ADVISORY COUNCIL ON INTELLECTUAL PROPERTY

Should plant and animal subject matter be excluded from protection by the innovation patent?

November
2004

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The Hon Warren Entsch MP
Parliamentary Secretary to the Minister for
Industry, Tourism and Resources
Parliament House
CANBERRA ACT 2600

Dear Mr ~~Entsch~~ Warren

I am pleased to present your with the Council's report on the exclusion of plant and animal subject matter from the innovation patent.

In preparing this report we widely circulated an issues paper and held round-table discussions with interested parties. Responses were fairly evenly divided between those who supported removing the exclusion, those who supported its retention, and those who did not have a conclusive position. Little firm evidence has been presented to ACIP, particularly of significant deficiencies in the current system.

Significantly less concern was expressed on the issue of animal subject matter than was the case for plant subject matter. On balance, ACIP considers that the case for removing the innovation patent exclusions for plants and animals, and for biological processes for their generation, has not been made out. It may be that in the future there is a need for innovation patent protection for animals, due to an increase in the development of genetically modified organisms, a potentially more costly form of breeding. However, ACIP considers that at present the existing systems appear adequate, and there is insufficient reason for change. It should be noted that this decision in no way implies a need for similar exclusions under the standard patent system.

I look forward to the Government's response to the report.

Yours sincerely

Professor Paul Greenfield
Chairman

1 November 2004

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1 Terms of Reference

Parliamentary Secretary the Hon Warren Entsch MP, having responsibility for patent, trade mark and design matters within the portfolio of Industry, Tourism and Resources, asked the Advisory Council on Intellectual Property (ACIP) in November 2000 to:

- consider the current exclusion from the innovation patent for plants and animals. If the council recommends removing the exclusion, it should consider the best method to progress the matter.

2 Executive Summary

The innovation patent was introduced in 2001 following an Advisory Council on Intellectual Property (ACIP) review of the petty patent system. ACIP had identified a demand for industrial property rights for lower level or incremental inventions that were not sufficiently inventive to qualify for standard or petty patent protection. This was of particular interest to small to medium sized enterprises. The innovation patent was designed to satisfy this demand by having a lower inventive threshold than that required for a standard patent, and to replace the petty patent system.

Although most second-tier patent systems in other countries restrict protection to three-dimensional products, there was general agreement within Australia that no field of technology should be excluded from the innovation patent. However, immediately before the Innovation Patent Bill was introduced into parliament, new concerns were raised over the implications for plant and animal subject matter. Rather than delay the introduction of the legislation, the government chose to proceed, but to exclude plants and animals and biological processes for their generation.

The innovation patent system is supplementary to the standard patent system. The innovation patent differs from the standard patent in that it has a lower inventive threshold, is granted after a formality examination and has a term of eight years. Substantive examination and certification is optional, although necessary before any legal action can be taken.

The patenting of plant and animal life is a controversial issue around the world. The main moral objection is that living matter forms part of our common heritage, and should not be regarded as a commodity over which exclusive rights are awarded. Such concerns are beyond the scope of this review. The main practical objection to the patenting of plant and animal life is that, due to the nature of conventional breeding practices, patent law is considered an unsuitable form of protection. In response to the latter, the International Union for the Protection of New Varieties of Plants (UPOV) was established. Protection for plant varieties in accordance with UPOV is available in Australia in the form of Plant Breeders' Rights (PBRs). A key feature of the PBR system is the provision of several exceptions to infringement, including non-commercial use, breeding of other plant varieties and the saving of seed grown by farmers for planting future crops. These exceptions are not available under the patent system. Australia has no equivalent low-level system of protection for animals, nor for biological processes for the generation of either plants or animals.

A wide range of views was put to ACIP on the exclusion from the innovation patent of plants and, to a lesser extent, processes for generating plants. The main argument in favour of removing the exclusion for plants (i.e. incorporating plant material within the innovation patent framework) is that PBRs provide inadequate protection for innovators due to their narrower scope and the provision of exceptions for various uses. These factors are seen to substantially reduce returns on investment, and so discourage the development of new plant varieties. Although some evidence of a need for innovation patent protection in this field was provided to ACIP, a significant failure of the existing system was not identified.

The main argument for maintaining the exclusion for plants is that the PBR exceptions for use are critical for the success of the system. Breeders and farmers depend on having some access to protected plant material. Providing a parallel form of lower-level protection without the exceptions embodied in the PBR system would cause major disruption in the industry. Also, the granting of innovation patents without substantive examination is seen as a major cause of uncertainty. The lack of examination contributes to the perception that the innovation patent and the PBR systems overlap in the level of inventiveness and innovation..

Despite the absence of lower-level protection for animals and processes for their generation, little concern was expressed over their exclusion from the innovation patent. Some assertions were made, however no evidence of a need for expanding protection in this area was demonstrated. Similarly, assertions were made that removing the exclusion would disrupt existing frameworks of the animal breeding industries, although again without evidence as to how.

The 1995 Competition Principles Agreement between the Council of Australian Governments establishes the principles for governments to apply in reviewing and reforming legislation. Legislation should not restrict competition unless the benefits of the restriction to the community as a whole outweigh the costs. ACIP considers that, as the exclusive rights provided by patents are a restriction on free competition, any extension of those rights should only occur where there is clear evidence that this is needed.

ACIP therefore considers the burden of proof to lie with those who wish to remove the innovation patent exclusions. A degree of benefit has been identified in removing the exclusion for plants, however little benefit has been demonstrated in removing the exclusion for processes of generating plants. ACIP believes there is the potential for significant overlap of subject matter that may be protected by both the innovation patent and PBR systems. Therefore, introducing innovation patent protection without including specific exceptions for uses, such as the breeding of new varieties and farm saved seed, would be likely to impose significant costs on the industry. Including such exceptions for use would reduce these costs, but would also reduce many of the advantages for breeders of having innovation patent protection. ACIP therefore considers that, on balance, the case for removing the exclusion for plants, and biological processes for their generation, has not been made out at this stage.

Where a proposal to restrict competition lacks clear benefits, the status quo should be maintained. As relatively little concern has been expressed over the innovation patent

exclusion for animals and processes for their generation, ACIP considers that there is insufficient reason for change at this stage. However, in the future innovation patent protection may be needed due to an increase in the development of genetically modified organisms, which is a potentially more costly form of breeding.

3 List of Recommendations

Recommendation 1

The current exclusion from the innovation patent of plants and biological processes for their generation should be maintained at this time.

Recommendation 2

The current exclusion from the innovation patent of animals and biological processes for their generation should be maintained at this time.

4 Background

4.1 *The Advisory Council on Intellectual Property*

The Advisory Council on Intellectual Property (ACIP) is an independent body established to provide advice to the Minister for Industry, Tourism and Resources and IP Australia on matters of policy and administration. The Council has been requested to take a broad strategic view of the role of intellectual property and its contribution to the development of Australian industry. Members of the Council are drawn from business and manufacturing sectors, the patent attorney and legal professions, the tertiary and research sectors, and technology and commercialisation groups.

4.2 *Introduction of the innovation patent*

The innovation patent was introduced in 2001 following an Advisory Council on Intellectual Property (ACIP) review of the petty patent system. The petty patent system was designed to provide a form of protection that was quick and easy to obtain, was relatively inexpensive and provided short term protection especially for inventions that had a short commercial life. Although the majority of users of the petty patent system were small to medium sized enterprises (SMEs), the system had limited success in meeting its intended objectives. ACIP identified a demand for industrial property rights for those lower level or incremental inventions that were not sufficiently inventive to qualify for standard or petty patent protection. ACIP recommended that the petty patent system be replaced by the innovation patent, which would address this shortcoming by introducing a lower inventive threshold than that required for a standard patent.

ACIP recommended that substantive examination of the innovation patent should occur only on request, but would be necessary for grant of the patent. The government chose instead to grant innovation patents after a formality examination so as to further reduce time and cost for applicants. Substantive examination would be available on request at any time and would be necessary before any legal action could be taken. It was recognised that the offset would be increased uncertainty over whether an innovation patent is valid.[1]

ACIP noted that most utility model or second tier patent systems in other countries restricted protection to three-dimensional products. There was, however, general agreement that no field of technology should be excluded. ACIP recommended that the innovation patent should be able to protect the same subject matter as the standard patent. The government agreed with this and noted the following:

> "Most applications for innovation patents are likely to be made for simple tools, utensils, machinery or equipment. The innovation patent is unlikely to be widely used in areas such as pharmaceuticals and veterinary products where regulatory requirements may result in delays in the development and marketing of the innovation. There appears to be no compelling reason to exclude any technology or subject matter which is currently patentable under the standard patent system.

[1] *Government Response to the Recommendations of the Advisory Council on Intellectual Property (ACIP) Report "Review of the Petty Patent System"*, Recommendation 7.
http://www.ipaustralia.gov.au/patents/what_innovation_review.shtml

> Moreover, limiting the type or extent of technology coverage might preclude the innovation patent system from covering new and emerging technologies."[2]

Immediately before the Innovation Patent Bill was introduced into parliament, concerns were raised over the implications of innovation patents for plant and animal subject matter. Such concerns had not been raised during earlier consultations and subsequently had not been examined by ACIP. Rather than delay the introduction of the legislation, the government chose to proceed, but to exclude plants and animals, and biological processes for their generation. The innovation patent commenced operation on 24 May 2001.

4.3 *The Review Process*

In July 2002, ACIP released an Issues Paper which was sent to over 140 organisations, asking for their views on whether or not the exclusion for plants and animals should remain. 33 written responses were received, and these indicated divergent views on the matter. Responses were fairly evenly divided between those who supported removing the exclusion, those who supported its retention, and those who did not have a conclusive position.

Due to the divergent views expressed in the submissions, on 18 June 2003 ACIP held a round-table discussion with interested parties to further explore the issues. 24 people (representing 22 organisations) attended the round-table discussions. Interested parties were then invited to submit additional written comments. Supplementary submissions were made by the Seed Industry Association of Australia (SIAA), Australian Centre for Intellectual Property in Agriculture (ACIPA), the Department of Primary Industries Victoria (DPIVIC) and the Grains Research and Development Corporation (GRDC). The Issues Paper, submissions and summary of the round table discussions are all available on the ACIP website at www.acip.gov.au.

In December 2002 the Australian Law Reform Commission (ALRC) was asked to conduct an inquiry into the patenting of genes and genetic and related technologies, with a particular focus on human health issues. The ALRC's report to the Attorney-General was tabled in Federal Parliament on 31 August 2004. The ALRC was not asked specifically to consider the impact of patents over genes or genetic technologies associated with plants and animals. However, the ALRC's final report noted that where an animal's genetic material is used to develop a therapeutic product or process to be used in human medical treatment, the patent issues may be relevant to human health and thus fall within the scope of the ALRC inquiry.[3] ACIP considers there to be little overlap between its review of the exclusion of plant and animal subject matter from the innovation patent and the ALRC inquiry.

[2] Ibid, Recommendation 9.

[3] *Genes and Ingenuity: Gene patenting and human health* (ALRC 99), para 1.8, Australian Law Reform Commission.

5 Second Tier Patent Systems

5.1 *General Principles and Characteristics*

Second tier patent protection exists in 48 countries around the world with differing requirements and conditions. No international agreement currently exists regarding second tier patent systems. This type of protection is known by a variety of names in different countries, and includes "utility", "innovation", "short term" and "petty" patents. Utility model protection is not available in the United States,[4] the United Kingdom nor the European Union. Many European countries, however, have national laws for their protection.[5] A table comparing the types of protection available in various countries is provided in Appendix 11.1.

In general, the rationale of second tier patent protection is to protect modest improvements in technical inventions that may not merit the cost of a patent application, and in so doing encourage innovation in the fields of technology to which second tier systems apply. The level of reward to the innovator must be appropriate to the level of inventiveness of the idea and so the terms of protection are not as long and other restrictions often apply. Second tier patents are particularly useful where the lifespan of the product is shorter than the time it takes to obtain a patent. In order to further accelerate the grant of the IP right, most countries are dispensing with substantive examination for these patents.

Second tier patent systems do not share the same international harmonisation as standard patent systems. In most countries that offer utility model patents, the main features that distinguish utility model patents from standard patents are the following:

- Lower criterion of inventive step
- Quick and simple registration without substantive examination by the national patent office
- Lower cost of acquisition and maintenance
- Shorter term of protection

In some countries the area of protected subject matter for second tier patents is identical to the patent system, however in most cases it is narrower than in the first tier systems. Utility model patents commonly accord protection to devices, tools, implements and utensils. The narrow definition in some countries of subject matter that may be protected can be traced back to the first utility model patent in Germany in 1891, which was introduced to protect three dimensional products, or "models," such as tools, implements, machinery or equipment that fulfilled a "configurational criteria". The rationale underlying the introduction of utility model patents was to protect small, incremental improvements that were practical but did not represent a step forward in the art.

[4] In the US, standard patents for inventions are called "utility patents". This should not be confused with the utility model patents in Europe as the US has no utility model system.

[5] Germany, Spain, France, Denmark, Portugal, Greece, Austria, Finland and Belgium have utility model protection while Luxembourg, Holland, Great Britain and Sweden have no utility model protection.

Many countries do not provide utility model protection for plants and animals. However in these jurisdictions standard patent protection for plants and animals is not available either. At present, the *levels* of protection offered by member states differ widely.

5.2 *European Community Utility Model Proposal*

Most European community member states provide national utility model protection. The European Commission is currently considering the introduction of a *Community Utility Model Convention* in order to harmonise the protection for utility model inventions in the European Community so that the rights are uniform and reciprocal. Since 1994 there have been many meetings and discussions throughout Europe on the desirability of the adoption of a community wide second tier protection system. There is, however, general resistance to an expansion of second tier protection across Europe and disagreement between countries on the requirements of such protection, including the scope of the subject matter that may be protected.

In 1999, the European Commission presented a proposal for a Directive on the protection of utility models.[6] Under the proposed scheme, the criteria for a utility model would basically be the same as for a patent, except that the level of inventiveness required would be lower, and the following subject matter would be excluded:[7]

- inventions, the exploitation of which would be contrary to public policy or morality;
- inventions relating to biological material;
- inventions relating to chemical or pharmaceutical substances or processes; and
- inventions involving computer programs.

