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Council for Trade-Related Aspects of Intellectual Property Rights

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REVIEW OF THE PROVISIONS OF ARTICLE 27.3 (b)

Information from Members

Addendum

AUSTRALIA

The present document represents the information requested by the Council for Trade-Related Aspects of Intellectual Property Rights which the Secretariat has received from Australia, by means of a communication from its Permanent Mission, dated 10 March 1999.

I. INTRODUCTION

Australia has a long established and well developed system for the protection of intellectual property which aims to advance the collective public interest by promoting innovation, access to and the application of new technologies, and investment in productive activities: it seeks to serve, in a balanced way, the interests of the general public, the research and scientific communities, and the commercial and industrial sectors. Australia welcomes this opportunity to exchange information on the functioning of national intellectual property systems in relation to the subject matter of Article 27.3(b) of the TRIPS Agreement, which comprises a range of technologies with potential economic and social benefits for all societies. This document accordingly provides responses to the questions circulated by the Secretariat and the complementary questions circulated by Canada, the European Communities, Japan and the United States (IP/C/W/126).

The main legislative provisions relevant to Article 27.3(b) are the *Patents Act 1990*[1] and the *Plant Breeders Rights Act 1994*,[2] which respectively provide the legislative basis for the patent system and the system for plant variety protection. Both laws have been notified to the WTO. The two systems operate independently in practice, and the grant of a right under one system does not in itself affect any entitlement under the other system, provided all conditions for eligibility are met.

Under the Patents Act patenting of biotechnology inventions is allowed. The issue of whether genes and life forms should be excluded from the patents system was considered during parliamentary debate to the legislation in 1989. The result of the debate was a single exclusion – human beings and biological processes for their generation. Therefore, in Australia, provided the patent application meets all the usual requirements for patentability (i.e. is novel, inventive, fully described etc.), a biotechnology patent will be treated no differently from any other patent application, in line with the

[1] Document IP/N/1/AUS/P/1.
[2] Document IP/N/1/AUS/P/2.

general TRIPS principle (Article 27) that patent rights should be available regardless of the field of technology concerned.

The Plant Breeder's Rights Act provides for certain exclusive commercial rights to a registered plant variety. Only new or recently exploited varieties can be registered. A new variety is one which has not been sold with the breeder's consent. A recently exploited variety is one which been sold with the breeder's consent for up to 12 months in Australia and for overseas varieties this limit is up to four years (with the exception of trees and vines for which a six year overseas prior sale limit is permitted). To be eligible for protection the applicant must show that the new variety is distinct, uniform and stable. To obtain acceptance of an application and provisional protection it must be established that there is a prima facie case that the variety is distinct from all other varieties of common knowledge. To obtain a grant of PBR the applicants must verify these claims normally by conducting a comparative test growing which includes the new variety and the most similar varieties of common knowledge.

II. RESPONSES TO THE ILLUSTRATIVE LIST OF QUESTIONS PREPARED BY THE SECRETARIAT (DOCUMENT IP/C/W/122)

A. PATENT PROTECTION OF PLANT AND ANIMAL INVENTIONS

1. To what extent are inventions concerning plants or animals, whether products or processes, patentable under your country's law, if they meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement?

All inventions, whether products or processes, concerning plants and animals, are eligible to be patented under the Australian *Patents Act 1990* (Patents Act) provided they meet all other requirements of patentability as set out in the Act. Human beings and the biological processes for their generation are the only exceptions (section 18(2)). The requirements of the Patents Act are consistent with the conditions for patentability set out in Article 27.1 of TRIPS.

2. Where any such inventions are not patentable, even if they meet these conditions:

(i) To what extent is this due to per se exclusions from patentability?

(ii) To what extent is this based on other grounds (for example because conditions for patentability other than those stipulated in Article 27.1 are not met or in order to protect ordre public or morality (see Article 27.2 of the Agreement)?

See answer to Question 1. The Australian Patents Act has no specific exclusions from patentability (except section 18(2)), based on ethical or moral grounds, of inventions being either products or processes and concerning plants and animals. However the grant of a patent for an invention may be refused on the ground that the use of the invention would be contrary to law (section 51(1)).

3. Please describe any specific provisions, guidelines, final judicial decisions and administrative rulings of general application concerning the application of the conditions for patentability stipulated in Article 27.1 to subject matter addressed by Article 27.3(b).

See answer to Question 1. The definition for patentable inventions is set out in section 18 of the Patents Act.

