

INQUIRY INTO DEVELOPMENT OF HIGH TECHNOLOGY INDUSTRIES IN REGIONAL AUSTRALIA BASED ON BIOPROSPECTING

SUBMISSION BY IP AUSTRALIA

Terms of reference

The House of Representatives Standing Committee on Primary Industries and Regional Services will inquire into and report on the following areas, with particular emphasis on the opportunities in rural and regional Australia:

- **the contribution towards the development of high technology knowledge industries based on bioprospecting, bioprocessing and related biotechnologies;**
- **impediments to growth of these new industries;**
- **the capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia; and**
- **the impacts on and benefits to the environment.**

SCOPE OF THIS SUBMISSION

This submission discusses the Australian intellectual property (IP) systems administered by IP Australia as they relate to the inquiry provision specifically addressed to IP rights, that is:

- the capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia.

Further, in view of the statement in the Committee's Issues Paper that:

*"The practical adequacy of intellectual property protection and the retention of Australian ownership of knowledge derived from our natural resources will also be reviewed."*¹

IP Australia considers it appropriate to provide the Committee with an overview of the patent system as it relates to the patenting of biotechnological inventions including biological material.

¹ *Bioprospecting and Regional Industry Developments in Australia – Some Issues for the Committee's Inquiry*. Paper based on a Client Memorandum prepared for the committee by the Information and Research Service of the Department of the Parliamentary Library

Therefore this submission will:

- provide a general introduction to IP Australia's role in the administration of Australia's IP system;
- provide an overview of the patent system as it relates to the patenting of biological inventions;
- discuss the domestic policy environment and Australia's international obligations with regard to the patenting of biological inventions;
- discuss the capacity of the patent system to encourage the development of industries arising from the use of biotechnologies; and
- outline some of the IP Australia programs designed to help educate Australians on the advantages of intelligent and strategic use of the IP system.

IP AUSTRALIA'S ROLE

IP Australia is the Commonwealth government agency responsible for administering Australia's intellectual property (IP) 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 *Trade Marks Act 1995* and the *Designs Act 1906*. IP 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 however, as, for example, many of the areas copyright covers could also be described as being related to industrial activity.

Australia's IP 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 patent, trade mark or design 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 IP 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.

IP 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, IP 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 (Paris Convention) and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), have in shaping national IP 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 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 up to 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 1990* (the 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.

The only express exclusion concerning the patentability of inventions is subsection 18(2) of the Act, which prohibits patenting of “*human beings and the biological processes for their generation.*”

The range of patentable inventions associated with biotechnology includes:

- isolated genes, gene products and DNA;
- isolated microorganisms, nucleic acid vectors and viruses;
- methods of transformation and genetic manipulation;
- apparatus or methods for biotechnology applications;
- processes using enzymes or microorganisms to liberate, separate, purify or clean;
- pharmaceuticals, beverages, foods, food supplements and chemicals produced by plants, animals, cell cultures and microorganisms;
- cell cultures and tissues obtained from plants and animals;
- plants and animals *per se*.

Protection for new plant, algal and fungal species may also be sought through plant breeder’s rights. The *Plant Breeder’s Rights Act 1994* is administered by the Department of Agriculture, Fisheries and Forestry – Australia and provides exclusive rights to the sale of protected varieties and their reproductive material.

Although “life forms” such as microorganisms are considered patentable, simply collecting biological material is insufficient for obtaining valid patent rights. For example, while isolated genes and gene products are considered patentable inventions, the patent application must provide a description of a use for the claimed gene or gene product. In the absence of a disclosed use, a gene or gene product is regarded as a mere discovery and is therefore not patentable. Therefore, if a gene implicated in a condition such as multiple sclerosis was the subject of a patent application a patent would not be granted unless the gene had been isolated and purified, and the application provided a full description of a use for the gene.

DOMESTIC POLICY

The Senate considered the patenting of biological inventions in their deliberations on the Patents Bill 1989. Although they chose to exclude human beings and biological processes for their generation from patentability, they adopted no further exclusions in relation to the patenting of life forms, genetically modified organisms, animal tissues or cell lines.

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 Patent Act [sic] 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.”²

The report supported the practice of granting patents for life forms and biological materials that meet the usual standards for patentability. The report also concluded that patenting was seen to encourage investment in biotechnology and contribute to the dissemination of information relating to scientific innovations.

At present IP Australia routinely grants patents for plant and animal cell lines, microorganisms, DNA sequences, plant and animal tissues and plant and animal varieties. This practice is consistent with other Patent Offices such as the European Patent Office and the US Patent Office that also grant patents for a broad range of biological inventions.

² Paragraph 7.113. *Genetic Manipulation: The Threat or the Glory?* Report by the House of Representatives Standing Committee on Industry, Science and Technology. February 1992

INTERNATIONAL OBLIGATIONS

As a signatory to the TRIPS Agreement, Australia is obliged to provide certain minimum standards of IP 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.”

Therefore, 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 the practice of our major trading partners, and other national IP offices.

Australia is also a signatory to a number of international patent treaties, including the Patent Cooperation Treaty, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) and the Paris Convention.

