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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Nineteenth Session
Geneva, March 31 and April 1, 1987

REVISION OF THE CONVENTION

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COMMENTS FROM THE INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INDUSTRIAL PROPERTY

Document prepared by the Office of the Union

1. By letter of March 13, 1987, the International Association for the Protection of Industrial Property (AIPPI) submitted:

(i) the resolution adopted by AIPPI at Rio de Janeiro (Brazil) in May 1985 with respect to patent protection for biotechnological inventions (annex I hereto);

(ii) the guiding principles given by AIPPI to its Executive Committee to meet at Sidney (Australia) in April 1988 concerning the relationships between protection by means of patents for biotechnological inventions and protection for plant varieties, and the patentability of animal varieties (annex II hereto).

2. In its letter, AIPPI expressed the view that these documents reflect the main suggestions for the development of legislation and the positions of the major influential circles.

[Annexes follow]

Question 82

Patent Protection for Biotechnological Inventions

Resolution

After having considered the reports of the National Groups (Yearbook 1984/IV) and the Summary Report on Question 82 (Yearbook 1985/1),

AIPPI notes that

- an inconsistency exists between the actual laws which are based upon the general principle that a living organism *per se* cannot be the subject matter of a patent, and the state of science which nowadays makes it possible to describe and repeat procedures for the modification of a living organism

- patent protection for particular biotechnological inventions exists in most States

- processes involving the industrial use of living organisms are generally patentable

- microorganisms *per se* and other biolocical materials, including plants, *per se*, are patentable in many States

- plants and even animals are also protectable in some States by special rights.

AIPPI
recognizes that the development of new techniques has made biotechnology of great economic importance and observes that, to encourage the development of these new techniques, there is a great desire to protect biotechnological inventions by patents and to harmonize the patent practices of different countries.

AIPPI
also recognizes that the application of new techniques in biotechnology could give rise to serious moral or ethical problems, and considers that those problems should be primarily regulated by laws specifically dealing with these issues to which the patent laws of nearly all countries refer in excluding from patentability inventions contrary to morals or public order.

AIPPI
is of the opinion that biotechnological inventions should be protected by the application of the existing principles of patent law and that the creation of a special body of law is not necessary. Accordingly, a subject matter in the field of biotechnology should be patentable if it meets the usual criteria for patentability.

In particular:

- there is no reason to consider an organism, be it a microorganism, plant or animal, as not being a patentable subject matter merely because it is living or merely because its genes have not been modified,

- other biological material, e.g. plasmids, enzymes, etc., should be considered patentable subject matter,

- a process for obtaining or using a living organism or other biological material, should be considered patentable subject matter,

- no reason exists to exclude from patent protection, biotechnological inventions relating to any particular field of industrial application, for example food, medicines or chemical products,

- although protection of plant varieties under laws conforming to the UPOV convention presents a valuable system of protection and should continue, it is essential that techniques newly applied and products obtained thereby in the field of the development of new plants, and capable of meeting the patentability requirements, should become generally eligible for patent protection, and therefore, prohibition of double protection should not be maintained or provided for,

- if a written description is sufficient to make the living organism, or other biological material, available to a person skilled in the art, then deposit should not be required, but nevertheless, deposit should always be considered as completing the requirement of sufficient disclosure particularly in relation to the repeatability of the invention, recognizing that practical problems in relation to some organisms will have to be solved,

- since the release of deposited material could be abused, the conclusions of AIPPI at the congresses of San Francisco and Munich in relation to microorganisms,

namely that

a) a microorganism should not be accessible to the public until an enforceable right exists,

b) release should be for research only,

c) the organism should not be passed on to third parties,

d) the organism should not be exported from the country of release and

e) in the event of a violation of the undertaking, the burden of proof should be upon the receiver of the organism,

should be applicable to organisms, and other biological material.

- In general, there exists no reason to limit the scope of protection of patents for biotechnological inventions.