4. Where plant varieties are not as such patentable subject matter under your country's law, please indicate the extent to which the scope of protection under patents for inventions concerning plants can nevertheless embrace plant varieties or a botanical taxon whose plants express a trait covered by the claims of a patent.

In Australia, plant varieties are patentable subject matter.

5. Please provide any definitions used under your country's law with regard to subject matter specifically excluded from patentability or specifically patentable (e.g. micro-organisms, microbiological processes, non-biological processes, plant varieties).

See answer to question 1. Section 18(2) of the Patents Act provides that:

> Human beings, and the biological processes for their generation, are not patentable inventions.

6. To what extent is subject matter that is identical to what occurs in nature patentable under your country's law?

If a claim defines a product or composition *per se* which already exists in nature it is neither a "manner of manufacture" nor novel and therefore is considered non-patentable under the Patents Act. If there has been any technical intervention of man to change the form of the product from that in which it existed in nature, the product would be patentable, provided it meets the requirements of patentability such as inventiveness and novelty. Thus a claim to protein x, which existed in nature, is unpatentable whereas a claim to an isolated and purified protein x would be patentable. Specific DNA sequences are generally considered fragments of chromosomes. As they do not occur in isolation in nature, they are patentable. Methods or processes of making products that occur in nature are patentable.

7. Explain the requirements under your country's law for ensuring adequate disclosure of the patentable inventions referred to above.

In Australia, a patent application must be published about 18 months after its earliest priority date. The public is notified in the *Australian Official Journal of Patents* (AOJP), copies of which are held in IP Australia offices around Australia. Published patent specifications are then made available to the public and are sent to certain libraries and overseas patent offices. From late January 1999, it is planned to also deliver the specifications on CD-ROM and via the internet.

Section 40(2)(a) of the Patents Act sets out the requirements of a complete specification:

> "A complete specification must:
> describe the invention fully, including the best method known to the applicant of performing the invention."

The specification is considered sufficient if, on reading it, a skilled worker can understand the nature of the invention and how to put it into practice. The skilled worker must have a reasonably competent knowledge and skill in the art to which the patent applies. He/she can use this knowledge and skill to rectify any mistakes, supply omissions in the specification or to conduct routine trials as long as this does not require the exercise of any inventive faculty. If the skilled worker has to exercise prolonged research, inquiry, experimentation or further invention in order to put the described invention in practice then the specification would not be sufficient. In summary, where a skilled worker could practise an invention using well known techniques without an undue burden of

experimentation, the Patent Office would not require specific details or examples concerning the practice of the invention to be provided in the specification.

Section 41 of the Patents Act sets out the additional requirements for specifications relating to micro-organisms.

In summary, a deposit is strictly necessary if:

(1) an invention involves the modification or cultivation of a micro-organism (other than where the micro-organism itself is an invention); and

(2) a person skilled in the relevant art in the patent area could not be reasonably expected to perform the invention without having a sample of the micro-organism ; and

(3) the micro-organism is not reasonably available to a person skilled in the relevant art in the patent area.

The Patent Office would also require a deposit if the claimed micro-organism could not be reasonably expected to be obtained by reproduction or generated based on the information supplied in the specification, for example where the invention resides in an organism produced by a random mutation process or is a specific hybridoma secreting a particular monoclonal antibody.

Otherwise deposits are not required but applicants can choose to deposit if they wish. The Patent Office accepts that a written description can in some circumstances provide the skilled worker with enough detail to reproduce the inventive micro-organism and that this information would be a sufficient disclosure.

The Patent Office does not accept deposits made with institutions other than those recognised under the Budapest treaty. However if the invention and claims relate to a use, cultivation or modification of a micro-organism, the office accepts that deposits other than those made by the applicant could be readily available as required by point (3) above. In that circumstance, the applicant would not require a Budapest Treaty deposit.

The Patent Office accepts any form of deposit that is reproducible and which is accepted by international depository authorities (including plant cell cultures, plasmids and seeds) but notes that international depository authorities have limitations on the nature of materials they will accept and the Patent Office is bound by any such limits.

8. What rights are conferred upon owners of the patents referred to above? Are product and process patents subject to the same rules as other patents? Do they benefit from the same protection as stipulated in Article 28 of the TRIPS Agreement?

