

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)

Information from Members

Addendum

UNITED STATES

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

The information provided below is offered for consideration by the Council for TRIPS regarding practices in the United States related to patent protection concerning plants and animals, and plant variety protection. The information is limited to issues that are relevant to the subject matter of Article 27.3(b). In that regard, any information concerning animals is strictly confined to animal organisms other than a human being, as the latter was never considered patentable subject matter in any WTO Member.

We offer this information in response to the invitation from the TRIPS Council expressed through the illustrative list of questions prepared and circulated by the WTO Secretariat.¹ Please note that we have elected to phrase and respond to the issues in a slightly different form. We believe the information as provided below, and as contained in our response to a similar fact-finding exercise conducted in the OECD², responds to those issues raised by the illustrative list of questions that are relevant to the review specified in Article 27.3(b). We also believe that the presentation of information in this form³ will facilitate preparation of a synoptic table that can simplify the review process by comparing relevant elements of patent and plant variety systems in WTO Members.

A. PATENT SYSTEM ISSUES

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

Yes. To be patentable, every invention must also satisfy the requirement of utility set forth in Section 101 of title 35, United States Code, as well as the requirement under Section 112 of title 35, United States Code, regarding that invention's written description and/or enablement.

¹ Document IP/C/W/122

² See the Annex to the present document

³ See document IP/C/W/126

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.*

No.

- (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.*

No. Plants or animals are not excluded from being patentable if they are the subject of an invention. Of course, plants and animals occurring in their natural state are not inventions.

- (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.*

Yes. The same basis as recited in the answer to question 1 above.

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 sexual reproduction of an animal)? If not, please identify the legal basis under which a patent on such a process would be denied.*

No, if the claim is limited to naturally occurring essentially biological processes comprising the steps for sexual or asexual reproduction of a plant or sexual reproduction of an animal. Such a claim would fail to meet one or more of the patentability requirements of novelty, non-obviousness and utility under Sections 101, 102 and 103 of title 35, United States Code.

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)?*

No. Under US law and practice, a patent may not be granted on a claim that is limited to subject matter indistinguishable from the form in which it is found in nature. For example, a claim drawn to a naturally occurring bacterium, per se, would fail to satisfy the requirements for novelty and utility (Section 101 of title 35, United States Code). However, these requirements, as well as the requirement of non-obviousness, are considered to be met, when a claim is directed to an isolated and/or purified composition containing naturally occurring subject matter that exhibits new or unexpected properties.

B. PLANT VARIETY PROTECTION SYSTEMS

Explanatory note about the US system for the protection of plant varieties and plant-related inventions

Under US law, anyone who develops a new *plant variety* may obtain one of three forms of protection, two of which depend on the manner of reproduction of the plant variety:

- If the variety was developed through *sexual reproduction* or *tuber propagation*, the breeder may obtain a plant variety protection certificate under the Plant Variety Protection Act (Section 2321 *et seq.* of title 7, United States Code) administered by the Plant Variety Protection Office of the Department of Agriculture.
- If the variety, other than tuber propagated plants, was developed through *asexual reproduction*, the breeder may obtain a plant patent under the Plant Patent Act (Section 161 *et seq.* of title 35, United States Code) from the United States Patent and Trademark Office.
- Regardless of its method of propagation, the developer of a new plant *invention*, i.e., a plant variety or an invention concerning plants of a higher taxonomic classification, may obtain a utility patent under the general Patent Law (i.e., an invention patent under Section 101 of title 35, United States Code) from the United States Patent and Trademark Office.

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

Yes, for sexually reproduced and tuber propagated plant varieties, under the Plant Variety Protection Act (Section 2321 *et seq.* of title 7, United States Code).

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 Plant Variety Protection Act conforms to the 1991 Act of UPOV.

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, with respect to plant variety protection certificates issued under the Plant Variety Protection Act.

(With respect to utility patents issued under the general Patent Law, or plant patents issued under the Plant Patent Act, such acts would not require prior authorization from the holder of the patent if the acts were done for purely non-commercial purposes. Acts with a commercial motivation or purpose however, would provide a basis for a finding of infringement of the patent, if done without prior authorization from the right holder).

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

Yes.

(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, with respect to plant variety protection certificates issued under the Plant Variety Protection Act.

(With respect to plant patents issued under the Plant Patent Act, their protection extends only to specific acts of asexual reproduction of the protected variety, or sale or use of the *plant* that is the subject of the grant. Harvesting and reuse of *seeds* from such a plant involve *sexual* propagation of the plant, and as such would not be covered by the plant patent rights).

(With respect to utility patents issued under the general patent law, such acts would require the prior authorization of the patent owner).

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?

No.

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)?*

Yes, with respect to plant variety protection certificates issued under the Plant Variety Protection Act. The applicable periods of time are (a) for disclosures within the United States, one year, and (b) for disclosures outside the United States, (i) six years for new tree or vine varieties, and (ii) four years for all other types of varieties.

(With respect to plant patents and utility patents, protection can be obtained, notwithstanding a disclosure of the plant variety or plant invention up to one year prior to the date of application for protection).

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, with respect to plant variety protection certificates. The determination of novelty for a variety is presently made through reference to the phenotype or expressed characteristics of the plant variety.

No, with respect to plant patents, for the same reason (i.e., the evaluation of novelty and non-obviousness of the plant variety is based on phenotypical or expressed characteristics of the plant variety).

No, with respect to utility patents. If a gene is present in the plant in its natural state, its identification alone cannot be a basis for protection, regardless whether it is expressed or unexpressed. To rely on genes for patentability of a plant, they would have to be introduced into the plant by human intervention. Introduction of a gene that does not express a difference in the characteristics of the plant may render it novel and arguably non-obvious under the general Patent Law. However, the criterion of utility would not be met, as the unexpressed gene did not change the original utility of the plant, as occurring in nature.