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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

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POSSIBLE CONSEQUENCES OF BIOTECHNOLOGY
IN THE FIELD OF INTELLECTUAL PROPERTY PROTECTION

Prepared by the Subgroup Biotechnology

INTRODUCTION

Improving the performance of living matter as a result of changing its characteristics is achieved by the introduction of modified genotypes. In fact, this is what mankind has been doing since it first started to select the most appropriate individuals of plant and animal populations for further multiplication. This selection only evolved into purposeful breeding, as far as plants are concerned, at the beginning of the twentieth century. This involved programmes of crossing and back-crossing of specific individual plants in order to develop a plant showing the desired genetically fixed characteristics. Plant breeding then started to become a sophisticated technology through which human intervention resulted in the existence of new plant genotypes. The costs and effort involved in plant breeding and the importance of its results to agriculture justified the introduction of protective rights for the plant varieties developed. International arrangements for this kind of protection are laid down by the UPOV Convention. There is no international arrangement particularly designed for the protection of results of animal breeding.

Undoubtedly, biotechnology will contribute to the development of new plant and animal genotypes. On the one hand, it will generate new processes able to modify existing genetic patterns. In particular, techniques to switch parts of DNA-molecules may prove to be of great importance. On the other hand, biotechnology is expected to produce chemical compounds which can be inserted in the genetic structure of plants and animals and, thus, function as part of the genetic information. In fact, biotechnology brings within reach ways of plant and animal breeding which have been, up until now, most fundamental. Since it is liable to shorten breeding programmes and even to produce plant and animal varieties which could not be obtained without it, biotechnology will become very important for plant and animal production.

As with the technology known at present, the development of plant and animal genotypes by the use of biotechnology will certainly require a lot of research and large investments. As far as plants are concerned, the breeding results thus obtained are protectable according to the UPOV Convention. The question arises as to whether the UPOV Convention should also cover breeding results other than plant varieties.

A second issue relates to the protectability of processes or substances by industrial patents. In the case of a patent for a process for modifying living matter or for a substance capable of being a genetically fixed part of living matter, the protective right might additionally cover the living matter, its offspring or every genotype containing the protected substance. Is the balance between effective protection and the public interest, supposedly present for patent rights for technical instruction and non-living matter, still struck when the patent right covers living material as well?

It is observed that the new techniques could give rise to the need for modifications of the UPOV Convention, other than possible extensions to more types of breeding results.

* * *

In essence, the consequences of biotechnology for the intellectual property protection of living matter are as follows:

a) With respect to living matter, plant varieties excluded, there is no protective right that is appropriately equipped for living matter. The UPOV Convention is limited to plant varieties, while the requirements of patents, in particular of inventive step and novelty, are not sufficiently suitable for the protection of the various breeding results.

b) Industrial patents on genetic components and on processes may cover the breeding products. Therefore, patents and protective rights on individual types of breeding products might interfere with each other.

The above-mentioned points are subdivided and dealt with below.

1. BIOLOGICAL TAXA ELIGIBLE FOR PROTECTION

In the field of industrial property protection, every process or substance is eligible for protection. Following that principle, there should be no restrictions on the species of living matter eligible for protection. With regard to the findings listed under 3 concerning the requirements for protection this would not raise severe technical problems. The Subgroup therefore recommends that the Convention lay down this principle. In case there might be a need for exceptions, the conditions for them should be clearly set out in the Convention.

2. SUBJECT OF PROTECTION

a) Plant material other than (varieties of) plants

Due to newly developed biotechnological methods, it may increasingly become the case that the main use of certain living plant material is not to let it grow into mature plants before harvesting them, but to use it as it is (e.g. as callus, cells, cell-lines, or parts of cells). This kind of material as such cannot be the subject of protection under the UPOV Convention. At present, the patentability of such material is not clearly established; in any case it would suffer from the problems of patenting living matter (criteria for granting a patent; scope of protection is related to a particular use of the substance). Since the principles of the UPOV Convention are designed for the protection of living matter, protection should be provided for such material along the lines of that Convention. Therefore, the Subgroup recommends that the Convention provide for titles of protection for plant material other than (varieties of) plants.

b) Plants above the variety level

The protection of entities of plants defined only by special characteristics which may also be embodied in the combination of characteristics of other varieties (e.g. given compounds or resistances) would lead, for practical purposes, to the protection of characteristics as such and cover whole groups of varieties.

The protection of entities of plants defined by characteristics which all or almost all plants of a species have in common would lead to the protection of a whole species and cover all varieties of that species.

In both cases, progress in breeding and developing individual varieties of the species would be hampered. Furthermore such a practice would raise legal uncertainty as it might be difficult to adequately define the subject matter of the protective right and thus also the scope of protection as far as this depended on the protective claim.

The Subgroup recommends maintaining the principle of protecting only varieties defined by their combination of the important characteristics and not to extend the protection to entities of plants defined by characteristics or combinations thereof above the variety level.

c) Genetic components

Genetic components (DNA-sequences as agents of genetic information) may be regarded, on the one hand, as plant material. On the other hand, genetic components, being chemical compounds, are not self-replicable and do not share the particularities of other plant material. In any case, the issue of protecting genetic components deserves full attention since such protection may cover several entities of (protectable) living matter (such as plant varieties and animal species). That consequence might hamper the development of those entities. The Subgroup recommends discussing this question under the heading of interaction between different kinds of protection (see 7).

d) Processes for creating/multiplying living material

The subject matter of process protection is not the living matter as such, but technical instruction. Thus, the protection of breeding and multiplication processes comes closer to the principles of patents than to those of the UPOV Convention. Nevertheless, it has to be kept in mind that a patent for a breeding process extends to the material directly obtained by the process. The scope of protection for breeding processes (does it extend to the variety resulting from the breeding process or even to other varieties deriving from that variety?) has considerable implications for the protection of varieties. The Subgroup recommends that this question be discussed under the heading of interaction between different kinds of protection (see 7).

3. REQUIREMENTS FOR GRANTING PROTECTION

As new forms of living matter, in general, can only be achieved by variation of existing living matter within the usually rather narrow limits imposed by biological conditions, the requirement of inventive step is not appropriate for the results of breeding activities. Therefore, the principle of distinctness should be maintained. In this connection the question of "important characteristic" may deserve further consideration.

To allow clear definition of the matter to which protection relates, it is necessary that individuals show a greater or lesser resemblance to a given genotype. This calls for the uniformity requirement.

Since the genetic information of living matter may alter in the course of reproduction, it is essential to require that the protected object remains in conformity with the genotype which was originally the subject matter of protection. This calls for the stability requirement.

The granting authority should in every case examine, on the basis of technical information, whether the requirements of D.U.S. are fulfilled. However, it should be left to the member States to decide whether the authority conducts the technical examination on which it bases its assessments in respect of D.U.S. itself or has it carried out by others (including the applicant). This approach becomes more important as the range of protectable matter broadens (see also 1 and 2 a)).

The principle that a given subject of protection must be given a generic denomination should be kept. This means of identification is necessary in order to inform the user about the genetically fixed characteristics of the matter, since the user cannot obtain such information from the matter itself. Since the denomination is to be connected with a certain genotype and the free use of the denomination is to be guaranteed, the denomination should be generic.

Since a mere description is not sufficient for reproduction of the type of living matter concerned (usually material is needed for this purpose), the novelty requirement as laid down in the Convention, including a period of grace, is very appropriate for all living matter. The UPOV novelty requirement also takes into account the fact that, since breeding quite often takes place in open fields, disclosure before the date of application for protection is usually unavoidable. The patent novelty requirements might be an obstacle to the grant of rights for living material.

The Subgroup therefore recommends maintaining the requirements for protection as laid down in the present Convention but the question of official conduct of D.U.S. tests should also be considered.

4. SCOPE OF PROTECTION

According to the principles of the Convention, the right can be exercised with respect to material derived from any multiplication of the protected variety. Because of new methods of multiplication (e.g. multiplication by cell culture on one's own premises), new circumstances of multiplication (e.g. multiplication in foreign countries followed by the import of the harvested product) and new kinds of use for the living material (e.g. extraction of compounds within closed systems without any commercialization of propagating material), the scope of protection should go beyond the multiplication and commercialization of propagating material. The Subgroup recommends that the scope should be extended in principle to any use of the protected matter unless covered by an exemption or the exhaustion principle. In the light of the new techniques, it recommends studying whether the following exemptions should be maintained:

- private, non-commercial use;

- research, including use as an initial source of variation for the purpose of creating other varieties;

- commercialization of material of such other varieties;

- the multiplication on one's own premises (farmers' privilege).

As a consequence of the extension of the right to any use, the Subgroup recommends that the right be exhausted after the first legitimate commercialization of any material, in whatever state (seed, final product, processed product). As in the present Convention, the right must revive for each case of reproduction/multiplication of the protected matter.

