HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS INQUIRY INTO THE SCIENTIFIC, ETHICAL AND REGULATORY ASPECTS OF HUMAN CLONING

SUBMISSION BY IP AUSTRALIA

Terms of reference

The committee shall review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council entitled *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* dated 16 December 1998.

INTRODUCTION AND SCOPE OF THIS SUBMISSION

IP Australia thanks the Committee for its invitation to make this submission to its inquiry into the scientific, ethical and regulatory aspects of human cloning. Having considered the Australian Health Ethics Committee of the National Health and Medical Research Council report, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* (the Report) and the submissions already provided to the inquiry, IP Australia notes that there is no direct reference to the intellectual property protection system in the report and only passing references to the patent system in two of the submissions. However, issues concerning the patenting of human beings and biological material are often raised in the context of the regulation of human cloning. With this in mind, IP Australia considers it appropriate to provide the Committee with an overview of the patent system as it relates to the patenting of human beings specifically, and to the patenting of biological material more generally.

This submission therefore does not focus on specific matters raised in the Report but provides a general description of IP Australia's role in the administration of Australia's intellectual property system and sets out the rationale behind the patent system. The submission pays particular attention to the patenting of human beings, human tissue and DNA and also discusses both domestic policy considerations and Australia's international obligations with respect to patenting of biotechnology.

IP AUSTRALIA'S ROLE

IP Australia is the Commonwealth government agency responsible for administering Australia's intellectual property legislation as it relates to patents for inventions, registered trade marks and registered industrial designs. It is a division of the Department of Industry, Science and Resources and operates on a full cost-recovery basis.

The main acts administered by IP Australia are the *Patents Act 1990* (the Act), the *Trade Marks Act 1995* and the *Designs Act 1906*. Intellectual property is commonly divided into two branches:

- *industrial property* which is chiefly the responsibility of IP Australia and covers some of the areas that are related to industrial products and processes, ie, patents, trade marks and designs; and
- *copyright* which relates primarily to literary, musical, artistic and audiovisual works.

The division is not hard and fast as, eg, many of the areas copyright covers could also be described as being related to industrial activity. The term industrial property in this submission will refer to patents, trade marks and designs.

Australia's intellectual property policies are based on the long-held premise that economic development and the well being of society are advanced through the introduction and dissemination of new products, processes and services. Granting exclusive rights encourages innovation by providing investors with a degree of security from the effects 'free riding' for their investment in inventive activity leading to new patentable products and processes, the development of trade marks that facilitate easier product identification and the development of designs that improve the aesthetic appearance of products.

The acquisition of industrial property rights, unlike copyright, requires that the person seeking those rights must make application for that right to the appropriate office: the Patent Office, the Trade Marks Office or the Designs Office. Applications are examined to make sure that they comply with the relevant criteria laid down in the appropriate Act. After that process a right is granted or refused depending on the outcome of the examination and any hearing process within the applicable office. (A hearing is an internal review of a decision to grant or refuse a right). Decisions regarding the grant or refusal of a right by the Commissioner of Patents, the Registrar of Trade Marks or the Registrar of Designs are appealable to the Federal Court.

The industrial property rights granted by IP Australia are statutory rights, which grant some form of exclusivity over the manufacture, use or sale of a product, process, label or packaging. The rights are personal property and are capable of assignment and of devolution by law. Because the rights are personal property it is the responsibility of the owners of those rights to protect and enforce them. IP Australia has no direct involvement in the enforcement of those rights although it does advise the Government on policy related to enforcement issues.

Industrial property rights granted by IP Australia have effect only in Australia and certain external territories. If such rights are required in other countries, an application must be made in each country in which protection is sought. Such applications will be considered, and appropriate rights granted, in accordance with relevant national law. Generally speaking, intellectual property laws around the world are fundamentally similar to Australia's. This partially reflects the influence that various international treaties, such as the Paris Convention for the Protection of Industrial Property 1883 and the World Trade Organization (WTO) Agreement on

Trade-Related Aspects of Intellectual Property Rights (TRIPS), have in shaping national industrial property laws.

