of measures to address the risks associated with new breakthroughs in genetics research, including:

- patent reform including access to compulsory licensing and an 'experimental use exemption';
- public engagement and education on matters concerning genetics in healthcare;
- increased training in medical genetics for a range of healthcare providers;
- consideration of genetic technology assessment to ensure people have access to high quality, objective health technology assessment and health economic analysis in the genetics field; and
- additional quality standards and review processes to deal with availability of new testing methodologies.[73]

8.6 IP Australia is progressing a proposal for an explicit 'experimental use exemption' in the Patents Act. Compulsory licensing provisions already exist under Australia's patents legislation.

8.7 In 2006, the Organisation for Economic Co-operation and Development (OECD) published guidelines setting out principles and best practices for the licensing of genetic inventions used for human health care purposes, *Guidelines for the Licensing of Genetic Inventions*[74]. The guidelines are intended to assist OECD and non-OECD governments in developing governmental policies to encourage appropriate behaviours in licensing and transferring of genetic inventions. Similar licensing provisions have been developed under the auspices of the Association of University Technology Managers in a document titled "*In the Public Interest: Nine Points to Consider in Licensing of University Technology*" [75] which the Australian National University has endorsed.[76] The ALRC 99 Report also recommended that Commonwealth granting bodies such as the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) review the *National Principles of Intellectual Property Management for Publicly Funded Research* and associated guidelines, to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[77]

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[73] Ontario Report to Provinces and Territories, 'Charting new Territory in Healthcare', January 2002.

[74] The guidelines can be found at http://www.oecd.org/document/26/0,3343,en_2649_34797_34317658_1_1_1_1,00.html

[75] http://www.autm.net/aboutTT/Points_to_Consider .pdf.

[76] Australian National University Submission to the Advisory Council on Intellectual Property issues paper on "Patentable Subject Matter".

[77] ALRC Report 99 (2004), recommendation 11-1. For other licensing-related recommendations refer to Part F of the report.

EXISTING MEASURES TO ADDRESS IMPACTS OF GENE PATENTS

Crown Use

9.1 The Crown Use provisions of the Patents Act[78] permit certain government entities to use, and to authorise others to use, patented inventions, without permission from the patent owner in certain circumstances. The use is only permissible where such use is for the services of the Commonwealth, the State or a Territory. The government would have to pay the patent owner or exclusive licensee remuneration for that use, in accordance with the Patents Act. These provisions might be able to assist government bodies where they can establish that such use is necessary for the proper provision of government services within Australia.[79] To IP Australia's knowledge, these provisions have been rarely litigated and interpreted by the courts.

Compulsory Licensing

9.2 Compulsory licensing provisions under the Patents Act[80] exist to require a patent holder to grant a licence to another to work their patented invention in certain circumstances. Such a licence would only be granted upon application to the court, and where the reasonable requirements of the public are not being met in accordance with the Patents Act.[81] Examples of where public needs are not being met include where a trade or industry is unfairly prejudiced or demand for the product is not reasonably met because of the applicant's failure to adequately supply the patented product on reasonable terms or grant licences on reasonable terms. To IP Australia's knowledge, this provision has been rarely litigated.

POSSIBLE CHANGES TO AUSTRALIA'S PATENT SYSTEM

Strengthening Patentability Criteria and Balancing Rights and Obligations

10.1 As mentioned earlier, IP Australia is proposing a number of reforms to the Patents Act seeking to:

- strengthen patentability criteria and thereby better align with the higher standards of other international jurisdictions, and

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78 See Chapter 17 of the Patents Act.

79 See subsections 163(1) and (3) of the Patents Act.

80 See Chapter 12 of the Patents Act.

81 See sections 133 and 135 of the Patents Act.

- improve the balance between rights and obligations within the patent system and increase certainty in the market place with respect to freedom to operate and the scope of monopoly.

10.2 These reforms include changes to legislative timeframes and patentability criteria (including those proposed by ALRC Report 99). The philosophy underpinning the proposed reforms is to ensure alignment between Australia's patent system and the currently higher standards of our major trading partners.

10.3 IP Australia will be engaging in public consultations of proposals during 2009. The proposed changes will apply equally to all patentable technologies.

Statutory Experimental Use Exemption

10.4 In addition to the changes proposed to legislative timeframes and patentability criteria, IP Australia's reform package will include proposals for an explicit 'experimental use exemption' in the Patents Act. An explicit 'experimental use exemption' was recommended by both ACIP[82] and the ALRC Report 99 (recommendation 13-1). Such an exemption may be a way of addressing concerns by the research community regarding their perceived lack of freedom to operate. The exemption would apply to research across all technologies, not just human genetic research.