5. DURATION OF PROTECTION

The existence of particular living material depends on maintenance activities of or on behalf of the holder of the right. As a result, it is in the interest of national economy to provide for a long period of protection, as this is the best safeguard for the material staying available.

The Subgroup recommends the provision of a longer period of protection than provided as a minimum period in the present Convention, possibly varying according to species (e.g. longer period for trees) and subject of protection (e.g. shorter period for cell material).

6. RECIPROCITY; NATIONAL TREATMENT

Following the main principles of intellectual property protection, and in connection with the application of protection to all species of living matter (see under 1), the Subgroup recommends that the Convention requires member States to apply "national treatment."

7. INTERACTION BETWEEN DIFFERENT KINDS OF PROTECTION

The possibility of a patent being granted on a process or a genetic component creates the possibility of the extension of the patent to a large number of genotypes derived from patented matter or by a patented process. If this should happen, variety rights might become dependent upon one or more patents in quite a number of cases and this would create the danger of hampering the development of new genotypes, which is contrary to public interest. Therefore, the Subgroup recommends the establishment of a clear borderline separating the two fields of protection. This could be done by introducing a provision in the Convention setting out the extent to which a patent may be enforced with respect to protected varieties of living matter. The patent should not go beyond the direct use of the invention. Direct use in this connection is understood to comprise only those acts by which the patented matter as such or the patented process as such is being used. Acts performed with material which is not itself patented (e.g. multiplication of plants which contain a patented gene) or acts performed in respect of material derived from a patented (breeding) process should not fall under the scope of the patent. On the other hand, the isolation of a patented gene and its use as such (e.g. in the transfer to another genotype) would be a form of direct use and be covered by the patent.

Since patent law generally does not regulate these questions, it seems possible to set up a provision in the UPOV Convention without conflicting with any patent law. If the question as to what extent a patent may cover a variety right can be settled in a satisfactory way, the question of double protection might have a different importance than it has now and therefore might be open to reconsideration.

8. PROTECTION OF MICRO-ORGANISMS

In many countries micro-organisms can be patented. However patenting still raises problems, especially in respect of the requirements for grant (e.g. deposit), because the subject matter of protection is living, self-replicable matter. A State might regard the main principles of the UPOV Convention as being better suited than those of the patent law to the protection of micro-organisms. Therefore, the Subgroup recommends giving the member States the possibility of applying the principles of the UPOV Convention to micro-organisms. If the State takes up this possibility it should be obliged to notify the Union accordingly.

9. PROTECTION OF ANIMALS

In most countries animals or animal species cannot be the subject of protection. At present there seems to be little or no need for such protection. This may change under the influence of biotechnology in the field of animal breeding and husbandry. Therefore, protection for animal species and animal material (the animal embryos and cell-lines) should be made possible in the future. Taking into account the fact that the subject of protection is living, self-replicable matter, the principles of the UPOV Convention seem better suited for this protection than those of the patent system. As it is not feasible at the moment to oblige States to grant such protection, the Subgroup recommends not to go further than introducing the possibility of applying the principles of the UPOV Convention to animal breeding. Again, notification should be obligatory.

10. POSSIBLE IMPLICATIONS OF CHANGES IN THE PROTECTION OF LIVING MATTER

It can be expected that the extension of the UPOV protection system to living material other than plant varieties would promote the development of high quality material and would have the same effect as plant variety protection has had so far for plant breeding.

Subject to the principle of exhaustion, the recommended scope of protection for living material is intended to close loopholes in the present protective law. No fundamental changes and, therefore, no real changes in the impact on agriculture are foreseen. However, special consideration has to be given to the exemptions, which may be of particular interest to developing countries.

The recommended borderline between patents and protective rights for living matter is expected to be in the interest of the development of new genotypes of living matter.

The inclusion of the principle of national treatment is expected to be in the interest of breeders and consumers of the member States.

Subject to the recommendation concerning the technical examination, it is not expected that the extension of the UPOV system to all plant species would raise fundamental problems in the present member States or would hamper the accession of non-member States to the Union.

It can be expected that a system striking an appropriate balance between effective protection on the one side, and public interest on the other, would be attractive for States considering the introduction of protective rights for living matter.

It is observed that a system especially designed for the protection of living matter is in the interest of the industry involved in creating the individual genotypes of living matter, either by essentially biological methods or by so-called biotechnological methods.

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