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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Seventeenth Session

Geneva, April 16 and 17, 1986

BIOTECHNOLOGIES AND PLANT VARIETY PROTECTION

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PROVISIONAL CONCLUSIONS OF THE BIOTECHNOLOGY SUBGROUP

Document prepared by the Office of the Union

1. The Biotechnology Subgroup met on April 14, 1986. Its main business was as follows:

(i) It heard a report by the Vice Secretary-General on recent developments in the field of competence of the Subgroup;

(ii) It had a thorough examination of a working paper entitled "Outline of the Intellectual Property Protection of Biotechnological Inventions and Their Results";

(iii) It took note of a document entitled "The Scientific and Technical Background of Plant Breeding" (which is to be continued).

2. The Annex to this document contains the text of the working paper mentioned in paragraph 1(ii) above as amended by the Subgroup.

3. At the end of the meeting, Mr. H. Kunhardt (Federal Republic of Germany) proposed that the Subgroup should be given the mandate of preparing a document to be used as basis for further decisions of the Council and covering the following items:

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(i) Present situation of intellectual property protection in the field of biology;

(ii) Reasons for the creation of a special protection system for new plant varieties;

(iii) Main elements of patent law and plant variety protection law, main differences between the two systems, possibilities of application of general patent law to plant varieties and problems raised by such application;

(iv) Possible consequences of new technology in the field of biology on the basic principles of the various protection systems;

(v) Problems raised in particular by organizations in respect of protection in the field of biology;

(vi) Possible solutions to those problems.

Mr. Kunhardt further proposed that the Office of the Union should be asked to prepare a working paper to serve as the basis for future discussions on these questions by the Subgroup, taking into account past discussions and already available documents.

[Annex follows]

ANNEX

OUTLINE
OF THE INTELLECTUAL PROPERTY PROTECTION
OF BIOTECHNOLOGICAL INVENTIONS AND THEIR RESULTS

I. PROCESS

1. Protection by Plant Breeders' Rights (Plant Patents or Plant Variety Protection Certificates)

Neither the UPOV Convention nor the national plant breeders' rights legislations provide for the protection of processes. This seems justified in view of the fact that nobody normally wishes to repeat the process leading to the same new plant variety. Persons wishing to use the new variety will prefer to multiply/propagate the finished product, i.e. the plants of the new plant variety.

2. Protection by Industrial Patents

(a) Under patent law, inventive processes, unless excluded by statute or judicial decision from patent protection, can be protected if the patentability conditions are fulfilled: they must be new, inventive (non-obvious) and industrially applicable. They must be repeatable and suitable for disclosure (and be disclosed). In addition to those mentioned in subparagraph (c) below, common exclusions in patent law are: scientific discoveries and theories, inventions whose publication or use would be contrary to public policy, inventions for the treatment of the human or animal bodies (surgery, therapy, diagnostic methods).

(b) As far as biotechnological processes are concerned, there might be particular problems as regards inventive character or industrial applicability. Some of these processes might only be usable in scientific research.

(c) The European Patent Convention and a number of national legislations exclude "essentially biological processes for the production of plants [or animals]" from patent protection; however, they do not exclude microbiological processes [or products thereof]. Thus, according to its wording, in the States in which this system applies, only the following processes for the production of plants [or animals] can be protected by industrial patents:

- (i) all processes which are not biological;
- (ii) biological processes which, however, are not "essentially" biological;
- (iii) essentially biological processes which cannot be characterized as processes for the production of plants, e.g. processes for the realization of steps leading to the production of plants. In these cases, however, there will be doubts as to industrial applicability;
- (iv) microbiological processes.

3. In some of these countries, exclusion is applicable only where the plants produced belong to a species for which plant variety protection may (already) be obtained.

4. In certain countries, protection of a process automatically covers the "immediate" product of the patented process. The intention of this provision was not to provide for a restricted type of product protection but to facilitate the prosecution of infringements of the process patent. Where processes for the production of plants are patentable and where such a rule exists, the first generation of plants, "immediately" produced with the help of the patented process, is thus covered by protection. As for plants of the subsequent generations, it is questionable whether they are still covered by the process patent. Doubts exist in particular where the plants of a subsequent generation are distinct from the first generation. It will be for the courts to decide what may still be considered "an immediate product." It also remains to be seen whether plants resulting from crossing the immediately produced plants with other plants or resulting from an additional breeding process be considered as an "immediate product" of the patented process.

II. PRODUCT (VARIETY)

1. Protection by Plant Breeders' Rights (Plant Patents or Plant Variety Protection Certificates)

(a) Under the UPOV Convention and under the national legislations based on it, protection can be granted for assemblies of plants which can be qualified as plant varieties and fulfill the following conditions: they must be distinguishable from any other variety which is commonly known; they must be commercially new (not yet offered for sale or sold in the country of application (one year period of grace possible) or within certain time limits (for longer than 4 or 6 years in any other country)).

(b) No distinction is made as to the method by which the new plant variety was bred. Thus plant varieties bred with the help of biotechnological processes are protectable without limitation, if the normal conditions for plant variety protection are fulfilled.