CONCLUSION

11.1 The ALRC Report 99 and other international reviews have not identified a systemic problem with access to diagnostic genetic tests. Our observation is that the current system appears to be functioning effectively in achieving its concurrent objectives of encouraging innovation, promoting diffusion of information, and providing access to and transfer of technologies. Existing provisions within the patent system can be used to deal with any impacts associated with the cost of, and access to, gene patents should problems arise. Licensing issues are often resolved through commercial negotiation; however, guidelines for publicly funded research may be an appropriate response to perceived difficulties.

11.2 Any proposed changes to Australia's patent system should have regard to and be consistent with our obligations under international agreements including TRIPS and Free Trade Agreements, including the requirement for technology neutral assessment of inventions.

11.3 That is not to say that Australia's patent system does not need fine-tuning. IP Australia's current patent reform package seeks to strengthen patentability criteria and in doing so remove the potential for broader patents to be granted here than in other international jurisdictions. IP Australia will also continue to monitor through its policy development and stakeholder engagement processes any other issues relating to Australia's patent system that require legislative reform.

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82 ACIP Report, 'Patents and Experimental Use', 2005.

Appendix A: Glossary

Amino Acid:

The molecular units of proteins. There are 20 different types of amino acids that link together in various combinations to form polypeptide chains that combine to form proteins. Each protein has a unique amino acid sequence that is specified by a gene.

Amino Acid Sequence:

The exact order or string of amino acids. Synonymous with polypeptide sequence.

Bacteriophage:

A virus that infects bacteria. (see vector)

cDNA:

Complimentary DNA. Single stranded DNA that is generated in the laboratory by a process known as reverse transcription of messenger RNA. A cDNA is representative of a gene expressed in a cell.

Chromosome:

Organized structures of DNA and proteins found in the cell. The chromosomal DNA comprises stretches of genes.

DNA:

Deoxyribonucleic acid. DNA is the chemical substance that carries genetic information. DNA is a double stranded polymer of deoxyribonucleotide subunits. Each unit is comprised of a nucleotide base. The four DNA nucleotide bases are Adenine (A), Guanine (G), Cytosine (C), Thymine (T) which pair A-T and C-G on complimentary strands.

DNA Sequence:

The order or string of the four nucleotide bases in a DNA molecule. Synonymous with polynucleotide sequence.

EST:

Expressed sequence tag. A short fragment of cDNA which can be used to identify the corresponding gene. (see cDNA)

Enzyme:

A class of proteins that catalyse chemical reactions in a biological system.

Gene:

A unit of heredity that is passed from one generation to the next. Structurally a gene is a discrete segment of DNA that carries information for the amino acid sequence of a protein.

Gene Mapping:

The mapping of genes to specific chromosomal locations.

Gene Therapy:

The introduction of genetic material into an organism's cells to treat a disease or condition usually arising from a missing or defective gene.

Genetic Engineering:

The artificial manipulation of genes and DNA and the genetic modification of an organism by recombinant DNA technology. (see recombinant DNA technology)

Genetic Marker:

A DNA sequence or gene located at an identifiable position on a chromosome that can be associated with a disease or genetically determined characteristic.

Genetic Testing:

Analysis of an individual's genetic material to detect or diagnose a genetic condition or heritable disease.

Genome:

An organism's genetic material: an organism's entire DNA.

Human Genome Project:

An international collaborative project to determine the complete sequence of the human genome. The complete sequence of the human genome was published in 2001.

Junk DNA:

(see non-coding DNA)

Mutation:

An alteration in the DNA sequence of an organism. Mutation is often associated with a heritable disease or increased predisposition to developing a disease.

Non-coding DNA:

DNA that does not encode a protein . Approximately 95% of the human genome is comprised of non-coding DNA. Sometimes referred to as junk DNA.

Nucleic Acid:

A molecule composed of nucleotide subunits. (see DNA or RNA)

Nucleotide:

The structural subunits of DNA and RNA composed of a sugar molecule, a phosphate group and a base. DNA bases are adenine (A), guanine (G), cytosine (C), thymine (T). RNA bases are adenine (A), guanine (G), cytosine (C), and uracil (U).

Plasmid:

An extrachromosomal unit of DNA found in some bacteria. (see vector)

Polypeptide:

A string of amino acids linked together. Polypeptides chains configure and organise to form proteins.

Primer:

A small string of polynucleotides that acts as a starting primer to which additional nucleotides can be added.

Probe:

A fragment of DNA or RNA that is used to detect complementary DNA or RNA.