In 2001, the European Commission published a Staff Working Paper inviting public comments on the introduction of a Community Utility Model.[8] Of the small number of responses received, three-quarters opposed the introduction of a Community Utility Model due to concerns regarding the risk of decreasing competitiveness of EU companies, the risk of decreasing legal certainty, and the unsatisfactory criteria of the level of inventiveness. It was also thought inappropriate to create such a right at a Community level, as utility models are predominantly used for national protection purposes. Consultations continue on the issue.

[6] http://www.europa.eu.int/comm/internal_market/en/indprop/model/utilityen.pdf
[7] Commission of the European Communities "Proposal for a European Parliament and Council Directive for the Protection of Inventions by Utility Model", Article 4 (Brussels, 1997).
[8] European Union, <http://europa.eu.int/comm /internal_market/en/indprop/model/utilreport_en.pdf>.

6 Issues Related to the Patenting of Plant and Animal Subject Matter

Generally, the main objections to allowing the patenting of plants and animals are:

- living matter forms part of our common heritage, and should not be regarded as a commodity over which exclusive rights are awarded;[9]
- the patenting of plants and animals encourages interference with nature, and will lead to a decline in genetic diversity; and
- devaluation of animal life and the suffering of laboratory animals.[10]

The current practice in Australia is that genetic material is patentable provided it meets the patentability requirements of being new and inventive, and is not treated any differently to inventions in other technologies.

Many commentators argue that patent law is not the appropriate realm to assess moral and public policy objections to scientific research. Patent offices do not possess the relevant expertise and resources to make ethical decisions, and refusing to grant patents does not prevent research in a given area.[11] Instead, regulatory bodies should be used to control scientific, technical or medical practices on ethical, health, safety and environmental grounds.[12] The *Gene Technology Act 2000* is an example of legislative control of scientific activity in Australia. This Act provides a regulatory framework for managing gene technology in order to protect the health and safety of people and the environment.

The converse argument is that the state cannot adopt a morally neutral stance on research it actively encourages through the granting of patents.[13] Instead, the state should define what kinds of inventions are excluded from patentability on moral grounds. This has been done in Australia with respect to patents for human beings. Subsection 18(2) of the *Patents Act 1990* provides that "human beings, and the biological processes for their generation, are not patentable inventions".

While ACIP was prepared to consider such moral and ethical issues in the course of this review, the submissions that were received did not address these points in any detail, nor did they form a major part of any of the arguments presented to the Committee. As a result, ACIP does not consider that it is appropriate for the review to form its conclusions based on these issues. Such issues may be better dealt with through mechanisms other than the patent system.

[9] Australian GeneEthics Network, Submission no. 71 to House of Representatives Standing Committee on Primary Industries and Regional Services Report on Primary Producer Access to Gene technology, titled "Work in Progress, Proceed with Caution", (2000) 11.
[10] Animal Patents: The Legal, Economic and Social Issues. Ed. W.H.Lesser, Macmillan Publishers Ltd, 1989 New York. E.S. Van de Graaf, "Patent Law and Modern Biotechnology", 1997 at 68.
[11] W.R. Cornish, *Intellectual Property* (3rd Ed, 1996) 195.
[12] C. Colston, *Principles of Intellectual Property Law*, Cavendish Publishing Ltd, London 1999.
[13] M. Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *AIPL*202.

7 International Obligations Regarding IP Rights for Plant and Animal Subject Matter

Australia is party to a number of international agreements that set out obligations in relation to the grant of IP rights on plant and animal subject matter.

7.1 *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)*

The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) came into force in 1995. This agreement mandates that member states must establish minimum standards of intellectual property protection. These standards include the requirement that member states provide patent protection for product and process inventions in all fields of technology.[14] However, the TRIPs Agreement permits members to exclude from patentability an invention which is necessary in order to "protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".[15] The TRIPs Agreement also allows member states to exclude plants and animals from patentability, but requires that members provide for the protection of plant varieties either by patents, an effective *sui generis* system, or by any combination thereof.[16] Members are free to choose what kind of protection to adopt.

This plant and animal exclusion is currently under review, with consideration being given to whether it should be maintained, expanded, narrowed or eliminated. A summary of the issues under discussion was released in August 2002[17].

In Australia, new plant varieties can be protected by both patents and plant breeder's rights.

7.2 *International Convention for the Protection of New Varieties of Plants (UPOV Convention)*

In the 1960s in Europe, patent law was considered unsuitable for protecting new plant varieties that were created using traditional breeding methods due to several practical reasons. It was recognised that there was a need to provide an alternative form of protection. The International Union for the Protection of New Varieties of Plants (UPOV) was established by the International Convention for the Protection of New Varieties of Plants. The UPOV Convention[18] was adopted 1961, came into force in 1968, and was revised in 1972, 1978 and 1991.[19] Australia ratified the 1991 treaty in 2000. The key features of the UPOV Convention are outlined in Appendix 11.2.3 in relation to the Australian system of Plant Breeder's Rights (PBR).

[14] Art. 27(1).
[15] Art. 27(2).
[16] Art. 27(3)(b).
[17] *Review of the Provisions of Article 27.3(b), Summary of Issues Raised and Points Made*, WTO Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/369.
[18] International Convention for the Protection of New Varieties of Plants, Dec.2, 1961, 33 U.S.T. 2703, 89 T.I.A.S. 100199.
[19] www.upov.int/

Australia would need to ensure that any changes to the innovation patent system would not be contrary to our obligations under these agreements.

7.3 *Other International Considerations*

There are also a number of other international fora where issues about IP protection for biological material (including plants and animals) are discussed. These include the Convention on Biological Diversity (CBD) — to which Australia is a Party; and the recently adopted Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) — which Australia has signed, but not yet ratified.

Australia would also need to ensure that any changes made to the innovation patent system would not be inconsistent with our obligations under the CBD and would not be inconsistent with the terms of the ITPGRFA should Australia decide to ratify that treaty.

8 National Legislation

8.1 *Australia*

The two primary pieces of Australia legislation relevant to this inquiry are the *Patents Act 1990* (Patents Act) and the *Plant Breeder's Rights Act 1994 (PBR Act)*. The Patents Act provides the legislative framework for both standard and innovation patens, and is administered by IP Australia, a division of the Department of Industry, Tourism and Resources. The PBR Act provides the framework for Australia's plant breeders' rights system, and is administered by the Plant Breeder's Rights Office, which was transferred from the Department of Agriculture, Fisheries and Forestry (DAFF) to IP Australia in October 2004.

8.1.1 Standard Patents

The main purpose of a patent system is to stimulate industrial innovation by granting exclusive rights to inventors in return for full disclosure to the public of their invention, thereby increasing public availability of information on new technology. The area of exclusivity ('scope') of the patent is defined by the claims of the specification. To be patentable, the claims must meet threshold tests set out in s.18 of the Patents Act. For a standard patent the principle tests are that the invention is a manner of manufacture, novel, inventive and useful.

8.1.2 Innovation Patents

The main purpose of the innovation patent system is to stimulate lower level industrial innovation, particularly by SMEs, that is not sufficiently inventive to qualify for standard patent protection. The threshold tests for an innovation patent are also set out in s.18 of the Patents Act. For an innovation patent the principle tests are that the invention is a manner of manufacture, novel, innovative and useful.

8.1.3 Plant Breeder's Rights (PBR)

The main purpose of the PBR system is to stimulate the development of new plant varieties by providing a degree of protection to breeders. The *Plant Breeders' Rights Act 1994* replaced the *Plant Variety Rights Act 1987* in order to conform to the 1991 revision of the UPOV Convention which Australia ratified in 2000. In order to be granted a PBR, a plant variety must meet threshold tests under the Act. The main tests are that the variety is new, distinct, uniform and stable.

8.1.4 Comparison of Rights

This section provides a brief comparison of the key features of plant breeders' rights, standard patents and innovation patents. More detailed information is provided in Appendix 11.2.

Subject Matter Protected

Plant Breeders' Rights	Innovation Patent	Standard Patent
"Plant variety" • including fungi and algae But not: • bacteria • bacteroids • mycoplasmas • viruses • viroids • bacteriophages	"Manner of manufacture" But not: • human beings • biological processes for generation of humans • plants/animals (non-microbiological) • biological processes for generation of plants/animals (non-microbiological)	"Manner of manufacture" But not: • human beings • biological processes for generation of humans

Duration of Rights

Plant Breeders' Rights	Innovation Patent	Standard Patent
20 years 25 years for trees and vines	8 years	20 years 25 years for certain pharmaceuticals

Exceptions to Infringement

Plant Breeders' Rights	Innovation Patent	Standard Patent
Private and non-commercial use Experimental use Breeding other plant varieties Farm saved seed Compulsory licence	Compulsory licence Prior use	Compulsory licence Prior use

Scope of Rights

Plant Breeders' Rights	**Innovation Patent**	**Standard Patent**
"Plant variety" "Essentially derived variety" • predominantly derived • retaining essential characteristics • no important (non-cosmetic) differences "Dependent variety" • not clearly distinguishable • reproducible only by repeated use	"Invention" "Essentially the invention" • retaining essential integers of the invention • no important differences	"Invention" "Essentially the invention" • retaining essential integers of the invention • no important differences

Exclusive Rights

Plant Breeders' Rights	**Innovation Patent**	**Standard Patent**
Re "propagating material of the variety": • produce/reproduce • condition for propagation • offer for sale • sell/import/export • stock for above	Re product "invention": • make • use • offer to make/sell • hire/sell/import • keep for above Re process "invention" • use • exploit a resulting product	Re product "invention": • make • use • offer to make/sell • sell/import • keep for above Re process "invention": • use • exploit a resulting product

Examination and Grant

Plant Breeders' Rights	Innovation Patent	Standard Patent
Acceptance • upon compliance with formalities • can't sue until grant Examination • compulsory (within 12 months of acceptance) Grant • upon successful examination	Acceptance • upon compliance with formalities • can't sue until certification Examination • optional (upon request or order of court) Certification • upon successful examination	Acceptance • upon successful examination • can't sue until grant Examination • compulsory (on request within period) Grant • upon acceptance and no (successful) opposition

Requirements for Protection

Plant Breeders' Rights	Innovation Patent	Standard Patent
Distinctiveness Uniformity Stability	Novelty Innovative step Usefulness	Novelty Inventive step Usefulness

8.1.5 National Legislation in Other Countries

Information on national legislation in other jurisdictions is contained in Appendix 11.3.

9 Arguments for and against the Plants and Animals Exclusions

The following section outlines the views provided in submissions to the review. ACIP addresses these discussions in Part 10.

9.1 *Burden of Proof*

The granting of patent rights can encourage the development and use of new technologies which would otherwise not occur. Rights-holders are able to obtain a return on their investment in research, and the full publication of inventions enables other innovators to both build on and around them. A fundamental issue for the review is whether there is evidence of a need to extend the rights available under the innovation patent. The exclusive rights provided by patents are an exception to the rule of free competition. A necessary consequence of exclusive rights is the creation of barriers to entry in the market and a stifling of competition. At issue is whether the burden of proof lies with those seeking an extension of available rights, or with those who wish to maintain the status quo.

The Intellectual Property Research Institute of Australia (IPRIA) submitted that a cautious approach must be taken. This was because "inclusion of (plant and animal subject matter) in the material protectable by innovation patents would be an expansion of the scope of intellectual property rights available…It is not always in the public interest to provide exclusive rights over all types of inventions, as such rights may not be economically beneficial in some industry sectors…The main use of utility models in Europe has been in industrial sectors such as mechanical and electrical engineering". Europe's unwillingness to adopt a Community-wide utility model "may suggest there is support for utility model protection when confined to traditional technical subject matter, but resistance against a wider scheme that would apply to all patentable subject matter."

IPRIA also argued that "in such a controversial area…the legislature should bear the burden to prove that the benefits of the stimulation of innovation in this area outweigh the possible risks involved…It is not enough to argue that there are no reasons to justify the *exclusion* of plant and animal subject matter…Empirical evidence is required on whether the current patent regime is operating effectively in this sector or whether increased IP rights in the form of innovation patents are needed to stimulate greater investment in research, development and commercialisation…In the absence of evidence showing further IP rights are required, the extension of the innovation patent to plant and animal subject matter should not occur."

The Department of Agriculture, Fisheries and Forestry (DAFF) argued that in considering extension of the innovation patent to plants and animals, issues such as private rights and public good, domestic and international trade and economic interests must all be weighed up. If it can be demonstrated that there are social benefits in closing any gap in protection, then all IP mechanisms must be considered, including a *sui generis* system for animals. The innovation patent is not necessarily the most appropriate vehicle.

Other submissions argued that there appeared to be little or no reason for the plant and animal exclusion. The exclusion was introduced with an absence of evidence to say that

material harm would occur if innovation patents for plants or animals were made available. In the case of animals, there is not even the potential for conflict with a *sui generis* system of protection, as none exists.

9.2 *Plants*

9.2.1 Need for Extending Innovation Patent Protection

Gap in Protection

Several submissions to the review believed that the innovation patent exclusions regarding plants created a significant 'gap' in protection for both plants and processes of breeding plants. Many submissions[20] believed there was a clear national benefit in allowing innovation patents for plant subject matter. The exclusion was seen as actively detrimental to research in Australia.

FICPI felt the exclusion was particularly a problem for SMEs, the very group the innovation patent system was intended to help. AgResearch NZ believed a gap only existed for processes, and transgenic and asexually reproduced plants, the latter due to their lack of distinctness.

The perceived gap in protection has two basic forms:

- Protection is available, but is considered insufficient or inappropriate;
- Protection is completely absent for certain plant innovations. Neither patents nor PBRs are currently available for the following plant subject matter:
  - New plants which involve an innovative step, but meet neither the threshold of inventive step, nor the PBR requirements of distinctness, uniformity and stability.
  - New biological processes for breeding plants which involve an innovative step, but not an inventive step.

A common argument[21] was that innovators needed to be able to choose between different forms of protection according to their circumstances and the nature of the innovation. Such freedom is available in all other fields of technology. Each form of IP right has its own advantages and disadvantages, and can be used in a complimentary, strategic manner.

