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Council for Trade-Related Aspects of Intellectual Property Rights

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REVIEW OF THE APPLICATION OF ARTICLE 27.3(b)

Information from Members

Addendum

HUNGARY

The present document represents the information requested by the Council for Trade-Related Aspects of Intellectual Property Rights which the Secretariat has received from Hungary, by means of a communication from its Permanent Mission, dated 2 February 1999.

From among the subject-matters indicated in Article 27.3 of the TRIPS Agreement, essentially biological processes for the production of plants or animals other than non-biological and microbiological processes are not considered as patentable inventions. The protection of plant varieties (as well as that of animal breeds) is provided for by patents.

The legislative background and some details of these statements are as follows.

A. PATENT PROTECTION OF PLANTS AND ANIMAL INVENTIONS

The substantive provisions (among them those relating to patentability) of the Hungarian Law No. XXXIII of 1995 on the Protection of Inventions By Patents (hereinafter: Patent Act) are fully compatible with the substantive provisions of the European Patent Convention (EPC). Accordingly - as it is prescribed in Article 53(b) of the EPC - essentially biological processes are not patentable in Hungary. There is, however, not an explicit provision of the law to this effect. Such processes are not patentable under Article 1 of the Patent Act. According to Article 1:

"(1) Patents shall be granted for any inventions which are new, involve an inventive activity and are susceptible of industrial application.

"(2) The following in particular shall not be regarded as inventions within the meaning of paragraph (1):

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

"(3) Patentability of the subject-matters referred to in paragraph (2) shall be excluded only to the extent to which a patent application or the patent relates to such subject-matter as such."

The essentially biological processes are considered to be the same category as the discoveries and consequently they are not patentable.

In the context of patentability of the subject-matters described in Article 27.3 of the TRIPS Agreement, the following provisions of the Patent Act have to be cited as well.

Under Article 5(2):

"Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall, in particular, not be regarded as susceptible of industrial application. This provision shall not apply, however, to products, in particular substances (compounds) or compositions, for use in such methods."

Under Article 6(2):

"No patent protection may be granted for an invention if the publication or exploitation thereof would be contrary to public policy or morality; exploitation may not be regarded as contrary to public policy merely because it is prohibited by law or regulation."

The notion of public policy and morality encompasses the fundamental institutions and principles of our legal system which express the decisive values of our social and legal order. Practically, the same legal provisions are included in this range which also belong here in the international practice. However, concrete judicial decisions have not yet been made in these issues (e.g. in connection with the patentability of animals).

Inventions relating to biotechnological processes are eligible for patent protection or not eligible for protection in Hungary according to the following categories:

(a) Under Article 5(2) of the Patent Act, methods of treatment of the human or animal body by surgery are not patentable as not susceptible of industrial application;

(b) Under Article 5(2) of the Patent Act, methods of treatment of the human or animal body by therapy are not patentable as not susceptible of industrial application, including, in particular:

- germ line gene therapy,
- somatic cell gene therapy,
- method of treatment by therapy based on the use of biopharmaceutical or other agents that indirectly effect genetic modifications;

(c) Under Article 5(2) of the Patent Act, diagnostic methods practised on the human or animal body are not patentable as not susceptible of industrial application;

(d) Eligible to be patented are methods involving gene manipulation of animals practised not for the purposes of therapy or diagnosis, e.g. animal experimentation or tests for

research purposes, unless the method used is contrary to morality by Article 6(2). Under Article 6(2) of the Patent Act all methods involving gene manipulation of humans are excluded from patentability;

(e) Under Article 1 of the Patent Act, essentially biological processes carried out by natural crossing are not patentable. Patentable are, however, processes in which there is technical intervention by man if such intervention plays a part in achieving the desired result and if the process may be characterized by at least one essential technical step.

It is part of the official examination to decide whether the subject-matter of the application is an essentially biological process. In this regard the totality of human intervention in the process and its impact on the result achieved has to be taken into account. If the human activity does not represent any contribution - apart from a trivial activity - to the process and to its result, the process is deemed to be an essentially biological process.

Furthermore, it has to be stated that animals *per se* and animal organs are patentable in Hungary. Animals and parts of animals produced by not essentially biological processes, including gene manipulation, are eligible to be patented under the general provisions relating to industrial inventions. Under Article 6(2) of the Patent Act, animals produced by the modification of their genetic identity and as a result of processes that would probably cause pain or physical harms to the animals without ensuring a proportionate advantage for humans or animals are not patentable on the basis of moral considerations. New animal breeds are patentable, the relevant provisions are included in a special chapter of the Patent Act.

By Article 6(2) of the Patent Act, humans, human body are not patentable; parts of the human body, thus human organs are not patentable either in their natural form. Eligible to be patented are, however, parts and products isolated from the human body, including cell lines, genes and nucleic or amino acid sequences, if they meet the general criteria of patentability.