THE PATENT SYSTEM

The origins of the Australian patent system lie in an exception to the U.K. Statute of Monopolies of 1624, in which the Statute outlawed Crown monopolies in general but made an exception for "any manner of new manufacture". The present Patents Act still requires that a patent application be in respect of a manner of new manufacture within the meaning of section 6 of the Statute of Monopolies.

The primary objective of the patent system is to encourage innovation and invention through promoting technology and industrial development. It provides inventors with an opportunity to gain, for a limited period, a return on their investment in genuine creative activity and a reward for their efforts.

The system requires the owner of the invention (or patentee) to disclose to the Australian public the working of the invention, enabling Australians to make use of up-to-date information about innovations. In return for that disclosure, the patentee is granted an exclusive right of limited duration that allows them to prevent others from manufacturing, using and/ or selling the patented invention in Australia during the life of the patent. In short, the patent system balances the benefits and costs to the community by providing exclusive rights in an invention to a patentee for a limited period.

Flowing on from the requirement to disclose the workings of inventions, the patent system provides a source of information that is useful for identifying market opportunities, and in the R&D process. The patent database is a unique source of past and present technological information. There are more than 30 million patent specifications worldwide, with about half a million new specifications published each year. The publication of the patent specification is often the first publication of the invention, and up to seventy per cent of the information in patents is not published anywhere else. Interested parties can access this information to determine the latest advances in a technological field. This enables them to make informed decisions on where to best direct their research resources, and to make sure they are not infringing the rights of others. It also provides a source of information, which can be used to develop follow-on products that do not violate the scope of the original patent.

Patents cover, generally, any device, substance, method or process that is new, inventive and useful. An Australian standard patent has a term of up to 20 years, although some pharmaceutical patents can have their terms extended for a further five years—this is in recognition of their reduced effective terms as a result of the long development time and regulatory requirements involved in commercialising a new drug after a patent is applied for. Artistic creations, mathematical models, plans, schemes or other purely mental processes cannot be patented.

In Australia patenting is allowed across all technologies provided the invention fulfils the statutory requirements of the Patents Act. Subsection 18(1) of the Act sets out what is a patentable invention, namely an invention that is:

- a manner of manufacture;

- novel and involves an inventive step; and
- useful.

There is, however, one express exclusion concerning the patenting of human beings—subsection 18(2) of the Act prohibits patenting of "*human beings, and the biological processes for their generation*".

Consistent with the provisions of subsection 18(2) of the Act, IP Australia will not grant patents for the following:

- human beings, foetuses, embryos or fertilised ova; or
- wholly biological processes that begin with fertilisation and end with birth of a human being.

The practice of IP Australia is to grant patents on applications in respect of inventions involving human genes, tissues and cell lines, and non-human clones and cloning procedures, providing such inventions meet the statutory patentability requirements such as novelty, inventive merit, industrial application and adequate disclosure of the invention in the patent specification. (A human cell line is different from naturally occurring cells in the human body. It is capable of continuous propagation in an artificial environment by continual division of the cells, unlike naturally occurring cells which die after a limited number of divisions.)

A mere discovery of a gene implicated in a condition such as multiple sclerosis would not be granted a patent, unless that gene had been isolated and purified, and a full description of an actual use of that gene was included.

It is the understanding of IP Australia that its practice in granting patents for inventions involving human genes, cell lines and tissue is consistent with the provisions of subsection 18(2) of the Act. This is premised on a widely accepted view that human genes, cell lines and tissues are not regarded as human beings, as distinct from foetuses and embryos which are regarded as human beings and hence are not patentable. However, while the applicability or otherwise of subsection 18(2) is reasonably straightforward in these instances, IP Australia also recognises there exists a grey area within which there is the potential for ambiguity concerning what constitutes a human being or a biological process for the generation of a human being.