The Paris Convention, like the TRIPS Agreement, provides that member countries accord each other national treatment. That is, as a member of the Paris Convention, Australia must give equal regard to all applicants filing under the provisions of the national patent system whether they represent local or international interests. Similarly, Australian applicants must receive equal treatment with the nationals of an overseas member country when applying for a patent in that member country.

The Budapest Treaty allows patent applicants with inventions involving microorganisms to comply with the patent law requirements for repeatability and full description of biological materials by depositing a sample of the microorganism with certain International Depository Authorities.

Australia actively participates in international meetings of bodies such as the World Intellectual Property Organization (WIPO) and the TRIPS Council to ensure that Australia’s interests are appropriately reflected in any decisions made in these fora regarding the future direction of developments within the IP system.

THE CAPACITY TO MAXIMISE BENEFIT THROUGH INTELLECTUAL PROPERTY RIGHTS AND OTHER MECHANISMS TO SUPPORT DEVELOPMENT OF THESE INDUSTRIES IN AUSTRALIA

The Committee's Issues Paper states:

“There is a need to ensure that the potential value of compounds is recognised from the outset and that intellectual property rights and knowledge are not sold off too early and too cheaply.”³

As outlined in earlier sections, the range of IP rights available to innovators in Australia is much the same as that available in overseas countries. In addition, international agreements like the TRIPS Agreement are leading to increased harmonisation of IP laws throughout the world. Also, patent treaties like, for example, the Paris Convention, ensure that Australian patent applicants receive national treatment.

However, having an adequate IP system in place is only one part of the equation. Australia will only be able to maximise the possible benefits available from IP rights if Australian innovators make effective use of the IP system both domestically and internationally.

IP Australia is actively implementing a series of strategies, each with the objective of raising levels of IP awareness and understanding within key target market sectors. These strategies involve IP Australia combining its more traditional messages regarding actual forms of IP with information on commercialisation and effective IP management. The key market sectors currently include the tertiary community, teachers and school aged children, business advisers such as accountants and lawyers, governments at all levels, inventor associations and small to medium enterprises (SMEs).

Although a full cost-recovery organisation, we will present in any location in which there is a demand. However, the message regarding the effective protection and commercialisation of IP is not geography dependent, and the information provided in our publications and available from our websites applies equally to regionally located organisations and researchers.

Tertiary Project

The tertiary sector is one that has an inherent need for a thorough understanding of IP and the skills to effectively develop an IP strategy. Research in public Australian universities extends across the research spectrum from fundamental to applied research, and contributes significantly to the national research effort. The amount of IP this research generates is significant. IP Australia's strategies are designed to increase the level of knowledge of IP amongst lecturers and students, as well as providing an understanding of the relationship between IP and commercialisation of research and technology.

³ *Bioprospecting and Regional Industry Developments in Australia – Some Issues for the Committee's Inquiry*. Paper based on a Client Memorandum prepared for the committee by the Information and Research Service of the Department of the Parliamentary Library

The main thrust of our strategy to this market sector involves a national seminar program. Over 30 universities (including many regional ones) will co-host a seminar which will feature a range of IP experts from the private sector and government. Each seminar will cover the ‘nuts and bolts’ of IP as well as detailed information on commercialisation and management of IP by discussing topics such as start ups, licensing technology, liability, raising capital and legal due diligence.

A second component of the university strategy is the website *IP Professor*. This site provides a range of online IP resources, specifically relevant to the tertiary sector. A major part of this site is an area where university based researchers can submit or view case studies of successful commercialisation processes and other people’s experiences in managing their IP.

School Education Project

IP Australia has developed an educational program entitled “*InnovatED*” consisting of an extensive teacher and student website and a CD-ROM based game to encourage kids to think that ideas are cool. The teacher’s website contains over one hundred self contained lesson plans. The plans have been prepared to meet established school curriculum objectives, while introducing the concepts of innovation, creativity and IP.

Designed for students in years 5-9, “*InnovatED*” has the objective of ensuring students fulfill their innovative potential. Teachers have written the lesson plans for teachers and range in topics from art to science. The student’s website features educational games and video footage of experts in the field of IP giving an insight into their work.

Business Advisers

This group represents a significant target market for IP Australia’s awareness education campaigns. As disseminators of business advice, they represent an ideal distribution channel for the IP message. However, research indicated that the levels of IP competency amongst accountants, solicitors and business advisers varied enormously. As a result, IP Australia is in the process of developing an extensive tool this group can use to enhance the level of service and amount of IP advice they provide to their clients.

The *IP Toolbox* provides information on mechanisms of protection, but focuses more on the business practice and management elements of IP. Chapters include *Conducting an IP Audit, Valuation of IP, Business Plan, Financing and Commercialising IP* and *Taxation and Government Incentives*. A prototype is now available with the full version scheduled for release later this year.

In addition, IP Australia manages a regular program of seminars targeted at business advisers. A key aspect of this program is to build ongoing relationships with key advisers and decision makers within this group.

We are also arranging an IP seminar, which will be held in each capital city. At this seminar IP experts will discuss management and commercialisation strategies.

Local Government, SMEs and Inventors Associations

IP Australia also undertakes a range of promotional activities targeted at each of these groups. These activities have included sponsorship of awards programs, relationship marketing campaigns communicating key IP messages, placement of editorials in science-based and small business magazines and attendance at conferences.