2. Protection by Industrial Patents

(a) Protection of plant varieties by industrial patents is excluded:

(i) in most UPOV member States and in a number of other States by express provisions in the patent law. The most striking example is Article 53(b) of the European Patent Convention;

(ii) in some countries, exclusion applies only where varieties of the species in question are eligible for plant variety protection; where this is not yet the case, the granting of a patent is not excluded; patents can of course only be granted where the normal patentability conditions (see above I, 2 (a)) are fulfilled;

(iii) in other countries, plant varieties are excluded by the practice of patent offices (they were so until recently in the United States of America for some forms of plant reproduction) or by agreement between the competent authorities;

(iv) in further countries, plant varieties do not qualify for patent protection in view of certain conditions for patenting.

(b) To some extent such practices are reflected in the UPOV Convention.

III. PRODUCT PROTECTION (PLANTS AND PARTS OF PLANTS)

[To be developed]

IV. PRODUCT PROTECTION (GENES)

1. Protection by Plant Breeders' Rights (Plant Patents or Plant Variety Protection Certificates)

Genes as such are not protectable under the UPOV Convention nor under the national legislations based on it. The only protectable matter is constituted by "finished" varieties. This goes back to the Diplomatic Conference of 1957 to 1961 and was confirmed by the Diplomatic Conference of 1978.

2. Protection by Industrial Patents

(a) The view has been held that genes qualify for patent protection on account of their being chemical compounds.

(b) Whether genes are to qualify for patent protection must be examined under the following aspects, in particular:

(i) Novelty and inventiveness (non-obviousness). For both "man-made" genes (should it be possible to produce such genes in the future) and genes already existing in nature, which are isolated, it depends on the patent law in question and its interpretation by the patent offices or courts whether they are considered new and/or inventive (non-obvious).

(ii) Whether the exclusion of plant varieties from patent protection under some legal systems also excludes genes should also be examined since plant varieties are a combination of genes. It can be argued that the exclusion of plant varieties from patent protection only satisfies the intentions of the legislator if genes are also excluded; otherwise, exclusion could be circumvented by dividing the variety into its different genes.

3. Where patent offices and courts consider genes to be protectable as such, it is necessary to know how far the scope of such protection will go in those cases. To be effective, the protected gene needs to be inserted into plants. The question arises whether the gene is not absorbed by the plant as a result of insertion, in other words whether it does not cease to be a separate object. Even where the "manipulated" plant shows the typical expression of the gene, this does not necessarily mean that the gene did not undergo changes in the host plant cell. Thus the following subsidiary questions will have to be

decided by the body that is to determine the scope of protection, generally constituted by the court hearing infringement cases:

(a) Does the scope of protection of the protected gene extend to the plants into which it is inserted?

(b) Does it extend to further generations of plants derived from that first plant?

(c) Does it extend to further generations if the plants have become morphologically or physiologically different, though still showing the expression of the protected gene?

(d) Does it extend to plants which are the result of a crossing of the plant into which a gene was inserted (or its derivatives) with plants of another variety (under which conditions)?

4. Where the protection of genes extends to a plant or an assembly of plants which can be characterized as a plant variety, there will be an overlapping with plant variety protection.

5. Differences Between Plant Breeders' Rights and Patent Protection

Plant breeders' rights and patents differ as follows:

(a) The scope of protection of plant breeders' rights only covers plants which have the same expressions of the important characteristics of the variety. Plants which are clearly distinguishable by at least one important characteristic no longer fall under the scope of protection of the original plant variety; they qualify for separate and independent protection under the plant breeders' rights system. There is no dependency unless the repeated use of the first variety is required for the production of the second.

On the other hand, the scope of protection of an industrial patent (if available) would cover all plants--and thus plant varieties--showing the characteristics claimed to embody the inventive idea when the patent was granted.

(b) The scope of protection of plant breeders' rights (unless extended by the national legislator on the basis of Article 5(4) of the UPOV Convention) covers only the production of propagating material to be marketed as such and the marketing of that material. The production of propagating material to be used by the producer himself, even where such use is for a commercial purpose, does not fall under the scope of protection. Thus, a farmer may save seed of a protected variety, produced by himself on his own premises, for use during the next growing season for the production of consumption material. This is often referred to as the "farmer's right to save seed," "farmer's exemption" or--incorrectly--as "farmer's privilege."

On the other hand, any production, storing or turning over of propagating material to be used for any commercial purpose--and not only for commercial use as such, i.e. as propagating material--would in all countries fall under

the scope of protection of an industrial patent; however, the patent law principle of the "exhaustion of rights" might be invoked in certain cases.

["Exhaustion of rights" to be explained]

(c) Material of varieties protected by plant breeders' rights may be freely used as a source of variation for the production of other new varieties (except in the case of hybrids). The use of such new varieties is free. There is no dependency. This is often referred to as the "research exemption."

Under most--if not all--patent laws, activities for trial purposes do not fall under the scope of patents, but it is claimed that the commercial use of a new variety, developed on the basis of the other variety, would depend on the authorization of the owner of the original variety. As yet, however, this has not been confirmed by court decisions. There has also been mention of the effect of the patent law principle of "exhaustion of rights."

6. Other Use

It must also be pointed out that seeds subjected to technical process, for instance coating of seeds with chemical substances, are not considered a plant variety within the meaning of the UPOV Convention. Patent protection for such processes or for the product resulting from them, for instance the coated seed, do not therefore apparently conflict with plant breeders' rights protection of the variety or varieties to which the seed belongs.

V. CONCLUSION

[Summary of possible points of conflict, overlapping, etc.]

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