[20] SIAA, Biotechnology Australia, the Department of Agriculture Western Australia (DAWA), the Department of Primary Industries Queensland (DPIQLD), the Department of Primary Industries Victoria (DPIVIC), the Federation of Intellectual Property Attorneys (FICPI Australia), IPTA, NSW Agriculture, the National Health and Medical Research Council (NHMRC), the Department of Primary Industries Water and Environment Tasmania (DPITAS) and Meat and Livestock Australia (MLA).

[21] Australian Research Council (ARC) Biotechnology Australia, DPIQLD, DPIVIC, NHMRC, FICPI Australia, IPTA, NSW Agriculture, Griffith University, University of Canberra, University of Adelaide, Professor Lazenby and MLA.

PBRs

PBRs are fairly quick to obtain, relatively cheap, and harmonious with systems in other countries. However, some consider PBRs to have the following major disadvantages:

- The scope of protection is too limited. This is due to:
  - uncertainty over coverage of essentially derived varieties;
  - the ease with which PBRs can be circumvented. A plant variety may take several years to develop and test, yet the PBR can be easily circumvented by making a minor genetic change using modern genetic manipulation techniques. This enables others to cash in on the earlier research and benefit from the priming of the market. The original breeder suffers a relatively quick decrease in market share.
  - the exemptions for farmer saved seed and private, non-commercial, breeding and experimental use.
- PBRs are more difficult to obtain compared with innovation patents;
- PBRs are more expensive than innovation patents, given that more PBRs are required to cover a group of varieties than would be required of innovation patents;
- Court action for PBRs is of high cost and complexity. Obtaining sufficient information to prosecute and the cost of going to court, combined with no guaranteed outcome, were seen as major problems.

These factors were seen to negatively impact on the whole industry by:

- substantially reducing the return on investment and lessening the commercial value of original varieties;
- reducing the amount of resources available for plant research and development;
- reducing the ability to compete internationally;
- increasing transaction costs through the use of contracts, and
- encouraging secrecy. Trade secrets provide less potential for negotiated access to innovation than do IP rights.

Arguments of this nature were made by the ARC, Bureau of Sugar Experiment Stations (BSES), DAWA, FICPI Australia, IPTA, NSW Agriculture and SIAA.

DAWA submitted that it currently has 34 grain varieties protected under PBR and "has been involved in the development and subsequent amendments of the PBR Act and therefore has a strong understanding of its benefits and failings…PBR allows further breeding without recourse to the original breeder of a variety and only requires the new variety to be distinguished by at least one essential characteristic or heritable trait. With modern gene manipulation techniques this can be achieved with as little as one gene being inserted. DAWA's concern is therefore related more to the 'gap' in the level of protection afforded by a patent over a PBR rather than the threshold for patentability per se". DAWA also provided data demonstrating the significant impact of competition on the earning potential of a new grain variety.

SIAA argued that the innovation patent was needed for a "top 20%" of innovations. These have high value traits and are time consuming and costly to achieve. Examples included:

- starches in cereals, potatoes;
- resistances to intractable diseases;

- health and nutrition traits;
- high semolina colour in durum wheats;
- foliage variants in ornamentals.

However, several submissions to the review believed there was no significant gap in protection for plant subject matter due to the availability of PBRs. DAFF, CSIRO, ACIPA, the University of the Sunshine Coast and the University of Sydney held this view. Professor Alec Lazenby argued that IP holders would consider there to be a gap, whereas non-IP holders would not. The GRDC "is not aware of any cases where this 'gap' has caused any research not to be carried out or commercialised", despite GRDC's close involvement with private sector researchers, who are more conscious of the availability of IP.

Some submissions considered that standard patents, the PBR system and contract law provided adequate protection for plants. Some saw researchers moving away from IP rights into using contract law alone. GRDC pointed out that under Section 11 of the *Plant Breeders' Rights Act 1994* a PBR holder may licence the right to produce or reproduce the material to another. According to GRDC "over the last three or four years it has become increasingly common for breeders to require, as a condition of the licence to growers to grow the registered variety, that the grower pay an end point royalty to the breeder. The end point royalty is collected at the point of harvest, and is usually set at a rate of $x per tonne of harvested material." GRDC said this ensured sufficient return on breeders' investments.

AgResearch NZ argued that the inclusion of the clause in the PBR Act which provides protection for essentially derived varieties goes some way to addressing problems with the use of protected material by people other than the property right holder.

Standard patents

Standard patents have no limit on the number of claims, can last for up to 20 years, and provide a broad scope of protection which extends to essentially derived varieties, processes and use of crops. To their disadvantage they can be:

- slow to obtain;
- expensive to obtain;
- complex to write, and
- subject to opposition proceedings.

The last two were seen by some to reduce the certainty of rights granted.

Some submissions argued that standard patents are currently the only means of protecting against gene manipulation of new varieties, but plant varieties may not have the necessary level of inventiveness to qualify. For example, DAWA submitted that "the majority of the grains breeding R&D undertaken by DAWA result in incremental improvements in yield, quality, disease resistance etc. As such it is unlikely that the new varieties developed by DAWA would qualify for protection under the full patent system…The only effective option currently available to the DAWA for the protection of its elite crop varieties is through PBR." The SIAA also believed the costs of the current exclusion included the higher cost of gaining standard patent protection.

DPIVIC is now focused on "pre-competitive" crop breeding. In the case of wheat, effort is focused on pre-breeding and germplasm development instead of variety development.

This changing role will likely see the use of PBRs diminish as a means of IP protection, and innovation patents would be more suitable.

Both the NHMRC and University of Melbourne believed that the innovation patent exclusion for plants is cause for concern because it may influence introduction of a similar exclusion for the standard patent.

Innovation patents

Innovation patents provide a broad scope of protection, and are quick, cheap, simple enough to be obtained without specialist knowledge, and they avoid delays due to the absence of an opposition process. Their disadvantages include:

- restriction to a low number of claims;
- publication of the invention soon after filing, thus restricting future options, and
- a maximum term of eight years.

DPIQLD and ARC argued that both innovation and standard patents are becoming more appropriate forms of protection for plant varieties due to the increasingly complex technology in the field. Generation of genetically modified plants using molecular biology and plant transformation techniques is increasing, and there appeared to be a corresponding increase in the use of the patent system to protect inventions in this area. SIAA and NSW Agriculture thought the innovation patent well suited to the plant variety market, particularly for SMEs. DAWA thought that "varietal improvement arising from the breeding program would potentially suit an innovation patent where an innovative step as opposed to an inventive step is accepted."

Professor Lazenby submitted that it is now logical for the transgenics to be patentable because their production is expensive. Many problems could be circumvented if new cultivars of crop and pasture plants bred by conventional methods were only able to be protected by PBRs, and genetically modified material was able to be protected by patents.

Similarly, DPIVIC believed that "a third, middle level of IP protection, would be valuable because it would encourage investment in plant breeding, it would complement the changing strategic focus of plant breeding programs, and would likely allow greater protection and return on investment in allowing only negotiated access to plant material for breeding or gene introgression purposes." However, DPIVIC support for inclusion of plants was based on the assumption that a large majority of varieties covered by PBR would not qualify for an innovation patent, and so there would be little overlap between the two systems. DPIVIC would envisage:

- "the majority of new plant varieties, displaying only incremental improvements associated with conventional breeding methods, would continue to be protected by PBRs;
- the minority of new plant material and/or varieties, displaying significant levels of innovation via novel traits or gene introgression, are protected by innovation patents; and
- small percentages of new plant material and/or varieties, displaying high levels of innovation, are protected by standard patents."

In addition to providing a more rigid system for commercialising partners to negotiate under common law, another benefit of removing the exclusion for plants was thought to

be greater opportunity for technology transfer. FICPI Australia noted that the early publication of innovation patents helps to disseminate information to the public which may otherwise be kept hidden, and much more quickly than through the standard patent system. IPTA and Meat and Livestock Australia (MLA) also noted that infringement actions can be instigated much faster through use of innovation patents, including by filing an innovation patent divisional from a standard parent and quickly obtaining certification. At the Round Table held in June 2003, the point was made that the innovation patent would provide better protection for essentially derived varieties than that afforded under the PBR system.

However, GRDC argued that it would not be practical to extend innovation patent protection to specific plant subject matter, such as germplasm and biological processes for generation of plants. The difficulties in Europe in differentiating between plants and plant varieties have shown this "would award legal protection on the basis of the semantic skills of patent attorneys".

Some argue that the innovation patent is an unsuitable form of protection for plants due to its shorter term and domestic focus. The Australian Institute of Marine Science (AIMS) submitted that it would have no interest in the innovation patent for plant subject matter. "For biodiscovery research and development, the time frame of eight years for an innovation patent is completely unsuitable. For example, for drug discovery, the time line from lead discovery in the crude extract of the source organism to the pills available to the market…is typically at least eight years…An innovation patent system that included biota would provide opportunity to patent too early and for too little time, and in reality impede commercial opportunities."

La Trobe University also foresaw it would have little interest in innovation patents for plants, as the major cost in patenting was for attorney fees. This made the lower official fees almost irrelevant and the shorter term of protection a less attractive deal. The University of Adelaide thought there would be minimal need for the innovation patent in plants, as it should be used for short 'fad' type product cycles.

The University of Sydney and the MLA argued that researchers and SMEs should be encouraged to take a global approach and cover international markets, meaning they should only use standard patents. The University of Sydney also noted that major Australian research organisations are unlikely to ever use the innovation patent, because their products are internationally competitive. Australian standard patents have been brought up to international standards through recent amendments to the Patents Act, making it a more rigorous and useful system.

MLA noted that plant varieties are not patentable in Europe, Asia and South America. Even if innovation patents were available for plants in Australia, breeders will still have to obtain PBR in other countries. Similarly, ACIPA noted that there is no universal acceptance of a second-tier patent system, and argued this increased the difficulty of commercialising innovation patents in other jurisdictions. The PBR system is deemed superior because of its international framework.

9.2.2 Access by Non-IPR Holders

IP protection for plants has always been considered a special case internationally, due to the communal importance of plants and the incremental nature of their development. The international PBR system was specifically designed to provide reasonable access to new varieties and balance public and private good, and many consider that this system has been successful. DAFF's experience is that, broadly, industry, users and consumers support the limited monopoly rights of the PBR scheme. ACIPA drew attention to the political support for the PBR exclusions amongst rural and regional constituencies of the federal government.

A major concern expressed by many submissions was that removing the plant exclusion from the innovation patent would interfere with longstanding industry practices and have a serious negative impact on access to plant material and varieties for farmers and researchers. DAFF argued that the innovation patent is ill suited for plants because, amongst other things, it:

- "imposes significant limitations by providing capacity for total 'lock-up' of patented plants from later use in commercial research and development;
- limits the commercialisation of incremental spin-off innovations/improvements;
- has no automatic requirement to provide reasonable public access to the invention at reasonable quality, quantity and price;
- does not include a provision allowing farmers to save seed for the sowing of subsequent crops."

Subsequently innovation patents for plants would limit the commercialisation of incremental spin-off innovations and improvements, reduce the efficiency and competitiveness of the industry and significantly reduce the levels of innovation. ACIPA, DPITAS, DPIVIC, Grains Council of Australia and GRDC also submitted arguments in this vein.

ACIPA argued that the lack of exemptions for both innovation and standard patents may impede the development of end-point royalties. The compulsory licensing provisions under the Patents Act are long, complex and unwieldy and so have largely remained dormant, and are unlikely to be of use to rural and regional communities. Under section 123 of the Patents Act the court can refuse to withhold remedies in cases of innocent infringement, however the circumstances in which such discretion can be exercised are limited. ACIPA argued that the case of *Monsanto v Percy Schmeiser*[22] illustrates some of the limitations of the patent system in dealing with agricultural technology.

GRDC argued that farm saved seed is crucially important to Australian growers for both technical and economic reasons. In Australia, wheat and barley are the most significant grain crops, and approximately 90% of each year's crop is planted using farm saved seed. Farm saved seed allows farmers to minimise costs and remain internationally competitive. Australian growers receive no subsidies, face high risks of crop failure due to variable climate, and produce yields which are typically one third that of other countries. At the round table some believed that farmers would "revolt" if they no longer had access to farm saved seed.

[22] *Monsanto v Percy Schmeiser* (2001) FCT 256

GRDC also made the point that "a patent holder is under little obligation to give approval or to allow a licence on reasonable terms, as long as it is itself meeting the reasonable requirements of the public by supplying the patented product or process...There is a widespread lack of experience and resources available for negotiation of licences in agricultural research in Australia. This has meant that research is often significantly delayed or does not occur at all." Obtaining a compulsory licence would be slow and expensive, and is rarely used in Australia.

DPITAS recognised the possible gains for plant breeders in removing the exclusion, but considered that this must be balanced against the wider public interest and the benefits of PBR exclusions. DPIVIC submitted that if there was significant overlap in protection between PBR and the innovation patent, then the exclusion should remain due to the potential costs of reduced access for researchers and farmer saved seed.

Some argued that the lack of exemptions for farm saved seed or research was a legitimate concern which could be overcome. ARC, Biotechnology Australia, AgResearch NZ and SIAA believed that the introduction of such exemptions should be considered for the innovation patent. This would provide the same level of access as PBR and limit adverse impact on the farming economy.

However, submissions from DAWA, DPIQLD, FICPI Australia, IPTA, NHMRC, SIAA and NSW Agriculture argued that removing the plant exclusion from the innovation patent would be unlikely to be contrary to the national interest. Innovations must still be new, and any impact would be the same as for other technologies. Some costs may be greater for users, however users may also benefit from an increase in innovation due to greater incentives to conduct research. University of Adelaide suggested the impact on non-IP right holders "could be said to be reduced by the fact that in the agricultural field seeds/plants are tailored to the specific climate conditions in which they are grown. The likelihood therefore of transferring a plant variety from one place or another successfully without altering it in some way is slim."

DAWA argued that "an innovation patent could be used to restrict the rights of growers to retain seed, but this does not make a case for plant and animal subject matter to be excluded, as the PBR Act, coupled with contract law, can also be used in such a manner. It is DAWA's opinion that with the increasing reliance on end point royalties to generate a return on investment, the IP owners would not want to restrict the adoption of varieties in such a way." Biotechnology Australia believed there would be no adverse impact on the PBR system, as innovators will simply choose the appropriate system of protection according to the perceived level of novelty of the subject matter.