Protein:

Organic molecules composed of polypeptide chains of amino acids. Proteins have a crucial role in all biological processes. Some proteins such as enzymes act as signalling molecules that regulate the activity of cells. Other types of proteins form major structural components of the body. (eg. hair, skin, bone etc)

Recombinant DNA technology:

The cutting and joining together of DNA segments. Also the introduction of the recombined genetic material into a cell.

RNA:

Ribonucleic acid. RNA is a single stranded nucleic acid molecule comprising four nucleotide bases, adenine (A), guanine (G), cytosine (C), and uracil (U). There are several classes of RNA molecules. Messenger RNA or mRNA is transcribed from DNA and functions as the template for protein synthesis.

Sequence:

See Amino Acid sequence or DNA sequence

SNP:

Single nucleotide polymorphism. A difference or variation between individuals in a single nucleotide base in their DNA. One individual may have an adenosine (A) at a particular position in their DNA and another individual may have a cytosine (C) at the same position in their DNA. SNPs may influence an individual's likelihood of developing certain diseases or influence an individual's response to drugs and chemicals.

Synthetic DNA:

Recombinant DNA or DNA chemically synthesised in the laboratory (see recombinant DNA technology)

Vector:

A vector acts as a vehicle for the introduction of foreign genetic material into host cells. DNA or genetic material is inserted into the vector and if desired the vector can then be introduced into a host cell. Vectors are themselves DNA molecules derived from entities such as viruses or plasmids or bacteriophage.

Virus:

A sub microscopic entity consisting essentially of a nucleic acid core surrounded by a protein coat. Often associated with disease in humans and other organisms. (see vector)

Appendix B: TRIPS Agreement Article 27

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[83] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which 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 their law.

3. Members may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   (b) 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. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[83] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Appendix C: The International Patent Classification System (IPC)

The International Patent Classification, which is commonly referred to as the IPC, divides technology into eight sections with approximately 70,000 subdivisions. Each subdivision has a symbol consisting of Arabic numerals and letters of the Latin alphabet.

The appropriate IPC marks are indicated on each patent document (published patent applications and granted patents). The IPC marks are allotted by the national or regional industrial property office that publishes the patent document based on the claims in the specification. A primary mark is allocated for the core invention, and a secondary mark is allocated to capture peripheral aspects of the invention.

Most inventions relating to genes and genetic technologies are normally accorded more than one IPC mark. For example, a gene patent claiming as follows will be awarded a primary and secondary mark:

1. The novel human gene sequence itself will be allocated a primary mark under C12N
2. The use of the sequence as a diagnostic will be allocated a second mark under C12Q

The Classification is a way of obtaining an internationally uniform classification of patent documents, and forms an effective search tool for the retrieval of patent documents by patent offices and other users, in order to establish the Novelty and evaluate the Inventive Step (including the assessment of technical advance and useful results or utility) of patent applications.

A representation of the hierarchical structure of the IPC

Class symbol	C 12	
Subclass symbol	C12 N	
Main group symbol	1/00	Micro-organisms etc.
Sub group symbol	1/20	Bacteria; Culture media therefor
Main group symbol	15/00	Mutation or Genetic Engineering
Sub group symbol	15/12	Genes encoding animal proteins
Sub group symbol	15/29	Genes encoding plant proteins
Sub group symbol	15/70	Vectors or expression systems specially adapted for E. coli

An invention concerning an isolated human gene sequence would have the IPC mark C12N15/12

An invention relating to media for the growth and proliferation of bacteria would have the IPC mark C12N1/20

Appendix D: IPC main groups and subgroups most relevant to genes and genetic technologies

IPC groups	Technology
C07K4/00 to C07K4/12	Partially defined peptides having up to 20 amino acids
C07K4/00 to C07K4/825	Peptides having more than 20 amino acids
C07K16/00 to C07K16/46	Immunoglobulins, monoclonal and polyclonal antibodies
C07K17/00 to C07K17/14	Carrier bound or immobilized peptides
C07K19/00 to C07K19	Hybrid peptides
C12N15/09	Recombinant DNA technology
C12N15/10	Processes for the isolation, preparation or purification of DNA or RNA
C12N15/11	DNA or RNA fragments and modified forms thereof
C12N15/12 to C12N15/28	Genes encoding human and other animal proteins
C12N15/29	Genes encoding plant proteins
C12N15/30 to C12N15/32	Genes encoding microbial proteins
C12N15/33 to C12N15/51	Genes encoding for viral proteins
C12N15/52 to C12N15/61	Genes encoding for enzymes and proenzymes
C12Q1/00 to C12Q1/66	Methods and processes involving micro-organisms and enzymes
C12Q1/68	Methods and processes involving nucleic acid
C12Q1/70	Methods and processes involving virus or bacteriophage