Microorganisms and microbiological processes are patentable under the general criteria of the protection.

B. PROTECTION OF PLANT VARIETIES

Hungary has not introduced a *sui generis* system for the protection of plant varieties, as a consequence. Chapter XIII of the Patent Act contains the special provisions relating to the patent protection of plant varieties.

Hungary is member of the UPOV Convention (1961), and the Budapest Treaty on the Deposit of Microorganisms (1977). Hungary intends to ratify the revised text of the UPOV Convention (1991). For the ratification and application thereof, Hungary has to harmonize the relevant provisions of the Patent Act with the1991 text of the UPOV Convention. The ratification of the UPOV 1991 and the entry into force of the harmonized national law is expected by the end of 2000.

Conditions of protection

According to Article 105 of the Patent Act, a plant variety shall be patentable if it is distinct, uniform, stable and new and has been given a denomination suitable for registration.

The variety shall be deemed to be distinct if it clearly differs by one or more morphological or other measurable characteristics from any other variety whose existence is a matter of common knowledge at the date of priority.

The variety shall be deemed to be uniform if the relevant characteristics of its individuals are identical.

The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or at the end of each cycle of propagation.

The variety shall be deemed to be new if it has not been offered for sale or marketed with the consent of the breeder or his successor in title:

(a) in the country earlier than one year before the date of priority;

(b) abroad earlier than four years or, in the case of trees and vines, earlier than six years before the date of priority.

The denomination must, at the date of priority, be such that the variety may be identified. In particular, it may not consist solely of figures except where this is an established practice for designating varieties, it must not be liable to mislead, it must be different from the denomination of an existing variety of the same or closely related plant species and its use must not be contrary to public policy or morality.

Rights and obligations deriving from patent protection for plant varieties

According to Article 106 of the Patent Act a patent granted for a plant variety shall confer on the patentee the exclusive right in respect of:

(a) the production for the purposes of commercial marketing, the offering for sale or the marketing of the propagating material, as such, of the plant variety;

(b) the repeated use of the plant variety for the commercial production of another variety;

(c) the commercial use as propagating material of ornamental plants marketed for purposes other than propagation.

Entire plants, seeds or other parts thereof suitable for propagation shall be considered propagating material.

The propagating material of the patented plant variety may be exported only by the authorization of the patentee to a country in which the plant variety does not enjoy protection similar to that provided by the Patent Act.

The patented plant variety may be put into public production only after having been qualified by the State.

Duration of protection, maintenance

Under Article 106(4) patent protection shall have a duration of 15 years from the date of the grant of a plant variety patent or, in the case of trees and vines, of 18 years from such date.

The patentee shall be required to maintain the plant variety during the period of patent protection.

Granting procedure, examination of applications concerning plant varieties

The substantive examination of the patent application for plant variety falls within the competence of the Hungarian Patent Office. The application must meet the special formal requirements laid down by law.

Under Article 107 the substantive examination of the application carried out by the Hungarian Patent Office shall ascertain:

(a) whether the plant variety meets the requirements laid down in Article 105 of the Patent Act and is not excluded from patent protection under Article 6(2) of the Patent Act;

(b) whether the application complies with the requirements prescribed by the Patent Act.

Experimental testing, qualification

According to Article 107 the distinctness, uniformity and stability of the plant variety shall be assessed in the course of qualification by the State or on the basis of the results of experimental testing carried out for the purposes of patent procedure. The experimental testing shall be carried out in the territory of the country by an organization designated in special legislation.

The cost of experimental testing shall be borne by the applicant.

The results of experimental testing may be filed by the applicant within four years following the date of priority.

The results of experimental testing carried out by a competent foreign organization may be taken into consideration in the patent procedure with the consent of such organization subject to reciprocity. In the matter of reciprocity, the standpoint of the President of the Hungarian Patent Office shall be decisive. The Hungarian Patent Office shall notify the organization mentioned above of the acceptance of the results of foreign testing.

Revocation of patent granted for a plant variety, cancellation of variety denomination

According to Article 108 a patent granted for a plant variety shall be revoked:

(a) *ex tunc*, if the plant variety was not distinct or new or was excluded from patent protection under Article 6(2) of the Patent Act;

(b) with effect from the date at which the relevant decision has become final, if the patentee does not comply with the obligation relating to the maintenance of the plant variety.

The variety denomination shall be cancelled if it was not suitable for registration and another variety denomination shall be given.

C. PROTECTION OF ANIMAL BREEDS

Article 27(3)(b) of the TRIPS Agreement does not cover the protection of animal breeds. Chapter XIV of the Patent Act contains provisions on the protection of animal breeds; for further details see the above chapter of the Patent Act duly notified.