9.2.3 Complexity and Uncertainty

Closely related to the concern that innovation patents for plants would restrict research and development are concerns that the complexity, uncertainty and misuse of the IP rights system would be increased.

Ease of Availability and Misuse

The ease with which innovation patents are granted is a major cause for concern. It is believed that granting innovation patents for plants quickly, at low cost and without substantive examination will create an environment of uncertainty, litigation and misuse. According to ACIPA there is widespread dissatisfaction with the registration system of the innovation patent, with only about 10% of applications being examined. This was seen as devaluing the system as a vehicle for commercialisation and investment. DAFF, MLA and ACIPA argued that allowing innovation patents for plants could result in a large number of invalid patents on the register. This would invite legal conflict to a much higher degree than is the current case for PBR, where litigation is very rare. A consequence would be increased costs for non-IP rights holders and ultimately the community at large. Incremental breeding of plants adapted to Australian conditions would slow due to regulatory uncertainty.

At the Round Table held in June 2003 concerns were expressed about people in the industry not understanding the difference between examined and unexamined patents. Further education was not seen as being able to solve the problem.

DAFF and GRDC argued that granting patents for plants without examination creates the potential for the misuse of patents, such as creating 'spoilers' or cheap walls against competition. University of Sydney believed that multinational companies used cheap innovation patent portfolios to intimidate potential competitors and stifle research and development in Australia. Removing the exclusion for plants would exacerbate this problem. Australian SMEs have little understanding of IP rights and are reluctant to invest in developing an understanding. Extending the scope of innovation patents would only rule out more fields of engagement and innovative practice as companies avoid expending resources on uncertain and often unproductive legal disputes. There was also doubt whether the private sector would invest on the basis of an unexamined innovation patent.

DAFF argued that the innovation patent "does not facilitate the production of harmonised description of varieties needed for rigorous examinations against existing varieties, including those already covered by IP protection." DAFF and others were concerned that this coupled with a lower inventive threshold than the standard patent would result in a less useful system and restrict research and development, as it would lead to patents being granted for biological discoveries rather than inventions. This concern was affiliated to considerable uncertainty over the threshold of innovative step (see below).

MLA and ACIPA argued that the interests of patent owners and the community needed to be balanced, and that for minor, lower level inventions the increased cost and uncertainty would outweigh any benefits. In contrast, the PBR system was considered to have integrity and rigour due to use of practical trials and the services of qualified people.

ACIPA also argued that the ability to quickly and easily obtain an innovation patent will add to existing concerns over the use of standard patents in the biotechnology area, and may lead to fragmentation of ownership of enabling technology, defensive patents and blocking patents.

However, in response to the doubt expressed over whether the private sector would invest on the basis of an unexamined innovation application, some at the June 2003 Round Table argued that there appeared to be no reason not to have such an application examined and the uncertainty resolved.

The University of Melbourne acknowledged that "given the lower threshold of inventiveness required for an innovation patent and the ability to apply for an innovation patent without the involvement of a patent attorney, a greater amount of litigation could result through counter claims. However, it was also deemed the responsibility of the applicant for an innovation patent to take such issues into account." As with the lack of exemptions for farm saved seed or research, optional examination was considered by some to be a concern which could be overcome.

Innovative Step

Most of the criteria for PBRs and patents have become well understood. In comparison, the threshold of innovative step was introduced only relatively recently, and as yet no guidance is provided by case law.

Several submissions including DPIVIC, ACIPA, DAFF and AWB Limited considered the requirement of innovative step to be uncertain and untested. It is not known what level of improvement would be considered "substantial" and therefore qualify as an invention. The GRDC submitted that if the test of innovative step "is interpreted broadly (to a low threshold), there is a real risk that…this would enable the innovation patent system to replace the PBR system in those cases. This is highly undesirable, because the PBR system provides a much more appropriate balance of interests".

AIMS argued that "in the relatively unexplored marine realm, discoveries come easily. Vast areas of the marine sphere remain unexplored, and even in the relatively well studied marine habitats…the majority of biodiversity remains undescribed. These organisms and habitats in turn possess a plethora of undescribed chemical compounds, biomaterial types and other attributes…If widened to include biota, the innovation patent's lower inventive threshold and less rigorous examination and scrutiny process may promote a rash of cheap, easily obtained, poorly justified, and broad in scope 'discovery' patents which would prevent standard patent protection for a specific novel application of an attribute of that biota. The innovation patent would …provide an opportunity for unscrupulous operators to proactively park broad swathes of biota types and their attributes that showed commercial potential…, beyond their own research and development capability to progress the subject matter within the patent's life".

AIMS also argued that the problems of the innovation patent concerning macro-organisms apply equally to micro-organisms, which have long been recognised as having enormous potential for the production of natural products. Due to the low cost of tools there is now unprecedented opportunity to identify unculturable types, identify DNA, and culture previously unculturable organisms. Culturable micro-organisms enable economic, sustainable, large scale production. AIMS advocated that at least limited exclusion of micro-organisms from the innovation patent system be considered.

DAFF also believed that under the innovation patent system broad claims could be made over Australia's relatively undescribed biodiverse flora, including that sourced from traditional knowledge owners.

Overlap of Rights

Another issue is the degree to which PBRs would overlap with innovation patents for plants. This depends on whether the threshold of innovative step is equivalent to, or higher than, the criteria for a PBR. Distinctiveness, uniformity, stability, novelty, usefulness and inventive step are generally clearly defined and well understood criteria. However, the threshold of innovative step was introduced only relatively recently, and is considered by many to not yet be clearly defined or understood.

DPIVIC's support for inclusion of plants was based on the assumption that a large majority of varieties covered by PBR would not qualify for an innovation patent. DPIVIC argued there is a need for a more transparent and universal understanding of the requirements of "innovative step" to ensure innovation patents provide a real, alternative level of IP protection with an increased innovation threshold for acceptance over and above the PBR system.

DAFF, ACIPA, Grains Council of Australia and AgResearch NZ all believed that allowing innovation patents for plants would create three overlapping tiers of available protection for plants (PBR, innovation and standard patents). This would create confusion for those in the industry over what form of protection to apply for and to be aware of. ACIPA argued that as the majority of applications for PBR would also satisfy requirements for an innovation patent, there would be a clear-cut conflict between the two regimes. The inconsistency in exclusions and scope of protection may cause problems for plant breeders who are used to particular conduct being permissible under the *Plant Breeder's Rights Act 1994*.

DAFF believed that the potential for innovation patents to undermine existing PBR could lead to the holders of these rights suffering a loss and requiring compensation.

System in State of Flux

Some thought that, as the innovation patent system is still in its infancy, there was a lack of information regarding not only innovative step, but the costs, timeframes and prospects of success for certification and enforcement of innovation patents. Environment Australia, DAFF and ACIPA proposed ACIP wait until after the Australian Law Reform Commission inquiry into gene patenting and human health had been completed before conducting this review.

AWB Limited also argued that the plant breeding industry is currently undergoing rapid changes in technology and a major shift from public breeding programs to the private sphere. This will result in new players and niches, and an increased interest in and demand for IP rights. All these factors would be expected to affect the ACIP review.

ACIPA claimed that, while the High Court has confirmed the constitutional validity of PBR[23], there are still doubts about whether innovation patents are within the scope of "patents of innovation" under the intellectual property power of the Australian Constitution. ACIPA argued that the entire innovation patent system should be comprehensively reviewed in a few years. ACIP notes that the government agreed to a recommendation of ACIP's Review of the Petty Patent System to review the new system five years after its implementation, ie in 2006.

9.2.4 International Issues

DAFF argued that consideration must be given to the global environment in which Australian agricultural trade and economic interests compete. The patenting of biological material is a contentious and complex issue in trade related fora. Australia's trading partners generally treat plants and animals differently to other subject matter.

Social Aspects

As discussed above, internationally plants are treated differently to other technologies due to concerns such as the equitable sharing of benefits, food security, and developmental, environmental, cultural and moral considerations. International fora such as WIPO, UPOV, ITPGFRA and CBD are currently considering issues such as:

- The extent of IP rights on biological resources;
- The relationship between patent and other IP systems;
- The capability of existing IP rights systems be used to protect traditional knowledge;
- Access to and benefit sharing of the use of genetic resources; and
- Prerequisites on the grant of patents, including prior informed consent and agreed terms for the transfer of genetic material and access required by countries of origin.

DAFF made the point that the PBR system has been developed with many of these issues in mind, whereas the innovation patent has not. If Australia were to become party to ITPGFRA, removing the exclusion for plants from the innovation patent may affect Australia being able to meet its obligations. According to ITPGFRA, where material accessed under the multilateral system is protected by IP and not made available for further research, royalties must be paid. The majority of varieties currently protected by PBR may be subject to this if they are also able to be protected by the low-threshold innovation patent.

Both DAFF and AgResearch NZ submitted that the more restrictive IP rights on plants become, the more resistance will be forthcoming on the international scene, particularly from developing countries that need access to improved crops and seed supplies. DAFF submitted that "the credibility of Australia's negotiating position in international fora and hence its capacity to benefit from cooperative efforts in relation to IP in plants and animals…could be put at risk should the current exclusion be removed. Since Australia would be going against international practice in allowing a form of second tier patent

[23] *Grain Pool of Western Australia v Commonwealth* (2000) 46 IPR 515.

over biological materials with potential for false claims and biopiracy, (this) would likely constrain our negotiating positions" within the fora listed above.

Trade Aspects

DAFF argued that "harmonisation of Australia's IP system with international systems facilitates access and reduces costs…All countries are interdependent in their use of plant and animal genetic material in food and agriculture…Australia is a net importer of IP, which helps to maintain our competitiveness and to power our exports." The great majority of grain research, for example, is done using overseas germplasm. Innovation patents for plant varieties would decrease the importation of plant varieties into Australia for use in deriving new varieties adapted to local conditions. Exporters will not send their property to Australia unless they are satisfied that it can be safeguarded and not become subject to differing rules and claims. Developing countries are also probably the richest sources of untapped or undiscovered plant species and genetic resources, and so should not be alienated by overly restrictive practices in developed countries.

Australia is among a minority of countries that provide standard patents for plants and animals, but is one of 52 countries employing a *sui generis* PBR system for plants in harmony with international agreements.

9.3 *Animals*

9.3.1 Need for Extending Innovation Patent Protection

Due to the current subject matter exclusions for the innovation patent and the absence of a *sui generis* system like that of PBRs, protection is currently not available for the following animal subject matter:

- animals which involve an innovative step but not an inventive step;
- biological processes for the generation of animals which involve an innovative step but not an inventive step.

Most of the submissions to the review believed this situation to be a 'gap' in protection for animals and biological processes of generating animals. Many could see no logical reason for the innovation patent exclusion, as there was no *sui generis* system available for animals. There did not appear to be any justification for narrowing Australia's traditionally broad view of patentable subject matter, nor any national benefit in doing so. ARC, Biotechnology Australia, DAWA, DPIQLD, FICPI Australia, IPTA, DPITAS, NHMRC, MLA, University of the Sunshine Coast and DPIVIC all submitted arguments of this nature. However, overall there was significantly less concern at the gap for animal subject matter than was the case for plant subject matter.

DPIVIC argued that "an innovation patent would provide a second tier of IP protection that would be a more suitable mechanism for protection of lower level innovations. For example…the area of proteomics (gene expression)…The absence of an innovation patent may, as a result, currently be shifting researchers' focus toward larger projects with longer time-frames to increase the likelihood of a standard patent being obtained to secure the potential for economic returns. As such, the absence of an innovation patent could act as a barrier to entry to smaller industry players, or for smaller research and

development projects being undertaken. (This may) be limiting the overall rate of innovation in the industry."

Biotechnology Australia argued that "the current international research and commercial activity in both (the plant and animal) areas involve genetic manipulation and other advanced techniques, yielding technology developments involving varying levels of innovation that may qualify for protection under the innovation patent system. Excluding the…animal subject matter from such protection denies the Australian researchers and industry the protection of methodologies and…animal varieties resulting from these activities with potential for significant economic loss."

The NHMRC believed that "although in most cases the standard patent would appear to be a more appropriate system for protection…as there is no equivalent of the PBR system for animal subject matter this is an area of particular concern." There was concern that "the exclusion may ultimately have a negative impact on standard patents. Such an extension of the exclusion to standard patents would have a large negative impact on the health and medical research community in Australia because animal models play a large part in the discovery of novel therapeutic strategies."

As with plants, a common argument was that innovators of inventions which meet the inventive step threshold should be able to choose which form of protection meets their needs. The quicker, cheaper nature of the innovation patent could be more suitable than the standard patent in certain circumstances. This view was held by ARC, Biotechnology Australia, DPIQLD, FICPI Australia, IPTA, NSW Agriculture, University of Canberra and University of Adelaide. The point made by IPTA that an innovation patent enables infringement action to be instigated much more quickly than with a standard patent is also relevant for animals.

However, some argued that there was no evidence that the gap in protection was a problem. DAFF is of the view that the innovation patent is ill-suited for animals, and noted the practical difficulties in distinguishing existing breeds against an innovative step, and that difficulties in satisfying the reproducibility criterion make patents on animals quite rare. ACIP notes that the threshold for reproducibility is the same for innovation patents as it is for standard patents.

MLA, AIMS and La Trobe University considered the innovation patent unsuitable for protecting animal subject matter because the eight year term was too short to return the investment, particularly given the time is takes to build up commercial numbers of livestock. The University of Adelaide thought that, as with plants, there would be minimal need for innovation patents for animals, as this should be used for short 'fad' type product cycles.

9.3.2 Access by Non-IPR Holders

Similar arguments were made against removing the exclusion for animal subject matter as for plant subject matter, although not with the same degree of concern. Animals have a similar communal importance and an incremental nature of development as plants. Consequently providing IP protection for new animals has also been internationally

considered a controversial and special case. DAFF noted that no other country has seen fit to provide IP rights for animals other than through standard patents.

DAFF and ACIPA argued that allowing innovation patents for animals would be in conflict with animal breeders' established frameworks of ownership of animals and their reproductive capabilities. This would cause great concern amongst a number of industries, such as horse racing, kennel clubs and livestock producers. It is a long-held convention that ownership of an animal implies ownership of breeding rights. The relative ease of obtaining an innovation patent may enable patent holders to restrict the 'creeping' innovation on which most animal breeding is based. As with plants, innovation patents have the potential to lock up animals from further research and development, and limit the commercialisation of incremental spin-off innovations and improvements.

