

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)

Information from the European Communities and their Member States

Addendum

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 European Communities and their Member States, by means of a communication from the Permanent Delegation of the European Commission, dated 3 February 1999. The questions to which answers are provided are those which can be found in document IP/C/W/126.

The following elements of information are based on Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions¹, as well as on Council Regulation 2100/94/EC of 27 July 1994 on Community plant variety rights.²

A. PATENT SYSTEM QUESTIONS

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?*

Following Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety".

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.*

¹ Directive 98/44/EC on the legal protection of biotechnological inventions entered into force on 30 July 1998. It is the subject of appeal by one Member State before the European Court of Justice. According to Article 15 of Directive 98/44/EC Member States shall implement the provisions of the Directive not later than 30 July 2000. This directive has been notified by the European Communities under Act 63.2 of the TRIPS Agreement and will be available as document IP/N/1/EEC/P/4.

² Council Regulation 2100/94 on Community Plant Variety Rights entered into force on 1 September 1994. Articles 1,2,3,5 to 29 and 49 to 106 were applicable from 27 April 1995. This Regulation has been notified by the European Communities under Article 63.2 of the TRIPS Agreement and has been distributed in document IP/N/1/EEC/P/3.

See the answer to question 1 above.

- (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.*

Article 4 (1) of Directive 98/44/EC indicates that plant and animal varieties are not patentable.

- (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.*

Following Article 6(1) and (2)(d) of Directive 98/44/EC "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality..." and, in particular, "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" shall be considered unpatentable.

Recital 45 of Directive 98/44/EC specifies the "substantial medical benefit in terms of research, prevention, diagnosis or therapy".

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.*

No.

- (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 questions (3)(a) to (c) vary, please provide the definitions of a "plant variety" and an "animal variety" that are used by your examining authority.*

Following Article 2(3) of Directive 98/44/EC "The concept of "plant variety" is defined by Article 5 of Regulation (EC) N° 2100/94".

Article 5 of Regulation (EC) No.2100/94 reads:

"1. Varieties of all botanical genera and species, including, inter alia, hybrids between genera or species, may form the object of Community plant variety rights.

"2. For the purpose of this Regulation, "variety" shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- defined by the expression of the characteristics that result from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristic, and
- considered as a unit with regard to its suitability for being propagated unchanged.

"3. A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as "variety constituents.

"4. The expression of the characteristics referred to in paragraph 2, first indent, may be either invariable or variable between variety constituents of the same kind provided that also the level of variation results from the genotype or combination of genotypes."

Recital 30 of Directive 98/44/EC reads: "the concept "plant variety" is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties".

Recital 31 of the Directive 98/44/EC reads: "Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants."

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.*

No.

Article 4(1)(b) of Directive 98/44/EC reads: "essentially biological processes for the production of plants or animals" are not patentable.

Article 2(2) of Directive 98/44/EC reads: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

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)?*

Yes.

Article 3(2) of Directive 98/44/EC reads. "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

Following Article 2(1) of Directive 98/44/EC, "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system."

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. Council Regulation 2100/94/EC on Community Plant Variety Rights provides for a *sui generis* form of protection for new plant varieties. In addition, and according to the Preamble to Regulation 2100/94/EC, Member States may provide for national legislation that protects plant varieties.

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).*

1991 Act (confirmed by UPOV Council).

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 (if essentially derived from the protected initial variety or from a variety that is itself predominantly derived from that initial 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 (for certain agricultural crops).

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?

Yes (in the case of (c) above for farmers other than "small farmers").

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 (in the case of availability within the Community: 1 year; in the case of availability outside the Community: 4 years or – for trees or vines - 6 years).

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 resulting from such genes or germplasm of the plant variety?*

No.