The owners of all patents (including plant and animal patents) have a fixed term exclusive right to exploit the invention or authorise another person to exploit the invention. Provided renewal fees are paid, the term of a standard patent in Australia is 20 years from the date of filing the complete application.[3] As in most other countries, "exploit" includes the manufacture, use, importing and marketing of the invention. The exclusive right to exploit the invention is not unconditional in that, although the right provides for the exclusion of other parties, it does not confer on the patentee the right to perform the invention. Many patented inventions are developments of previous ones and the

[3] Extensions of up to five years can be granted for 20 year patents for pharmaceutical substances to compensate for the time taken to obtain regulatory approval.

rights overlap. In these situations the patentee may need to seek a licence from the rights holder of the earlier technology.

In Australia, product and process patents are subject to the same rules as other patents. However see also the answer to question 7.

Plant and animal patents confer on their owners the same protection as stipulated in Article 28 of the TRIPS Agreement. Owners of product patents by taking infringement action can prevent third parties from making, using, offering for sale, selling or importing patented products without their consent. Similarly, owners of process patents can prevent third parties from using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

9. Are there any specific exceptions to these rights (affecting the scope or duration of the patents referred to above)? To what extent are exceptions, available in respect of plant variety rights (e.g. those referred to under B.4(i) below), available in respect of rights conferred upon patent owners?

In Australia, there are no exceptions affecting the scope or duration of animal and plant patents in particular. See also the answer to question 10 below.

10. Are there any specific provisions under your country's law for compulsory licensing in respect of the patents referred to above?

There are no specific provisions under Australian law for compulsory licensing of plant and animal patents. However, in relation to patents generally (including plant and animal patents) there are two instances where a party can obtain the right to use a patented invention regardless of the technology without the authorisation of the patent holder:

(1) Under section 133 of the Australian Patents Act, a compulsory license can be granted to a third party if the patentee has not met the reasonable requirements of the public with respect to the patented invention and has not given a satisfactory reason for having failed to exploit the invention; and

(2) Under section 163 of the Australian Patents Act, the Commonwealth or a State of Australia can exploit the invention without infringement for the services of the Commonwealth or State. The patentee may be entitled to some compensation from the Commonwealth or State if their invention is used in this way.

B. PROTECTION OF PLANT VARIETIES

1. Does your country's law provide for the protection of plant varieties by plant breeder's rights, plant patents or any other sui generis system for the protection of plant varieties?

Protection of plant varieties is provided by a system of plant breeder's rights under the *Plant Breeders Rights Act 1994*.

2. (a) If your country is a party to the International Convention for the Protection of New Varieties of Plants (UPOV), please indicate which Act or Acts of the UPOV Convention your country has signed; which it has ratified; to which it has acceded; and to the standards of which its law conforms but to which it has not (yet) adhered.

Australia is party to the 1978 Act of the UPOV Convention. The Plant Breeder's Rights Act 1994 conforms to the 1991 Act of the UPOV Convention.

(b) If your country is not a party to the UPOV Convention, does the protection offered to plant varieties under your country's law conform to the standards of any of the Acts of the UPOV Convention and, if so, which?

Not applicable.

3. Please indicate whether concurrent protection under your country's plant variety protection law and its patent law is available (see also question A.4 above).

Yes. Eligibility for protection under the two systems is determined according to independent criteria.

4. Please provide the following details of your country's sui generis system for the protection of plant varieties:

(a) the relevant laws and regulations and, if they have been notified to the Council for TRIPS, a reference to the relevant WTO documents;

The Plant Breeder's Rights Act 1994 (notified to the Council for TRIPS as IP/N/1/AUS/P/2).

(b) the definition of "plant variety";

Section 3 of the Plant Breeder's Rights Act provides that:

"plant variety" means a plant grouping (including a hybrid):

(a) that is contained within a single botanical taxon of the lowest known rank; and

(b) that can be defined by the expression of the characteristics resulting from the genotype of each individual within that plant grouping; and

(c) that can be distinguished from any other plant grouping by the expression of at least one of those characteristics; and

(d) that can be considered as a functional unit because of its suitability for being propagated unchanged.

Note: Plant groupings for the purposes of this definition include genetically modified plant groupings.

(c) the conditions required for protection;

A variety is registrable if: it has a breeder; and is distinct, uniform and stable. It must also be new or only recently exploited (A new variety is one which has not been sold with the breeder's consent. A variety is taken to be recently exploited if propagating or harvested material of the variety has been sold, with the breeder's consent, for up to 12 months in Australia. For sales made in the territory of another contracting party (UPOV Member State) the limit is up to four years for all taxa (with the exception of trees and vines for which a six-year time limit on sales is permitted).