However, MLA suggested that the impact on non-IP right holders of extending rights for animals and processes for their generation may be limited by the innovation patent's eight year term. DPIVIC believed that removing the animal exclusion is unlikely to create barriers to the sharing of research findings between parties due to the formation of agreements between parties and the 'swapping' of innovation patents.

9.3.3 Misuse and Uncertainty

As with plants, there was concern that because innovation patents are granted quickly, cheaply and without substantial examination, the uncertainty and misuse of the IP rights system would increase. Again, the number of invalid patents on the register was thought a problem. DAFF argued that the lack of examination allows protected or commonly known animals to be accessed and misrepresented, and enables broad claims over Australia's relatively undescribed biodiverse fauna, including that sourced from the land of traditional knowledge owners.

The MLA was also concerned that examination of an innovation patent can usually be conducted at any time. "Given…that an innovation patent may be granted without claims, an applicant for an innovation patent may 'build' a number of aspects into their application and decide which aspects to pursue during examination and even tailor their claims well after the patent has been granted when a potential infringer is on the horizon." ACIP notes that while claims may be amended after a patent has been granted, the amended claims cannot define new material, and must remain within the scope of the original claims of the innovation patent as granted. MLA also argued that "the potential exists for an applicant to lay a minefield of innovation patents for competitors, with the result being that competitors or other interested parties may be forced to incur significant expense simply in order to determine the scope of protection afforded by an innovation patent or otherwise abandon the whole thing as being 'too hard'…The grant of unexamined innovation patents is of particular relevance in the area of infringement searching."

FICPI Australia argued that any social or other concerns over innovation patents for plants and animal subject matter should be addressed by targeted schemes, rather than through restrictions in patent legislation.

10 ACIP's considerations

10.1 *Burden of Proof*

The 1995 Competition Principles Agreement between the Council of Australian Governments established the principles for governments to apply in reviewing and reforming legislation. Legislation should not restrict competition unless the benefits of the restriction to the community outweigh the costs, and the objectives of the legislation can only be achieved by the restriction.

The innovation patent exclusion for plants and animals, and biological processes for their generation, forms the starting point for this review. ACIP considers that, as the exclusive rights provided by patents are a restriction on free competition, any extension of those rights should only occur where there is clear evidence that this is needed. It is not relevant to this ACIP review that, at the introduction of the innovation patent in 2001, no evidence was publicly provided of the potential harm of innovation patents for plants and animals.

ACIP appreciates that it is difficult to provide concrete evidence of the benefits of a thing that is not in existence. However, some examples of how the inadequacies of current IP protection may be identified include research concepts which were thought to have significant industrial potential, but which were not pursued, and poor returns on innovations which did in fact have protection, but of a nature which competitors were able to sidestep.

Although the burden of proof lies with those wishing to extend protection, the alleged costs of extending exclusive rights must also be clearly identified and well founded, so that a robust cost / benefit analysis can be conducted. Unsubstantiated theory cannot be given weight in such an assessment.

10.2 *Plants*

10.2.1 Availability of Rights

Subject Matter

Both PBRs and standard patents are available for plants and plant varieties. However, submissions to the review did not identify this overlap in protection to be of significant concern. This appears to be due to the standard patent's higher threshold of inventive step, and the small number of standard patents being granted for plants.

Due to the exclusion of plants and animals from the innovation patent, there is currently no overlap in subject matter between PBRs and innovation patents. Removing the innovation patent exclusion for *processes* of generating plants would not create any overlap for 'lower level' process inventions, as PBRs are not available for processes. Some submissions to the review expressed some concern at the lack of lower level protection for processes of generating plants, particularly in the area of modern gene manipulation.

Some concern was expressed at the lack of innovation patent protection for plants and plant varieties, as distinguished from processes. Removing the innovation patent exclusion for plants would, in theory, create an overlap in rights between PBRs and the innovation patent. This potential overlap is of major concern to many parties who made submissions to the review. ACIP has therefore given special consideration to this matter.

The degree of overlap between innovation patents and PBRs would depend on the proportion of plant varieties that satisfies both sets of criteria for protection. ACIP considers that few plant varieties eligible for a PBR would be expected to fail the innovative patent criterion of manner of manufacture, as most would be an artificially created state of affairs and have an economic application. The degree to which plant varieties would satisfy other thresholds is discussed below under Requirements for Protection.

Discovery versus Invention

Several of the submissions expressed concern that removing the innovation patent exclusion for plants may result in protection for biological discoveries, rather than true inventions, and the locking up of natural resources. ACIP notes that according to patent law, a discovery is a new product or process for which a practical use has not been disclosed. It is the intent and the practice of the innovation patent system that discoveries are not certifiable. The same standard of patentable subject matter applies to innovation patents as for standard patents. To be patentable an invention must be a manner of manufacture, meaning that it is an artificially created state of affairs, and that a practical, economic use has been identified and disclosed.

The practical use of an invention need not always be explicit in the claims of a patent. For both standard and innovation patents, claims to new products *per se* are common in most areas, including chemistry, pharmacology and genetics. However, a claim to a product *per se* does not prevent the patenting of a new use for the product. The inventor of a new use for a plant may be able to obtain a patent for that use, although he or she may need to obtain a cross-licence from the owner of the original patent in order to exploit his or her invention.

System Complexity

If the overlap between PBRs and innovation patents were significant, then one of the costs of allowing innovation patents for plants was identified in submissions to the review to be the complexity and confusion of operating parallel protection. Innovators may be able to obtain “two bites at the cherry”, and non-IPR holders would need to be knowledgeable about both systems. ACIP considers that such adverse consequences are possible, although they were not demonstrated to be likely.

Requirements for Protection

Overlap of Rights

As outlined above, if the innovation patent exclusion for plants were removed, the degree of overlap between innovation patents and PBRs would depend on the proportion of plant varieties eligible for a PBR which also satisfy the following innovation patent criteria:

- usefulness;
- sufficiency;
- novelty, and
- innovative step.

Usefulness

Although usefulness is not a requirement for grant of a patent, it is a criterion which may be assessed by the courts. The courts have interpreted usefulness to be a measure of whether an invention produces the results promised in the specification. ACIP considers that few plant varieties eligible for a PBR would fail this, as it would not be difficult to ensure any promises made matched the results of trials performed.

Sufficiency

To be eligible for a PBR, a plant variety must be assessed as being uniform and stable based on practical trials. Uniformity and stability are not criteria for standard or innovation patents, as it is not the patent system's role to assess whether an invention meets all the necessary industry regulations in order for it to be exploited. However, to be patentable an invention must be sufficiently described, meaning it is repeatable by a person skilled in the art. This assessment is based on a reading of the specification. Although the two criteria are quite different, due to its practical nature the PBR test forms a higher threshold. ACIP therefore considers that few plant varieties would fail the patent requirement of sufficiency.

Related to this is the question of whether allowing innovation patents for plant varieties would have adverse consequences, as the protected matter would not necessarily be uniform and stable. This would in fact impact on whether the protected matter should properly be considered a 'variety', as opposed to merely being a plant. The rigour of assessment of PBR applications is seen as an important element in the success of the system. ACIP considers that the potential exists for the innovation patent to encourage the development of plants which are not uniform and stable, and therefore create problems in the industry. However, it has not been clearly demonstrated that this is likely to occur. The lack of assessment of uniformity and stability for standard patents has not resulted in problems. ACIP notes that only small numbers of such patents have been granted.

Novelty

ACIP considers that a small number of new plant varieties may fail the criterion of novelty, as some may be new and distinct according to PBR law, but were publicly available before the priority date of the patent application.

It is therefore apparent that the degree of overlap between innovation patents and PBRs mainly depends on how many plant varieties which satisfy the PBR criteria would also meet the criterion of innovative step.

Innovative Step

The lower the threshold of innovative step, the higher the degree of overlap between innovation patents and PBRs. Many who made submissions to this review found innovative step to be a very uncertain threshold. According to Subsection 7(4) of the Patents Act, an invention involves an innovative step if it varies from the prior art in a way that makes a substantial contribution to the working of the invention. According to IP Australia's *Manual of Practice and Procedure, Volume 2 - National*[24], the innovative step test requires that the variation is not merely superficial, trivial or peripheral to the invention. The variation must be of practical significance to the way the invention works so that the person skilled in the art would consider it to make a "substantial contribution" to the working of the invention.

According to IP Australia no definitive measure of "substantial" applies, and each invention needs to be assessed on its merits. In most situations where the difference between the claimed invention and the prior art is part of the common general knowledge of the person skilled in the art, the working of the invention is unlikely to be substantially changed. Further guidance on substantial contribution is gained from cases which applied the (superseded) test for novelty as stated in *Griffin v Isaacs*[25].

As yet, case law provides no specific guidance on the criteria of innovative step. *Datadot Technology Ltd v Alpha Microtech Pty Ltd* [2003][26] is the only decision to date regarding an innovation patent. The applicant's innovation patent was found to be infringed, however the cross-claim for invalidity was dismissed for lack of evidence, and so the validity of the innovation patent was not contested.

To be eligible for a PBR a plant variety must be distinct from any other commonly known variety. Although evidence of actual cases is not available, ACIP considers that a significant proportion of plant varieties eligible for a PBR would vary from previous varieties in a way that makes a substantial contribution to the field, and therefore contain an innovative step.[27]

Conclusion

ACIP considers that there is reasonable prospect of significant overlap of subject matter able to satisfy the requirements for protection under both the innovation patent and PBR systems.

[24] Part 30.4.5.4.
[25] *Griffin v Issacs* [1942] AOJP 739 at page 740; 1B IPR 619.
[26] *Datadot Technology Ltd v Alpha Microtech Pty Ltd* [2003] FCA 962.
[27] This is supported by the SIAA claim that there is a "top 20%" of low-level plant innovations which would warrant innovation patent protection.

Grant Process

Speed and Cost

Applications for PBRs are assessed for distinctness, uniformity and stability based on growth and propagation tests. Such assessment means full registration of a plant variety typically takes 2.5 years (see Appendix 11.2.3). The standard patent system is similar to the PBR system in that full assessment is required for grant, resulting in a similarly long period to grant. The official fees for patents are also relatively low, but the bulk of the cost to applicants is usually in patent professional fees.

In comparison, the innovation patent system is designed so that applications may be submitted without the aid of a patent professional, and only those applications which are of commercial importance incur the higher cost and effort required for full assessment. Grant, examination and maintenance of an innovation patent are very quick and inexpensive. However, employing the services of a patent professional (as recommended by IP Australia) increases the cost to a level perhaps not much less than for a standard patent.

The need for the speed and lower cost of the innovation patent has been clearly expressed by some plant breeders. Also, innovation patents for plants would result in early publication of new varieties. Theoretically this would result in greater dissemination of knowledge in the field.

Assessment

Innovation patents in all technologies are granted, as distinct from certified, after only a formality examination. The government chose this option so as to reduce the compliance burden on applicants. The delay and cost of full examination is only incurred for those applications that require it. It was recognised that a consequence would be increased uncertainty over whether an innovation patent is valid. If the exclusion for plants was removed, this may result in invalid patents for plants being granted.

As the innovation patent is a relatively new system, little guidance has been provided on the threshold of innovative step. Consequently there is a higher level of uncertainty over the validity of certified innovation patents than there is for granted standard patents or registered PBRs.

Several of those who made submissions asserted that, if innovation patents were allowed for plants, the above two factors would cause greater uncertainty and cost than under current arrangements. ACIP considers that the ease of obtaining innovation patents does create the potential for increased inefficiencies due to defensive patenting and the building of ‘walls’ of unexamined patents. Theoretically, multinational companies may be interested in using the innovation patent system, despite it being a unique local system, because plant varieties are more likely to be suited to specific local conditions. However, there is no evidence to support this, as the bulk of innovation patent applicants are Australian, and only around 15 petty patents have ever been granted for plants[28]. Also, the relative simplicity and very low cost of having an innovation patent examined would allow many uncertainties to be resolved.

[28] IP Australia, March 2004.

10.2.2 Scope of Protection

Scope of Rights

A PBR for a plant variety includes within its scope varieties that are essentially derived from it and varieties that are dependent on it. Some submissions considered the protection for essentially derived varieties to be insufficient and uncertain. ACIP disagrees with this view, as the December 2002 report by an expert panel clearly found that essentially derived varieties include those with unimportant differences (see Appendix 11.2). ACIP therefore considers that PBRs do provide strong, reasonably certain protection in this regard.

Exclusive Rights

ACIP considers that the exclusive rights available under standard patents, innovation patents and PBRs essentially correspond.

Exceptions to Infringement

Exceptions are provided under the PBR system for several types of use and compulsory licence, and these are considered critical to its success. The lack of such exemptions under the innovation patent is the main reason some consider it superior for encouraging innovation, while this is of great concern to others due to the potential for innovation patents for plants to effectively sidestep the working of the PBR system.

Conflicting assertions and anecdotal evidence have formed the bulk of the submissions to the review. ACIP considers that there is little real evidence of the need to expand the rights of innovators to encompass the current exceptions for use by non-IP right holders. Gathering information on opportunities lost is obviously problematic, however a major deficiency in plant breeding in Australia has not been identified. Some information has been provided on the impact of competition on the earning potential of new grain varieties[29], and of a "top 20%" of low level inventions that deserved stronger protection[30]. However, the majority of arguments for allowing innovation patents for plants are based on assertions, and a general view that more protection for innovators is necessarily better. ACIP therefore considers that, although there would be some benefit in allowing innovation patents for plants, this would not be high.

Although no second tier protection is available for processes of generating plants, the evidence for allowing innovation patents for this area is even slimmer. Standard patents appear to offer sufficient protection for current gene manipulation technologies. ACIP therefore considers that the benefits in changing the legislation regarding processes have not been made out.

ACIP accepts that plants are a special field when compared with other areas of innovation. Due to the nature of plant breeding, the successful development of new varieties depends on non-IP rights holders being able to use protected varieties for

[29] DAWA
[30] SIAA

breeding new ones. The farming industry also relies to a large extent on farmers being able to save and use seed from grown varieties, although according to anecdotal evidence provided in some submissions this practice is declining due to the use of contracts between suppliers and growers. Some submissions made the point that the use of contracts in order to restrict use, both instead of and in conjunction with PBRs, reduced the need for innovation patent protection. ACIP expects such use of contracts to increase.