AIPPI
considers that the application of these principles and the harmonization of patent practice along the lines of these principles will encourage the development of biotechnology and allow patent practice to develop in parallel with scientific advancement.

[Annex II follows]

Question 93

Relationships between protection by means of patents for biotechnological inventions and protection for plant varieties Patentability of animal varieties$M.

State of the Question.

1. AIPPI studied the matter of patent protection in the biotechnological field (Question 82) at the meeting of the Executive Committee in Rio in 1985 (Reports from the Groups, Yearbook 1984/IV, Summary Report, Yearbook 1985/I, Discussion and resolution of the Executive Committee in Rio, Yearbook 1985/III).

AIPPI had first affirmed that in their view there was an inconsistency between the present laws which are based on the general principle that a living organism per se cannot be subject-matter of a patent, and the state of science which nowadays makes it possible to describe and repeat the procedure for modifying a living organism.

As regards more particularly the matter of protection for plant varieties, the AIPPI resolution expressed the view that:

'Although protection for plant varieties under laws conforming to the UPOV Convention presents a valuable system of protection which should continue, it is essential that the new techniques applied and the products obtained thereby in the field of the development of new plants and capable of meeting the patentability requirements should become generally eligible for patent protection and therefore prohibition of double protection should not be maintained or provided for.'

That resolution therefore affirmed that nothing should prevent plant varieties from being eligible for patent protection, at the same time as protection for plant varieties. However the way in which the resolution was drafted was not totally explicit as it appeared to link patent protection for new plants to the existence of new techniques for producing such plants.

The resolution suffered at the very least from a certain ambiguity.

In spite of a proposal from the Programme Committee, continuation of the study of this Question was not included in the programme for the London Congress in 1986.

However, after the meeting of the Executive Committee in Rio in 1985, a number of inter-governmental organisations studied questions relating to patent protection for biotechnological inventions and in particular inventions concerning plants and animals.

A group of experts from O.C.D.E. advised the governments of the member countries to try to arrive at solutions providing effective protection for new plants produced by 'genetic engineering' methods.

It was suggested that consideration be directed in particular to the question of whether that aim could be attained by way of patents or by way of specific legislation to protect plant varieties.

The need for more effective protection was emphasised.

The O.C.D.E. experts proposed that the person producing a new variety may enjoy the option of selecting the most appropriate form of protection.

It was also suggested that study be directed to ways of avoiding conflicts between the two systems of protection, while best reconciling the effects of the protection afforded (see BEIER CRESPI STRAUS - Biotechnologie et Protection par Brevets, une Analyse internationale, O.C.D.E., Paris 1985, pages 98/99).

The WIPO Committee of Experts dealing with biotechnological inventions, at the second session held in Geneva from 3rd to 7th February 1986, examined a report drawn up by the International Bureau of WIPO, entitled 'Protection for Biotechnological Inventions by means of Industry Property' (see Propriesulteseul industrielle 1986, pages 275 ff).

The International Bureau noted that certain national laws do not permit patenting of plant varieties or animal varieties and essentially biological processes for producing plants or animals. It concluded however that there did not appear to be any justification for that exclusion from patent protection. It proposed that all biotechnological inventions should be able to enjoy protection by a patent, and that a patent should be granted subject to the invention complying with the normal conditions for patentability, namely novelty, inventive step, industrial utility and sufficiency of disclosure.

The discussion before the Committee of Experts related largely to the problem of excluding plant varieties, animal varieties and essentially biological processes for producing same, from patent protection.

Except for the Delegation from Ireland, the Delegation from Japan and most of the Delegations of observers who proposed eliminating such exclusions, most of the governmental Delegations expressed the feeling that the time had not yet come to take a decision on the question of eliminating that exclusion from protection.

Those Delegations pointed out that major studies would have to be undertaken in order to decide whether the protection available at the present time was not sufficient and whether elimination of the exclusions would not run the risk of resulting in an imbalance between the interests of patentees and other interests involved, in particular the interests of the public.