To obtain acceptance of an application and provisional protection it must be established that there is a *prima facie* case that the variety is distinct from all other varieties of common knowledge. To obtain a grant of PBR the applicants must verify these claims normally by conducting a

comparative test growing which includes the new variety and the most similar varieties of common knowledge.

(d) the extent to which subject-matter that is already known to the public or identical to what occurs in nature is protectable under your country's sui generis system for the protection of plant varieties;

(See conditions for eligibility in question (c) above.)

(e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;

Protection is based on the expression of the characteristics of the genotype (see definition of variety in question (a) above. Techniques, such as DNA profiling, are not accepted as sole evidence in support of a claim for distinctiveness unless a causal relationship between the expression and the distinguishing sequence has been established.

(f) who is entitled to the rights;

Applications are accepted from the original breeder of a new variety (from their employer if the breeder is an employee of an organisation) or from a person who is the successor to the breeder or has acquired ownership rights from the original breeder by operation of law. Where two or more persons breed a variety, a joint application can be accepted.

(g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;

(i) Completion of Part 1 of the approved application form including: a brief description sufficient to establish a *prima facie* case that the variety distinct from other varieties of common knowledge features; a photograph of the variety, information on the location and manner by which the variety was bred; a statement that the applicant is the breeder or evidence to support the transmission of the right to apply from the original breeder; an acceptable denomination; particulars of protection in other countries; and the nomination of an accredited 'Qualified Person'.

(ii) Payment of the application fee.

(iii) If the variety is an Australian species, dispatch to the Australian Cultivar Registration Authority of a herbarium specimen;

(iv) Engagement of the services of the nominated accredited 'Qualified Person' to plan and supervise the comparative growing trial.

(v) Conduct a comparative growing trial to demonstrate Distinctness, Uniformity and Stability (DUS), including the completion of Part 2 of the application form and payment of the examination fee.

(vi) Deposit of propagating material in a Genetic Resources Centre.

(vii) Examination of the application by the PBR Office, which may include a field examination of the comparative growing trial; and including:

- publication of a description and photograph comparing the new variety with similar varieties in Plant Varieties Journal,

- followed by a six-month period of public exposure for objection or comment.

(viii) Upon successful completion of all the requirements, resolution of objections (if any) and payment of certificate fee, the applicant(s) receive a Certificate of Plant Breeder's Rights.

The Plant Breeder's Rights Act is administered by the statutory office of the Registrar of Plant Breeder's Rights.

(h) the rights conferred;

Successful applicants have exclusive rights in relation to propagating material to do, or license another person to do:

(i) produce or reproduce the material;

(ii) condition the material for the purpose of propagation (conditioning includes cleaning, coating, sorting, packaging and grading);

(iii) offer the material for sale;

(iv) sell the material;

(v) import the material;

(vi) export the material; and

(vii) stock the material for any of the purposes described in (i) to (vi) above.

PBR rights can be extended to the harvested material or products obtained from the harvested material when the grantee has not had a reasonable opportunity to exercise their rights in relation to the propagating material.

Rights can also extend to essentially derived varieties and dependant varieties.

(i) exceptions to the rights conferred, such as

- *acts performed for research or experimental purposes;*
- *acts performed to develop new varieties of plants;*
- *acts performed to commercialize such newly developed varieties;*
- *any "farmer's privilege" (e.g. acts performed by a farmer on his own land in respect of seed saved from the previous harvest);*
- *acts done privately and for non-commercial purposes;*
- *compulsory licensing.*

Exceptions are allowed (subject to the detailed provisions of the Act) for any act done in relation to a plant variety covered by PBR that is done:

- privately and for non-commercial purposes; or

- for experimental purposes; or

- for the purpose of breeding other plant varieties; does not infringe the PBR.

Further exceptions are allowed in relation to farm-saved seed (unless a particular taxa is declared exempt from this provision), and acts related to use of propagating material as a food, food ingredient or fuel or for any other purpose that does not involve the production or reproduction of the propagating material (e.g. the use of propagating material of a plant by way of allowing it to sprout and then eating it, or using it in the preparation of food, before it has developed further)

Certain compulsory licensing provisions may apply if the grantee of PBR in a plant variety does not take all reasonable steps to ensure reasonable public access to that plant variety. Reasonable public access to a plant variety covered by PBR is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand. This entails the granting of a license to sell and to produce propagating material of plants of that variety for sale on such terms and conditions (including the provision of reasonable remuneration to the grantee) as is considered would be granted by the grantee in the normal course of business.

New or existing grants of PBR may be made subject to conditions in the public interest.

(j) the duration of protection;

In tree and vine varieties, PBR continues for 25 years from the date of granting, and in all other varieties, for 20 years from the date of granting.

(k) transfer of rights;

Both the right of the breeder to make application for PBR, and a granted PBR, can be assigned or transmitted to another party by will or by operation of law.

(l) enforcement of the rights.

An action for infringement of PBR may be brought before the Federal Court. Infringement includes unauthorised infringement of the exclusive rights (set out in (h) above), an unauthorised claim to have one of these exclusive rights, and the use of a registered variety name in relation to any other plant variety or a plant of any other plant variety.

A counter-claim for revocation of a PBR may be made in infringement proceedings. The Federal Court is also competent to issue a declaration as to non-infringement, upon application.

III. RESPONSE TO COMPLEMENTARY QUESTIONS CIRCULATED BY CANADA, THE EUROPEAN COMMUNITIES, JAPAN AND THE UNITED STATES

A. PATENT SYSTEM QUESTIONS

1. In your territory, is there <u>any</u> basis for denying a patent on an invention consisting of an entire plant or animal that is novel and involves an inventive step?

Human beings and the biological processes for their generation are not patentable subject matter (section 18(2)). The grant of a patent for an invention may also be refused on the ground that the use of the invention would be contrary to law (section 51(1)).

2. If the answer to question 1 is 'yes', please respond to the following questions:

(a) Does your patent system exclude entire plants or animals as inventions? If it does, please cite the legal basis for this.

Not applicable.

(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes all, please cite the legal basis for their exclusion (e.g. lack of industrial applicability). If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded and cite the legal basis for their exclusion.

Not applicable.

(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step and are capable of industrial application? If so, please cite the legal basis for that exclusion from patent eligibility.

Not applicable.

3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?

(a) A patent claim that is not limited to a specific plant or animal variety.

Yes.

(b) A patent claim that is expressly limited to a plant or animal variety.

Yes.

(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.

Yes.

(d) If the answers you provide to question (3)(a) to (c) vary, please provide the definitions of a "plant variety" and an "animal variety" that are used by your examining authority.

Not applicable.

4. Is it possible to obtain a patent in your territory on a microorganism that is novel, involves an inventive step and is capable of industrial application? If not, please identify the legal basis under which these inventions are deemed ineligible to be patented.

Yes.

5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)? If not, please identify the legal basis under which a patent on such a process would be denied.

Yes.

6. Is it possible to obtain a patent in your territory covering subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?

If a claim defines a product or composition *per se* which already exists in nature it is neither a "manner of manufacture" nor novel and therefore is considered non-patentable. If there has been any technical intervention of man to change the form of the product from that in which it existed in nature, the product would be patentable, provided it meets the requirements of patentability such as inventiveness and novelty. Thus a claim to protein x, which existed in nature, is unpatentable whereas a claim to an isolated and purified protein x would be patentable. Specific DNA sequences are generally considered fragments of chromosomes, which do not exist in nature and are therefore patentable. Methods or processes of making products that occur in nature are patentable.

B. PLANT VARIETY PROTECTION SYSTEMS

7. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?

Yes.

8. If the answer to question 7 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?

Yes.

9. If the answer to question 8 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).

The 1991 Act.

10. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:

(a) acts performed for research or experimental purposes, or to develop new varieties of plants;

No.

(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics;

Yes, provided that:

(i) the distinct variety has been declared an essentially derived variety from the protected variety; or

(ii) the production of the distinct variety required the repeated use of protected variety (i.e. the distinct variety is a dependant variety).

(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land.

No, unless the taxa is one declared by regulation to be one to which the farm saved seed exemption does not apply (currently no taxa have been subject to such a declaration).

If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?

The exercise of PBR rights is at the discretion of the rights holder and legislation does not stipulate remuneration except in respect of the issue of a compulsory license or acquisition. However, in circumstances where the harvested material or product from harvested material has been produced without a reasonable opportunity for the grantee to exercise their right on the propagative material (eg through the operation of farm saved seed), and the use of that harvested material or product does not qualify as an exemption (see answer to question (*i*) above), the grantee may choose to exercise their rights on the harvested material or product as if it was the propagative material.

11. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection).

Only new or recently exploited varieties can be registered. A new variety is one which has not been sold with the breeder's consent. A recently exploited variety is one which been sold with the breeder's consent for up to 12 months in Australia and for overseas varieties this limit is up to four years (with the exception of trees and vines for which a six year overseas prior sale limit is permitted).

12. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?

No.