The lack of explicit exceptions under the standard patent system for using plants for breeding and research purposes does not appear to involve significant costs. This is due to the higher inventive threshold and the small number of such patents being granted. However, if there were significant overlap in plants able to satisfy the requirements for protection under innovation patent and PBR systems, the cost of the lack of exemptions for use under an innovation patent could be high. ACIP considers that removing Australian breeders' access to plant material would have a significant detrimental impact on the development of new breeds. The breeding of new varieties by competitors could be delayed until innovation patent protection on the source material has expired.

The introduction of innovation patents for plants would require the issue of access to be addressed, such as through introducing exemptions for use similar to those under the PBR system. This would of course reduce the benefits to innovators, as the only important differences between an innovation patent and a PBR would then be that the innovation patent is quicker, cheaper and does not require full examination for grant.

ACIP also notes that introducing exemptions specifically for plants is not necessarily a simple matter. Both Australian and foreign experience has shown that subject-specific patent laws invariably create significant uncertainty over where the boundaries of the affected subject lie. Such measures often become less effective as applicants circumvent them through construction of their claims.

International Issues

PBRs and standard patents (to a large extent) are internationally harmonised systems. The innovation patent is not. Due to the lack of exceptions to infringement, allowing innovation patents for plants may impact on Australia meeting its international obligations under ITPGFRA and CBD regarding fair and equitable access to and sharing benefits from the use of plant genetic material

According to DAFF, removing the innovation patent exclusion for plants would create difficulties for Australia's participation in the system set up under ITPGFRA, our relations with other contracting parties and our access to plant genetic resources. DAFF believed that it would also adversely impact on perceptions of Australia by other participants in fora such as CBD and WIPO, thereby constraining our negotiating positions.

ACIP considers that, if innovation patents were allowed for plants, the government would need to analyse the issue in detail and ensure that this did not impact on Australia's international obligations. This is not an appropriate role for ACIP at this stage.

Duration of Rights

Some argued that the innovation patent would not be attractive for plants due to its short term and domestic focus. Innovators should be encouraged to focus on international trade, and utilise standard patents and PBRs because they are internationally harmonised systems. Others argued that they would be interested in using innovation patents despite the short term, and that the use of innovations patents is up to the market to decide. ACIP considers that this issue is not a significant determinant of whether the current exclusion should be removed.

10.2.3 Options

The following table summarises the options available regarding the innovation patent, and the main advantages and disadvantages of each.

Options regarding the Innovation Patent

Option	Main Advantage	Main Disadvantage
No Change	No disruption of existing PBR system & industry practices.	Low encouragement of innovation in plants.
Modify the Exclusion • Exclude "plant varieties"	• Reduced disruption of PBR system; encourages innovation of plants & processes.	• Definition problems of plant vs "plant variety" as exemplified in Europe.
• Exclude plants	• Limited disruption of PBR system; encourages innovation of processes.	• Backdoor patenting of plants by way of "product by processes".
• Exclude "plant varieties" and "conventional" processes.	• Limited disruption of PBR system; encourages innovation of modern genetic techniques.	• Major definition problems of conventional vs non-conventional processes.
Remove the Exclusion, Modify the Rights • Include some PBR exceptions for use (eg breeding new varieties, farm saved seed).	• Reduced disruption of PBR system.	• Limited extra encouragement of innovation.
• Include all PBR exceptions for use	• Limited disruption of PBR system.	• Likely no extra encouragement of innovation.
Remove the Exclusion	Encourage innovation of plants in some sectors.	Disrupts PBR system, the extent depending on the overlap of systems.

10.2.4 Conclusion

Little firm evidence has been presented to ACIP, particularly of significant deficiencies in the current system. Consequently, only minor benefits in increasing protection for plant breeders have been identified. These benefits primarily lie in protecting the proportion of low level inventions that require significant investment and are particularly vulnerable to competition.

The extent of the costs of providing innovation patents for plants must next be considered. If the costs are only negligible, then the benefits may outweigh them and the innovation patent exclusion for plants should be removed.

ACIP considers that exceptions for breeding, experimentation and farm saved seed are crucial to the success of the PBR system. As the innovation patent does not have such exceptions, providing innovation patents for plants has the potential to be of significant detriment to the industry. Whether this potential is realised depends upon the degree of overlap of subject matter that may be protected by both the innovation patent and PBR systems.

If differences in the patentability criteria meant that only a few plant varieties could be protected by both a PBR and an innovation patent, then the lack of exceptions under the innovation patent would have minimal impact on users of the PBR system. The costs of allowing innovation patents for plants would therefore be low overall. However, if a significant proportion of plant varieties could be protected by both a PBR and an innovation patent, then the innovation patent system could effectively replace the PBR system, and the lack of exceptions would be of major concern.

Although there is some uncertainty, ACIP considers that a significant proportion of plant varieties eligible for a PBR would satisfy the innovative step criterion of the innovation patent. Therefore there would probably be a significant overlap in subject matter that may be protected by both the innovation patent and PBR systems. The cost to the breeding industry of introducing innovation patent protection for plants would be significant, and so outweigh the benefits identified above.

One option is to introduce within the innovation patent system exceptions for use similar to those under the PBR system. This would go a long way to reducing the costs to the industry, but of course also remove many of the benefits of innovation patent protection sought by plant breeders. Pragmatically, addressing issues of access for non-rights holders does not seem justified by the relatively minor benefits. On balance, ACIP considers that the case for removing the innovation patent exclusion for plants and biological processes for their generation has not been made out. It should be noted that this decision in no way implies a need for similar exclusions under the standard patent system.

Recommendation 1

The current exclusion from the innovation patent of plants and biological processes for their generation should be maintained at this time.

10.3 *Animals*

It is a convention of animal breeding industries that ownership of an animal implies ownership of breeding rights. Standard patent protection is available for higher levels of innovation. No lower-level system of protection is available for animals and processes for their generation. Nonetheless, significantly less concern was expressed on this issue than was the case for plant subject matter.

Submissions on this issue consisted entirely of speculation. Many thought that there was no logical reason for a gap in protection and that innovators should have the choice of using the innovation patent. However, no evidence was provided of a market failure due to a lack of protection in the animal breeding field. Some argued that the absence of lower level protection may be acting as a barrier to entry to smaller players, and that the lack of protection is discouraging the development of certain genetic manipulation techniques. It may be that in the future there is a need for innovation patent protection, due to an increase in the development of genetically modified organisms, a potentially more costly form of breeding. However, ACIP considers that at present the existing systems appear adequate.

Concerns with allowing innovation patents for animals included the disruption of existing systems, particularly as the innovation patent was thought to be open to abuse. However, such arguments were also predominantly theoretical. According to the Competition Principles Agreement, legislation should not restrict competition unless the benefits of the restriction to the community as a whole outweigh the costs. If significant new evidence arises of innovation in animal breeding being discouraged, then this issue should be reviewed. As with plants, maintaining the innovation patent exclusion for animals does not provide any support for introducing such an exclusion for the standard patent.

Recommendation 2

The current exclusion from the innovation patent of animals and biological processes for their generation should be maintained at this time.

11 Appendices

11.1 *Appendix 1: Comparison of Second-Tier Patent Systems Internationally*[31]

Subject Matter Protected

Same as for patents (ie. not plants & animals)	Belgium, France, Indonesia, Ireland, Malaysia, Netherlands, Vietnam
Same as for patents, except for plants & animals	**Australia**
Same as for patents (ie. not plants & animals), except for processes	Germany, Turkey
Physical devices and processes only	Austria, Slovakia
Physical devices and chemicals only	Czech Republic, Denmark
Physical devices only	Argentina, Brazil, Bulgaria, Chile, China, Finland, Greece, Guatemala, Hungary, Italy, Japan, Korea, Mexico, Philippines, Poland, Portugal, Russia, Spain, Taiwan, Ukraine, Uruguay

Note: These categories are a general guide only, as the exact definition of subject matter varies between countries.

Novelty Requirement

Local novelty only	Philippines, Spain
Foreign use not a bar to grant	Germany, Hungary, Russia
12 month grace period for disclosure	Turkey
6 month grace period for disclosure	Argentina, Austria, Czech Republic, Slovakia,
Same as for patents	**Australia**, Belgium, Brazil, Bulgaria, Chile, China, Denmark, Finland, France, Greece, Guatemala, Indonesia, Ireland, Italy, Japan, Korea, Mexico, Netherlands, Poland, Portugal, Taiwan, Ukraine, Uruguay, Vietnam.

[31] Adapted from J. Richards, *Petty Patent Protection*, Proceedings of the Fordham University School of Law International Intellectual Property Law and Policy Conference 1995 (Juris Publishing and Sweet & Maxwell, 1998), Tables I and II. Updated 2002 at http://www.ladas.com/Patents/PatentPractice/PettyPatents/PettyP_c.html

Inventive Step Requirement

Not required	Bulgaria, Indonesia, Mexico, Netherlands, Russia, Turkey, Vietnam
Lower standard than for patents	**Australia**, Austria, Chile, Denmark, Finland, Germany, Ireland, Japan, Portugal, Taiwan
Same standard as for patents	Belgium, France, Korea, Spain

Examination required before Grant

Limited examination	**Australia**, Austria, Belgium, China, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, Panama, Peru, Russia, Slovakia, Spain, Turkey, Ukraine, Uruguay
Substantive examination	Argentina, Brazil, Bulgaria, Chile, Guatemala, Indonesia, Korea, Malaysia, Mexico, Philippines, Poland, Portugal, Taiwan, Vietnam

Maximum Term of Protection

Six Years	Belgium, France, Japan, Netherlands
Seven Years	Greece
Eight Years	**Australia**, Belarus, Finland, Russia, Ukraine
Ten years	Argentina, Austria, Brazil, Bulgaria, Colombia, Chile, China, Czech Republic, Denmark, Germany, Guatemala, Hungary, Indonesia, Ireland, Italy, Mexico, Panama, Peru, Poland, Slovakia, Spain, Turkey, Uruguay, Vietnam
Twelve Years	Taiwan
Fifteen Years	Korea, Malaysia, Philippines

11.2 *Appendix 2: Australian National Legislation*

11.2.1 Patents

The most important of the threshold tests in the Patents Act are:

- The invention must be a manner of new manufacture within section 6 of the Statute of Monopolies. Human beings, and the biological processes for their generation, are excluded from patentability;
- The invention must be novel, in the sense that it has not been previously performed or published;
- The invention must be inventive and not merely an advance that would be obvious to a person skilled in the field of the invention;
- The invention must be useful.

Patentable Subject Matter
Australia has traditionally maintained a broad view on the range of subject matter that can be patented. The current test for manner of new manufacture is from the 1959 High Court of Australia decision *National Research and Development Corporation v. Commissioner of Patents* [32]. In summary, a manner of new manufacture is "a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the field of economic endeavour"[33].

Plants, animals and processes for their creation are considered manners of manufacture provided they are artificially created and of economic use. According to the Australian Patent Office Manual, a chemical substance or micro-organism which is discovered in nature without any practical application is not patentable subject matter. However, a micro-organism, protein, enantiomer or antibiotic discovered in nature can be claimed in its isolated form if the patent specification provides some practical application for the isolated substance. Also, a gene can be claimed as the gene *per se* (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant, isolated or purified gene[34]. As in all technologies, the claim need not be restricted to the practical use developed by the inventor.

Scope of Rights
A patent gives the patentee the exclusive right, during the term of the patent, to 'exploit' the patented invention in Australia, including the right to make, hire, sell, use or import the invention, and/or authorise another person to do so. A patent lasts for up to 20 years, with a further extension for up to five years available for certain pharmaceutical patents. Annual renewal fees are payable from the fifth year.

[32] *National Research and Development Corporation v. Commissioner of Patents*, (1959) 102 CLR 252
[33] *CCOM v Jiejing*, 28 IPR 481, (1994) AIPC 91-079
[34] *Australian Patent Office Manual of Practice and Procedure Volume 2 - National*, Part 8.2.5.3

The Patents Act Explanatory Memorandum states that the intent is not to "modify the present law relating to certain acts which have been held not to constitute infringement - for example, use of an invention for certain experimental or trial purposes"[35]. However, Australian patent law provides no express exclusion to the rights of a patent holder for research or experimental use. Neither is there any Australian case law on this issue, although some UK and NZ case law suggests an exemption may apply, though only in very limited circumstances.[36] The issue of whether an explicit patent research exemption should be available is currently the subject of both an ACIP review "Patents and Experimental Use" and the ALRC inquiry "Intellectual Property Rights and Genetic Materials and Genetic and Related Technologies".[37]

A patentee may, however, be ordered by a court to grant a person a compulsory licence to work the patented invention.[38] To make such an order the court must be satisfied that the person has tried to obtain a licence on reasonable terms and conditions, that the reasonable requirements of the public with respect to the invention have not been satisfied, and that the patentee has given no satisfactory reason for failing to exploit the invention. Terms are determined by the court if the patentee and the person cannot reach agreement. Compulsory licences have never been granted in Australia, although it is argued that they pose a threat which often encourages parties to reach agreement where they otherwise would not have.

In 2000 the Intellectual Property and Competition Review Committee found in its report[39] that the conditions under which compulsory licences may be ordered related to the promotion of domestic industry, rather than with achieving high productivity and the best use of resources. The Committee recommended amendments which would ensure that orders for compulsory licences are obtained through the Australian Competition Tribunal and are only based on competition principles. The government agreed to add such a provision to the existing grounds for obtaining a compulsory licence[40]; however this would be available through the Federal Court, as with existing compulsory licencing, rather than the Australian Competition Tribunal. A bill implementing these changes is yet to be drafted.

Applications

On average it takes about three years from filing for an Australian patent application to be granted. Applications are typically examined about two years after being filed, and if objections to patentability are raised the applicant is given a further 21 months in which to address them. Applicants have significant power to speed up the process, but are allowed this time to determine the viability of their invention, to coordinate prosecution of the Australian application with foreign applications and to reduce up-front financial burdens.