2. In the light of the way in which the question has developed, the Programme Committee proposed that it should be put on the Agenda of the Executive Committee Meeting in Sydney, and that a questionnaire should be drawn up.

The starting point for the study of this matter may be the AIPPI resolution adopted in Rio on Question 82, which expresses a position of principle but which if appropriate should be re-affirmed in clearer terms and, on the other hand, the suggestions from the O.C.D.E. group of experts as well as the results from the second session of the WIPO Committee of Experts held in February 1986.

It is necessary to take account of the continuing development in 'genetic engineering' and other modern production processes which involve very substantial levels of investment and which at the same time give a fresh quality to inventions in this field.

Questions put to the groups.

The National Groups are invited to reply to the following questions.

First part: relationship between protection by means of patents for biotechnological inventions and protection for plant varieties.

I – Present legislative situation.

A. Does the legislation in your country afford particular protection for plant varieties? What is the domestic law?

Does the country belong to the UPOV Convention?

1. To what objects does the particular protection for plant varieties extend?

a) Plant varieties.

-How many varieties are admitted to legal protection at the present time?

-How many useful plants and how many ornamental plants?

b) Parts of plants and other biological materials.

2. Under what conditions is protection afforded?

a) Novelty, distinctiveness.

b) Other conditions: uniformity, stability, etc...

3. Is initial examination necessary?

- Scope of examination.

- What organisations deal with examination: Patent Office or others.

4. Content and scope of the protection.

a) Does protection extend only to the multiplication material (seeds, tubers, cuttings etc..) or also to the final product?

b) What exploitation rights are granted to the proprietors?

c) Limitations, for example free use of the protected varieties, as a base material for producing other varieites, compulsory licences, etc...

5. Economic importance of plant varieties: statistical data.

B) As well as and/or instead of particular protection, does your domestic legislation also make provision for patent protection in respect of the following:

1. Plant varieties in the sense of particular legislation relating to protection for plant varieties.

2. Entire plants or multiplication material therefor, which do not constitute plant varieties within the meaning of point 1.

3. Parts of plants or other biological materials.

4. Inventions for processes concerning the development of new plants (microbiological, biochemical and macrobiological processes).

C. Application of the general conditions of patent law to inventions concerning plants.

1. Novelty, inventive step and industrial utility.

2. Sufficiency of disclosure and reproducibility.

3. Deposit of living material.

4. Content and scope of protection.

a) Does protection extend to the products obtained by the patented process?

b) Limitations.

D. Relationship between protection for plant varieties and protection by means of patents.

1. May the inventor or the proprietor choose as alternatives between particular protection and protection by means of a patent?

2. May he choose the two forms of protection for the same subject matter?

What limitations arise in such a situation in regard to using the rights against other parties?

II – Reforming trend.

1. Are there in your country draft laws or specific proposals aimed at introducing particular protection or protection by means of patents for plant varieties or aimed at regulating the relationship between the two kinds of protection?

2. If so, in your view is there a need for protection and how should the new legislation deal with questions I – A to D?

Second part: patentability of processes for producing animals.

I – Does the legal system in your country make provision for particular protection for producing animals? Legal basis?

What is the subject of the protection and what are the rules governing it?

II – Are inventions concerning the production of animals patentable:

1. Product patents (for new varieties of animals, etc...)

2. Process patents, in particular in respect of processes for producing animals.

III – If inventions relating to the production of animals are patentable, is that category of invention subject in principle to the same conditions as in regard to protection by means of patents of plant varieties or are there differences? (Reproducibility, disclosure, deposit, etc...)?

IV – Reforming trends.

1. Are there in your country draft laws or specific proposals aimed at introducing particular protection or protection by means of patents for animal varieties or aimed at regulating the relationship between those two kinds of protection?

2. If such draft laws or proposals do not exist, do you consider that a need for protection can be seen?

How should future legislation deal with questions I to III?

[End of document]