To date there has been no judicial consideration of subsection 18(2) and it remains unclear which inventions would be strictly caught by that provision. In the absence of any judicial consideration, IP Australia is required to give applicants the benefit of the doubt in relation to the patentability of inventions concerning human material. This follows from the decision of the High Court in the case of *Commissioner of Patents v Microcell* (1959) 102 CLR 232, which held that the Commissioner ought not to refuse acceptance of an application and specification unless it appears practically certain that a patent granted on a specification would be invalid.

To date IP Australia has granted 4 patents for cloning processes applicable to non-human mammals and routinely grants patents for both human and animal cell lines, DNA sequences and non-human animal varieties, provided these inventions meet the statutory requirements for patentability.

It should be noted that the use of inventions such as human genes, cell lines and tissue would still be subject to other regulatory legislation. The nature of a patent right is a "negative right". It does not create a right for a patentee to use their invention, it merely constitutes a right for a patentee to prevent others from using their invention. For example, a patent for a gun does not give the patentee a right to use that gun—the patentee must still conform with normal gun control legislation. Similarly, if a patent were granted for a human cell-line the use of that cell-line would still be subject to restrictions imposed by other legislation.

DOMESTIC POLICY

The Senate, when considering the patenting of biological inventions during its deliberations of the Patents Bill 1989, chose to amend the Bill to exclude human beings and biological processes for their generation from patentability. This provision became subsection 18(2) of the 1990 Patent Act. However, the Senate adopted no further exclusions in relation to the patenting of other life forms, genetically modified organisms, human tissues, cell lines or genes.

This issue was further addressed by the House of Representatives Standing Committee on Industry, Science and Technology. Their 1992 report, *Genetic Manipulation: The Threat or the Glory?* was the result of an extensive consultation process involving submissions, exhibits and public hearings. The report discussed broad issues concerning patenting of DNA sequences, genetically modified organisms and animals and considered the economic rationale for patenting. In compiling the report the committee concluded that there was:

" no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort. The Patents Act is not the appropriate vehicle for hindering, or preventing, the development of technologies to which society may have an objection. If that is the aim more direct means such as legislation should be used." [1]

The report also concluded that patenting was seen to encourage investment in biotechnology and contribute to the dissemination of information relating to scientific innovations.

The committee found that in the absence of patenting:

" a trade secrets attitude would appear in the development of products by companies which would affect the release of information"[2]

and that disallowing patenting:

" would deter the development of industry in Australia, deny rewards for products developed in Australia, deny the public access to products, many of which are pharmaceuticals, developed overseas."[3]

[1] Paragraph 7.113. Genetic Manipulation: The Threat of the Glory? Report by the House of Representatives Standing Committee on Industry, Science and Technology. February 1992
[2] Paragraph 7.111
[3] Paragraph 7.109

There was no specific discussion of human cloning in the report and the only reference to the patenting of human beings was to illustrate that although human beings were excluded from patentability in Australia genetically modified life forms and living organisms were not.

The report supported the practice of granting patents for those non-human life forms and human tissues, cell lines and genes that meet the usual standards for patentability. Subsequent to the report there have been no further amendments to the *Patents Act* excluding any life forms or biological materials from patentability.

INTERNATIONAL OBLIGATIONS

As a signatory to the TRIPS Agreement, Australia is obliged to provide certain minimum standards of intellectual property rights.

For the purposes of this inquiry the most relevant provision is Article 27 of the TRIPS Agreement, which provides that:

"…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."

Article 27.3(b) provides that:

"Members may exclude from patentability:
(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."

As a signatory to the TRIPS Agreement, Australia is obliged to provide patent protection for a range of biotechnological inventions but may choose to exempt from patentability animals, plant varieties and biological processes for their generation. IP Australia's practice to regard non-human animals, plant varieties and biological processes for their production as patentable inventions is consistent with the findings of the House of Representatives Standing Committee discussed in the preceding section. This practice is also consistent with practice with our major trading partners, for example, Europe. In July 1998 the Council of the European Union adopted a new Directive on the legal protection of biotechnological inventions. While inventions contrary to morality (eg cloning, use of embryos and genetic modification to animals likely to cause suffering) are not patentable, the new Directive permits the patenting of inventions concerning biological material.