Official IP Australia fees amount to about $1800 over the first eight years of a patent's life. The average total cost of pursuing a patent to grant in Australia using patent attorney

[35] Page 5
[36] *Frearson v Loe* (1876) 9 Ch D 48, 66-67.
[37] http://www.alrc.gov.au/inquiries/current/patenting/index.htm
[38] s.133-140
[39] *Review of Intellectual Property Legislation under the Competition Principles Agreement*, IPCRC, September 2000, http://www.ipcr.gov.au/
[40] http://www.ipaustralia.gov.au/pdfs/general/response1.PDF

services typically ranges from $7,000 to $10,000. Applicants have the option of applying for patents in other countries via the Patent Cooperation Treaty (PCT) system. The cost of filing a PCT application ranges from about $12,000 to $15,000. The overall cost of a PCT patent granted in a number of countries is approximately $100,000 over its lifetime.

Only a very small number of patents are granted each year in Australia for new plant breeds and processes for their creation (about 12 each). An even lower number are granted each year for new animals and processes (about 5 each). Most patented animals are used as models for medical research into human diseases. In comparison, the top five fields in which standard patents are granted are organic chemicals, pharmaceuticals, medical engineering, telecommunications and control/instrumentation. Around 1000 are granted in each field per year.

11.2.2 Innovation Patents

To be patentable, the claims of an innovation patent specification must meet the following main thresholds under section 18 of the *Patents Act 1990*:

- The invention must be a manner of new manufacture in the same manner as for standard patents, except that plants and animals, and the biological processes for the generation of plants and animals, are excluded from patentability.[41] Innovation patents are, however, available for microbiological products and processes;

- The invention must be novel in the same manner as for standard patents, in the sense that it has not been previously performed or published;

- The invention must involve an innovative step, in that there is a difference between the invention and the prior art which makes a substantial contribution to the working of the invention;

- The invention must be useful.

Scope of Rights
A maximum of five claims is allowed, but with no restriction on the type of claim. Innovation patents can only be enforced once they have been examined and certified. A third party can request examination, in which case the examination fee is shared equally between the third party and the applicant. A certified innovation patent gives the patentee the same rights as for a standard patent, and is also subject to the compulsory licence provisions. The patent can last for up to eight years, with annual renewal fees payable from the second anniversary.

Applications
On average it takes about one month for an innovation patent to be granted, and examination typically takes one month to be completed once it has been requested. If there are objections to patentability the applicant has six months in which to address this.

[41] s.18(3)

Without examination, official IP Australia fees amount to around $1100 over the eight year life of an Innovation patent. Examination and certification adds a further $290.

The top five fields in which innovation patents are granted are consumer goods and equipment, information technology, transport, handling/printing and agricultural/food machinery. Due to the system being relatively new and the flexible nature of the process, a stable pattern of use is yet to emerge. Each year a total of approximately 900 innovation patents are granted (unexamined) l, with around 100 of these being certified (after examination).

Approximately 70% of innovation patent applicants are individuals, the other 30% being organisations. This compares with about 15% individuals, 85% organisations for standard patent applications. About 90% of innovation patent applicants are Australian, compared with about 15% for standard patent applicants. Only about 5% of innovation patent applicants that are organisations are easily identifiable as multinationals. Less than 1% of innovation patent applicants are research/public organisations such as Australian government agencies, research councils, universities or CSIRO. This compares with about 9% for standard patent applications from Australian applicants.

Most innovation patent applications are sealed after being filed. About 10% of innovation patent applications are examined, and 7% of applications are certified. This compares with 87% of standard patent applications being examined, and 73% of applications being granted.

11.2.3 Plant Breeders' Rights

When Australia's PBR scheme was established, particular care was taken to balance private and public good rights. The following issues were taken into account:

- The need to bridge the previous gaps in intellectual property protection for plants;
- Australian agriculture is a major export industry[42], but relies on imported IP;
- Much agricultural commercial research and development in Australia is done under conditions of market failure. Rural Research and Development Corporations were introduced to promote greater efficiency and competitiveness, with funds sourced from industry statutory levies and the Commonwealth;
- Plant-based agriculture relies on access to the latest improvements and new variations; and
- Breeders utilise a wide range of existing breeding materials, and produce and commercialise small incremental improvements.[43]

[42] In 2001-2002 farm exports contributed $31.1 billion to the Australian economy, representing around 65% of total agricultural output (*Australian Agriculture, Fisheries and Forestry at a Glance 2003*, DAFF).
[43] *Submission to the Advisory Council on Intellectual Property, Examination of the Exclusion of Plants and Animals from Patentability under the Innovation Patent*, Department of Agriculture, Fisheries and Forestry, November 2002.

Criteria for Protection

The Australian PBR system provides protection for plant varieties. This includes transgenic plants, fungi and algae, but does not provide protection for bacteria, bacteroids, mycoplasmas, viruses, viroids or bacteriophages.[44]

A PBR can only be granted if a variety meets the following criteria[45]:

- Newness. A new variety is one which has not been sold with the breeder's consent, or has been only recently exploited. A recently exploited variety is one which has been sold with the breeder's consent for up to one year in Australia, and for up to four years overseas, with the exception of trees and vines for which a six year overseas prior sale limit is permitted.

- Distinctness. The variety must be distinct from all other varieties of common knowledge, and this is normally verified by conducting a comparative test growing which includes the new variety and the most similar varieties of common knowledge.

- Uniformity. A variety must be sufficiently uniform in its relevant characteristics, subject to the variation that may be expected from the particular features of its propagation.

- Stability. The relevant characteristics of a variety must remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

Scope of Rights

A PBR is granted for a period of 20 years from the date of grant or, in the case of trees and vines, for 25 years, provided annual renewal fees are paid. An Australian PBR provides an owner with the right to direct the production, sale and distribution of the new variety, receive royalties from the sale of plants, or to sell or licence their rights. This extends to varieties which are 'essentially derived' from the protected variety and certain dependent plant varieties. In certain circumstances, principally if the breeder has not had a reasonable opportunity to exercise the right on the propagating material, a PBR extends to harvested material and, subject to a similar set of qualifications, to products obtained from harvested material[46].

A PBR does not extend to processes of producing the variety; private, experimental or breeding use; nor to seeds saved from a farm crop, unless the crop is declared by regulation to be one to which farm saved seed does not apply. Currently no crops have been declared in this way. Also, the public has a right to reasonable access to the variety in terms of quantity, quality and price. The Secretary of DAFF has the power to provide a compulsory licence in appropriate circumstances[47]. The Federal Court may refuse to award damages, or make an order for the account of profits, if the infringer was not aware of and had no reasonable grounds for suspecting the existence of the PBR.[48]

[44] *Plant Breeders Right's Act 1994*, s.3
[45] s.43
[46] s.11 to s.15
[47] s.16 to s.19
[48] s.57

Essentially Derived Varieties

According to s. 4 of the Act, a plant variety is considered to be essentially derived from another variety if:

- it is predominantly derived from that other plant variety; and
- it retains the essential characteristics that result from the genotype of the combination of genotypes of that other variety; and
- it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.

A December 2002 report by an expert panel provides clarification of issues relating to 'breeding' and 'essential derivation' under the Act[49]. The Panel found that a breed is not essentially derived if it has an 'important' difference, and that this was consistent with the intent of the Act, which is to encourage new varieties and not copies. The Panel recommended that an owner's rights to essentially derived varieties should be extended to non-PBR varieties, and that the responsibility to determine essentially derived varieties is more appropriately a matter for the courts.

Applications

It typically takes 2.5 years to register a PBR in Australia. Full registration costs around $2000 in official DAFF fees, followed by an annual renewal fee of $300. The expertise of a Qualified Person is required for certain aspects of the application process, and many applicants employ the services of a Qualified Person for the entire application.[50]

Around 300 applications are made per year, reaching a total of around 3900 since the *Plant Breeder's Rights Act 1994* came into force. In 2000-2001 21% more applications were received than in 1998. Approximately 60% of all applications come from other countries. On average, one new variety is granted PBR every day, and at least 20 new varieties in the major export crops category are registered every year.[51]

[49] *Clarification of Plant breeding Issues under the Plant Breeders' Rights Act 1994*, Expert Panel on Breeding, December 2002, http://www.anbg.gov.au/breeders/index.html

[50] http://www.affa.gov.au

[51] *Submission to the Advisory Council on Intellectual Property, Examination of the Exclusion of Plants and Animals from Patentability under the Innovation Patent*, Department of Agriculture, Fisheries and Forestry - Australia, November 2002.

11.3 *Appendix 3: National Legislation in Other Countries*

11.3.1 European Patent Convention

Plants

Plant variety rights schemes were developed in some European countries in the 1960s. The *Strasbourg Convention of 1963*[52] provides that Contracting States are not bound to provide patents for plant and animal varieties. In 1973 the European Patent Convention (EPC) was signed, creating a regional arrangement that allows patent protection to be obtained in 19 member states by filing a single patent application at the European Patent Office (EPO). For legislative simplicity, the EPC adopted the wording of the *Strasbourg Convention* and specifically excluded "plant varieties" from patentability since they are protected under the UPOV Convention and national plant breeders' rights laws[53]. At the time when these legislative instruments were developed, the potential importance of biotechnology could not have been foreseen.

The EPO practice has been to narrowly interpret the exclusion of "plant varieties" in Article 53 as preventing conflict between patent and PBR systems.[54] The EPO considers that the purpose of the EPC exclusion was that European patents should not be granted for subject matter eligible for other protection, in accordance with the prohibition of dual protection under the 1978 UPOV Act.[55] The EPC and the 1961 UPOV Convention were intended to be complementary. Thus the Board of Appeal has held that a patent is for plant varieties, and therefore not patentable, only where the claimed subject matter is directed to plant varieties. Claims in which specific plant varieties are not individually specified are patentable, and this approach has been adopted by the EPO Implementing Guidelines.[56]

The prevailing interpretation by the EPO seems to be that the provisions do not exclude claims for plants "*per se*" but only claims for "varieties" of plants. Transgenic plants can be patented, so long as they are not expressed in "plant variety" terms and the invention is not confined to the modification of a particular plant variety. There seems to be increasing awareness that plant variety rights are more equipped to protecting plants at the varietal level while patents are suited to protecting products of plant biotechnology.

[52] Council of Europe, <http://conventions.coe.int/Treaty/EN/Treaties/Html/047.htm>.
[53] EPC, Art. 53.
[54] In *Ciba Geigy* (EPO T 49/83 – OJ 1984, 112) the EPO held that treated plants were capable of protection if the invention is not limited to a specific plant variety. However, in *Plant Genetic Systems* the EPO held that a plant becomes a plant variety when its genotype is altered by genetic engineering such that it satisfies the UPOV definitions of stability, homogeneity and capability of propagation. A claim that included plant varieties within its scope would not be allowed. After much controversy, *Novartis* (G 0001/98, 20 December 1999, OJEPO 2000, 111) appealed a test case relating to genetically modified plants, and the Enlarged Board of Appeal held that a claim will *not* be excluded from patentability under the EPC where specific plant varieties are *not* individually claimed.
[55] *Novartis*, Decision T 1054/96 Technical Board of Appeal 3.3.4., at 3.6, 13 October 1997.
[56] Rule 23c(b). This rule was modified to incorporate the *Novartis* decision.

Animals

Article 53 of the EPC also excludes "animal varieties" from patentability. The preparatory documents for the EPC do not refer to the purpose of excluding animal varieties from patentability.[57] There is no international system for the protection of animal varieties, no legal or economic reasoning for the exclusion, and it does not seem to be in accordance with original intention of contracting states. It appears that animal varieties were excluded from patent protection under the EPC on ethical grounds.

As with plant varieties, the EPO has construed the article narrowly, showing a willingness to grant patents for animals. Since there is no established system for protecting animal varieties, there is no established definition of what exactly constitutes an animal variety. The first Board of Appeal decision dealing with the patentability of an animal (*Harvard Oncomouse* case) noted that the terminology of "animal varieties" has a different meaning in the three official languages. This was used as an indication that the legislature intended to exclude patents on "animal varieties" rather than animals generally.

The Technical Board of Appeal of the EPO held that the expression "animal variety" refers to the lowest subdivision of species rather than something more general. Therefore, a claim for a mouse that was genetically manipulated to be sensitive to carcinogenic substances was not an animal variety and thus could be patentable under the EPC. It appears that the EPO transferred the reasoning applied in relation to plant varieties to animal varieties.[58]

The EPO Guidelines interpret the exception according to "ordre public" or "morality" as a test of whether the public would consider the invention so abhorrent that the grant of patent rights would be inconceivable.[59] In the Harvard Oncomouse case the Board applied a "careful weighing up of the suffering of animals and possible risks to the environment on one hand, and the invention's usefulness to mankind on the other".[60] The benefit of the Harvard Oncomouse invention to mankind in facilitating cancer research was found to outweigh possible animal suffering or environmental risks, and so it constituted patentable subject matter. Oppositions to this patent have been filed by many individuals, animal rights groups and church organisations, and are yet to be resolved.

[57] R. Nott, 'Patent Protection for Plants and Animals' (1992) 14(3) *EIPR* 79 at 82.
[58] W.R.Cornish, *Intellectual Property* (3rd ed, 1996) 193.
[59] Section C-IV, 3.1.
[60] W.R.Cornish, *Intellectual Property* (3rd ed, 1996) 470.

11.3.2 European Directive on the Legal Protection of Biotechnological Inventions

The objectives of the European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions (1998) are:

- To clarify the distinction between what is patentable and what is not;
- To harmonise national patent laws in the European Union (EU); and
- To provide uniform legal interpretation of specific points in relation to the patenting of living materials.[61]

The Directive ensures the patentability of living matter ("biological material") in general and establishes a narrow and specific exclusion in relation to plants and animals. The Directive provides that "plant and animal varieties and essentially biological processes for the production of plants or animals, including crossing or selection, are not patentable".[62] Thus, parts of animal varieties or animals produced by a patented method such as genetic engineering can be patented in the EU.

However, the Directive authorises EU Member States to *exclude* biotechnology inventions from patentability where their commercial exploitation conflicts with "ordre public" or morality[63]. The Directive contains an illustrative list of examples of such inventions, which includes processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The Directive entered into force in July 1998 and was to be implemented by Member States by July 2000, although only seven of the 15 member states have done so to date. The European Commission has referred the other eight to the European Court of Justice. Although the Directive does not possess binding force on the EPO, it has an indirect effect on the practice under the EPC.

Article 16(c) of the Directive stipulates that the Commission shall provide an annual report on the development and implementation of patent law in the field of biotechnology and genetic engineering. The first such report was released in October 2002 with the main conclusion that all Member states must swiftly implement the Directive or Europe will fall behind its competitors in this crucial sector.

11.3.3 United States

Plants

In the US patents have been granted for plants since 1930 under the *Plant Patent Act*, codified at 35 United States Code (U.S.C) 161-164. This statute provides protection for asexually reproduced plants, other than a tuber propagated plant or plants found in an uncultivated state. There is no provision for farm produced plants. In 1970 the *Plant*

[61] Official Journal of the European Communities (L 213/13) 30 July 1998, *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*.
[62] Art. 4.
[63] Art. 6.

Variety Protection Act[64] established a form of protection for new varieties of seed grown and tuber propagated plants, and complies with the 1991 UPOV Convention. Farmers have the right to use farm saved seed to reproduce plants on their farm, unless a variety has been identified otherwise.

Traditionally the USPTO did not grant utility (ie. standard) patents under 35 U.S.C 101 because it deemed products of nature not to be within the terms of the utility patent statute. Following the decision of *Diamond v. Chakrabarty*[65] in 1980 where the Supreme Court held that genetically altered bacteria constituted statutory subject matter, the US now provides patent protection for "anything under the sun that is made by man". The Court further stated that when determining patentability, the relevant distinction is not between living and inanimate things, but whether living products could be seen as 'human-made' inventions. According to the Supreme Court, a determination of patentability based on public safety concerns should be left to the legislative sphere rather than the court system.

The subsequent decision of *Ex parte Hibberd*[66] further extended the scope of patent protection in the US. The 1985 case of *Ex parte Hibberd* followed the *Chakrabarty* principle and held that US utility patents could be granted for genetically modified plants regardless of the protection available under the *Plant Patent Act of 1930* and the *Plant Variety Protection Act of 1970*. In 2001, the Supreme Court held that newly developed plant breeds (and thus sexually reproduced plants) are patentable subject matter, and that utility (standard) patents may be issued for plants.[67]

Animals

The *Chakrabarty* decision provided the grounds for granting patents for higher life forms. In 1987, the Board of Appeal in *Ex parte Allen*[68] considered animals to be patentable subject matter by holding that polyploid oysters were a non-naturally occurring manufacture or composition of matter and satisfied the criteria for proper subject matter. The court relied on the *Chakrabarty* decision and placed little emphasis on the ethical and moral objections to the granting of patents for living matter. Soon after the *Allen* decision, the USPTO issued an announcement that the US patents would be granted for "non-naturally occurring non-human multicellular living organisms including animals".[69] Subsequently, the USPTO issued a patent in 1988 to the transgenic mouse known as the Harvard Oncomouse. Although heated debates ensued concerning the patentability of an animal, the USPTO has accepted transgenic animals as patentable subject matter.

Public outrage surrounding animal patenting was evidenced in the 1989 Animal Legal Defence Fund challenge,[70] when animal and farmers rights groups argued that the USPTO did not possess the authority to issue the 1987 statement on the patentability of animals. The court held that the appellants lacked standing and rejected their arguments

[64] 7 U.S.C Chapter 57
[65] *Diamond v. Chakrabarty* 447 U.S. 303 (1980).
[66] 227 USPQ 443.
[67] *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 122 S.Ct. 593 (2001).
[68] *Ex parte Allen*, 2 U.S.P.W.2d (BNA) 1425, 1425-27 (PTO Bd. Pat. App. & Inter. 1987).
[69] Animal-Patentability, 1077 Official Gazette of USPTO 24 (1987).
[70] *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 924 (Fed. Cir. 1991).

that the general public has an interest in limiting patentability by statute. The court did not address wider societal concerns regarding animal patenting but stated that the appellant's action may not have the desired effect of preventing animal development research because excluding subject matter from patentability does not prohibit research or development on animals. The court noted that under the principles espoused by the *Chakrabarty* decision, the question in determining patentability is simply whether the "subject matter is made by man."[71]

11.3.4 Canada

Plant Breeder Rights

PBR are provided for sexually or asexually reproducing varieties under the *Plant Breeders' Rights Act 1990* in harmony with the 1978 UPOV Convention. All plant species except for algae, bacteria and fungi are eligible for protection.

Patents

The Canadian Patent Office has consistently held the view that while the Canadian *Patent Act 1985* does not exclude plant and animal subject matter as such, the Act does not allow the patenting of higher life forms such as plants and animals.[72] Canada does not have a second tier patent system.

The patent for the *Harvard Oncomouse* was rejected by the Canadian Patent Office in 1993, which held that the animal was made primarily by nature rather than humans. The Commissioner of Patents upheld the rejection in 1995, as did a federal trial court in 1998. A majority of the Canadian Federal Appeals Court reversed these decisions in August 2000 and approved the patent, stating that the patenting of animals was not prohibited by the Canadian *Patent Act*. Considerable reliance was placed on the majority opinion of the United States Supreme Court in *Chakrabarty*.[73]

On appeal, in December 2002 the Supreme Court of Canada decision *Commissioner of Patents v. President and Fellows of Harvard College*[74] reversed the Federal Court decision. The 5:4 majority held that a higher life form is not patentable because it is not a "manufacture" or "composition of matter" within the meaning of "invention" in s. 2 of the *Patent Act*. The Court considered that the adoption of the *Plant Breeders' Rights Act* and the fact that the *Patent Act* is ill-equipped to deal with higher life forms were indicators that Parliament never intended for higher life forms to be patentable. The Court suggested that it be for Parliament to decide significant policy issues that appeared to require a dramatic expansion of the traditional patent regime. The majority also considered that the self replicating ability of life forms meant that the scope of a patent would extend to cover the progeny containing the patented invention, an increase in rights not in line with other fields. The potential impact of this on the agricultural industry was noted. The Court did however confirm that the process claims for creating the Oncomouse and the claims to lower life forms, such as DNA and cellular constructs were patentable. Consequently the actual impact of this decision on biotechnology

[71] Id at 928, citing *Ex parte Allen*.
[72] Manual of Patent Office Practice, Ch. 16, section 16.05 Living Matter and section 16.04 Examples of Non-Statutory Subject-Matter.
[73] *President and Fellows of Harvard College v. Commissioner of Patents [Respondent] and Canadian Environmental Law Association [Intervenor]* (2000) A-334-98.
[74] (2002), 21 C.P.R. (4th) 417 (S.C.C.)

patents may be limited. Lower lifeforms such as microorganisms continue to be patentable

The Canadian government has recognised the issue as one of significant public interest, and established the Canadian Biotechnology Advisory Committee in September 1999 to give policy advice on matters relating to biotechnology. The Committee released a report on the *Patenting of Higher Life Forms and Related Issues*[75] in June 2002, which recommended that higher life forms (seeds, plants and non-human animals) that meet the criteria in the *Patent Ac*t should be patentable, subject to certain limits.[76] The Canadian government has not yet responded to this report.

11.3.5 Japan

Plant Breeder Rights

PBR are provided under *Seeds and Seedling Law 1998*, in conformity with the 1991 UPOV Convention.

Patents

Like the EPC and the European Directive, Japanese patent law excludes from patentability inventions that are contrary to public order or morality.[77] However, unlike the EPC and the Directive, the Japanese Patent Office considers that morality and safety issues are irrelevant for the purposes of determining whether plants and animals are eligible for patenting; rather these should be addressed by other legal measures.[78] As a consequence animal and plant inventions constitute patentable subject matter, and Japanese patent law makes no distinction between plant and animal "varieties" or plants and animals themselves.

The "Implementing Guidelines for Inventions in Specific Fields"[79] stipulates "An invention of a plant per se does not have an inventive step, where characteristics of the plant created can be easily predicted from the characteristics of publicly known plants within the species to which the plant belongs, and where the invention does not have advantageous effects that a person skilled in the art cannot foresee." According to conventional practice it is very difficult to obtain a patent for a plant variety bred by traditional biotechnology. This is because most such plant varieties are created through crossing within the same species, hence exhibiting very similar characteristics, and it is relatively easy from a technical point of view.[80]

The guidelines for patenting of animals is almost identical to that of plants, however there are a large number of patents to animals bred by traditional biotechnology. This may be partially due to many laboratory animals being bred with a novel characteristic

[75] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (2002).
[76] Limits include exceptions for farmers, innocent bystanders (see *Monsanto Canada Inc. v. Schmeiser*) and research and experimental use.
[77] Japanese Patent Law, Law No. 121 of 1959, amended by Law No. 220, Article 32.
[78] A. Watanabe, 'Animal Patent Protection' (1994) 3 *Inst. Intell. Prop. Bull*. 140 at 144.
[79] Chapter 2 Biological Inventions, 1. Genetic Engineering, 3. Plants, 1997.
[80] Y. Hiraki, 'Bio Patent' (1999), Asia-Pacific Industrial Property Center, Japan Institute of Invention and Innovation, 48.

for experimental purposes not found in known animals, and so meeting the inventive step requirements.[81]

Utility Models

Japanese law provides Utility Models as second tier patent protection. This form of protection lasts for 6 years and is intended for items which have a short life cycle and the potential for early implementation. Forms of products, structures, or combinations of related items which were created using creative technological concepts based on natural laws and rules[82] may all be protected. Methods relating to products may not be protected if they only relate to shapes and forms of products. A lower level of creativity applied to creation of a technological concept is required than is the case for patent law.

[81] *Ibid*, 50.
[82] New Utility Model Law, Art 2 and 3.

11.4 *Appendix 4: Participants in the Review*

ACIP thanks all parties who participated in this inquiry, particularly IPRIA and DAFF, who made major contributions to parts of this report.

11.4.1 Submissions

The following made submissions in response to the Issues Paper and June 2003 round-table discussions:

1. Australian Research Council
2. Biotechnology Australia
3. Bureau of Sugar Experiment Stations
4. Department of Agriculture, Western Australia
5. Department of Primary Industry, Queensland
6. Australian Federation of Intellectual Property Attorneys
7. Griffith University
8. Institute of Patent and Trade Mark Attorneys of Australia
9. NSW Agriculture
10. National Health and Medical Research Council
11. Seed Industry Association of Australia
12. University of Canberra
13. University of Melbourne
14. University of Adelaide
15. Commonwealth Scientific and Industrial Research Organisation
16. Department of Primary Industries, Water and Environment, Tasmania
17. Intellectual Property Research Institute of Australia
18. La Trobe University
19. Prof. Alec Lazenby
20. Meat and Livestock Australia
21. University of the Sunshine Coast
22. Australian Centre for Intellectual Property in Agriculture
23. Australian Institute of Marine Science
24. AWB Limited
25. Department of Agriculture, Fisheries and Forestry
26. Department of Primary Industries, Victoria
27. Environment Australia
28. Grains Council of Australia
29. Grains Research and Development Corporation
30. Sheepmeat Council of Australia
31. University of Sydney
32. University of Wollongong
33. AgResearch Grasslands

11.4.2 Round Table

The following attended the round-table discussion held in Melbourne in June 2003:

1. Mr David Adamthwaite	Meat and Livestock Australia & the Sheepmeat Council of Australia
2. Mr Chris Adriaansen	Department of Primary Industry, Queensland
3. Mr Stewart Anderson	Department of Primary Industry, Victoria
4. Mr Geoff Budd	Grains Research and Development Council
5. Mr Karl Divers	AWB Limited
6. Dr John Golding	University of Sydney
7. Ms Melanie Howlett	Intellectual Property Research Institute of Australia
8. Mr Peter Huntsman	Federation of Intellectual Property Attorneys
9. Dr Peter Janssen	La Trobe University
10. Mr Peter Jones	Meat and Livestock Australia Ltd & the Sheepmeat Council of Australia
11. Dr Charles Lawson	Australian Centre for Intellectual Property in Agriculture
12. Mr David Liesegang	Agriculture Victoria Services Pty Ltd
13. Mr Len Marsden	Australian Research Council
14. Mr Chris Melham	Seed Industry Association of Australia Ltd
15. Mr Bala Murali	Department of Agriculture, WA
16. Mr Peter Neilson	Seed Industry Association of Australia Ltd
17. Dr Mathew Rimmer	Australian Centre for Intellectual Property in Agriculture
18. Mr Malcolm Royal	Institute of Patent and Trade Mark Attorneys of Australia
19. Prof Brad Sherman	Griffith University
20. Ms Karen Sinclair	Federation of Intellectual Property Attorneys
21. Prof Mohan Singh	The University of Melbourne
22. Dr Kamal Singhe	Department of Industry, Tourism and Resources
23. Mr Doug Waterhouse	Department of Agriculture, Fisheries and Forestry - Australia
24. Dr Elane Zelcer	National Health and Medical Research Council

11.5 *Appendix 5: Abbreviations*

ACIP	Advisory Council on Intellectual Property
ACIPA	Australian Centre for Intellectual Property in Agriculture
AIMS	Australian Institute of Marine Science
DAFF	Department of Agriculture, Fisheries and Forestry
ALRC	Australian Law Reform Commission
ARC	Australia Research Council
BSES	Bureau of Sugar Experiment Stations
CBD	Convention on Biological Diversity
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAWA	Department of Agriculture Western Australia
DPIQLD	Department of Primary Industries Queensland
DPITAS	Department of Primary Industries Water and Environment Tasmania
DPIVIC	Department of Primary Industries Victoria
EC	European Commission
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FICPI	Federation of Intellectual Property Attorneys
GCA	Grains Council of Australia
GRDC	Grains Research and Development Corporation
IGC	World Intellectual Property Organisation Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IP	Intellectual Property

IPRIA	Intellectual Property Research Institute of Australia
IPTA	Institute of Patent and Trade Mark Attorneys of Australia
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MLA	Meat and Livestock Australia
NHMRC	National Health and Medical Research Council
NRE	Former Department of Natural Resources and Environment Victoria
PCT	Patent Cooperation Treaty
PBR	Plant Breeders' Right
SIAA	Seed Industry Association of Australia
SMEs	Small to Medium Sized Enterprises
TRIPS	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
USC	United States Code
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization