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UPOV

CAJ/XXIV/4

ORIGINAL: English

DATE: April 3, 1989

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Twenty-fourth Session
Geneva, April 10 to 13, 1989

THE INTERFACE BETWEEN PATENT PROTECTION
AND PLANT BREEDERS' RIGHTS

Draft memorandum prepared by the Office of UPOV in cooperation with
the International Bureau of WIPO

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ANNEX I

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ANNEX II

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I. INTRODUCTION

1. The Council of UPOV decided in its twenty-second ordinary session (Geneva, October 18 to 19, 1988) that the Office of the Union should propose a co-operation with the International Bureau of WIPO in the preparation of a document to serve as the basis for discussions in a joint UPOV/WIPO committee of experts meeting, which would deal with the relationships between patent protection and plant variety protection. The Council further decided that a draft of such a document should be submitted to the twenty-fourth session of the Administrative and Legal Committee of UPOV (see UPOV document C/XXII/14, paragraph 128).

2. The WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, at its fourth session (Geneva, October 24 to 28, 1988), recommended with knowledge of the UPOV proposal that a joint WIPO/UPOV meeting be convened to discuss the interface between patent protection and plant variety rights and that such a joint meeting be preceded by a joint study by the International Bureau of WIPO and the Secretariat of UPOV, which should, in the measure possible, ascertain the legal situation relating to the interface between the two forms of protection, identify key areas for discussion, describe the arguments raised in discussions to date, in both WIPO and UPOV, for and against suggested approaches to the interface between the two forms of protection (see WIPO document BioT/CE/IV/4, paragraph 132).

3. The Office of UPOV has prepared, in cooperation with the International Bureau of WIPO, this draft memorandum. The approach of the draft memorandum is to first describe the subject matter involved in the interface between patent protection and plant breeders' rights and to follow this with an historical review. Possible shortcomings from the standpoint of innovators in respect of the protection within both the patent and plant breeders' rights systems are then reviewed. An indication is given of the possible impact that a revision of the UPOV Convention and improvement of patent protection could have in remedying such shortcomings and issues outstanding after any such revision and improvement are analyzed. To further elucidate the situation and facilitate discussion, Annex I contains examples of the application of the existing law to possible example varieties, and Annex II analyzes examples of possible assumed situations concerning the protection of innovations in the plant field (covering both patent and breeders' rights aspects) with indications, for the purpose of discussion, of possible consequences. The draft memorandum is for discussion purposes only and remains subject to review in the light of deliberations in the twenty-fourth session of the Administrative and Legal Committee and in the light of any decision to be made by the Governing Bodies of WIPO.

II. THE SUBJECT MATTER INVOLVED

A. The Nature of the Plant Variety

4. In nature plants live as wild species, freely cross-pollinating within the species and occasionally with plants from related species and continuously evolving as they survive or fail to survive in response to the changes in the many natural hazards which exist in the environment. As farming developed it imposed artificial selection on crop plants. This selection pressure resulted in the emergence of land races, local crop "varieties" developed in primitive agricultural systems by human and natural selection over long periods of time. The first plant breeders set about the systematic improvement of these land

racess by selection within the land race gene pool. The resulting "varieties" based on a limited number of plants were more uniform than the land races from which they were derived. Modern varieties, frequently the progeny of a single plant, are even more uniform.

5. The term "variety" designates a concept used in the identification and classification of plant material.

6. In addressing the general task of classification and of distinguishing any class of objects (e.g. plants) from any other class of objects it is usual to bring together classes of similar objects so that observations can be made of the distinguishing features of the individuals within a class which interests us. To locate a specific object, perhaps a car in a car park, we would describe it by number of doors, color, shape and any other specific features; for absolute certainty registration number and engine block number could be deployed. It should be noted however that any group of objects can always be classified in different ways depending upon the objective of the classifier. A classification of cars for the purposes of sale would see price and technical specification as primary criteria with color as the final consideration rather than the first. An effective system of classification requires a defined purpose, e.g. the distinguishing of varieties one from another and rules for classification uniformly applied. If different parties use different rules their results cannot be reliably compared.

7. In seeking to conclude whether particular plant material constitutes or belongs to a "variety" the classifier must exercise judgement but inevitable elements in making a judgement will include the extent of its distinctness from other material, its homogeneity in the sense that variations from a standard description are within reasonable limits, and its stability in the sense that it will retain its distinguishing features from one generation to the next. An essential element influencing the judgement is the reproductive process involved in the multiplication and perpetuation of the plant material involved.

8. Many plants can or must be multiplied for practical purposes by vegetative propagation: a part of a plant containing the whole complement of genes is used to produce a new plant. Examples of traditional vegetative propagation are: the use of tubers, bulbs and the like or cuttings, layering and grafting. In vitro propagation is also a form of vegetative propagation. Since no sexual process is involved, a very high degree of homogeneity and stability may be obtained. The typical variety involved in this instance is designated as a "clone." It is the progeny of a single individual obtained by vegetative propagation; it may be as little as a single cell or protoplast.

9. The second process involved in plant multiplication or perpetuation is sexual reproduction, which involves the seed. In the sexual process, the genetic information is separated into two homologous halves in the gametes (the pollen grain and the ovule) and recombined at fecundation. A small fraction, however, which is contained in the cytoplasm, is transmitted by one parent only, mostly by the mother plant.

10. One group of sexually reproduced plants are naturally self-pollinating (autogamous) or may be forced to self-pollinate without inconvenience. This self-pollination has the effect that the homologous halves of nuclear genetic information become increasingly similar. After the sixth generation each plant will produce offspring that are virtually identical to the parent plant. In this instance, the typical variety is constituted by such offspring; it is designated as a "pure line variety."

11. Other plants cannot be self-pollinated for various reasons or would suffer from inbreeding depression, i.e. become weaker with each succeeding generation of self-pollination. The plant breeder then must ensure a proper balance between the homogeneity required for the variety to reach the desired level of overall performance in the various breeding objectives (e.g. yield, quality of the product, earliness, resistance to stress, disease and pests, etc.) and the heterogeneity required by the biological constraints. Various strategies are possible in this respect, leading to various types of varieties. In this instance varieties are all populations with individual plants differing from each other within a limited range.

12. The progeny of a crossing between two genetically different parents may express, in respect of certain characters, both the genetic information received from the mother plant and from the father plant, or show a superiority over the parents ("hybrid vigor"), or again present other advantages. Such advantages may be exploited by creating lines through self-pollination and crossing such lines on a large scale, under conditions ensuring that there is no or limited self-pollination or contamination by foreign pollen, to produce hybrid seed. Such hybrid seed, which can only be produced by using the described crossing process, represents a "hybrid variety." An F_1 hybrid is the cross of two lines; it shows a very high degree of homogeneity. A double-cross hybrid is the cross of two F_1 hybrids; it is heterogeneous, within the limits of the genetic diversity present in the four parent lines constituting the formula of the hybrid.

13. The materials which comprise a variety at any one time may be a whole plant or plants, seeds, any part or parts of plants which embody the full complement of genes of a complete plant. It is becoming an accepted practice to store plant varieties and other material in plant collections in the form of appropriate plant parts in tissue culture. Since every plant cell is totipotent (i.e. it embodies the complete genetic code for the whole plant and can, subject to technological restraints, be used to regenerate a whole plant) this means in practice that a plant variety can be represented at a point in time by a unit as small as a single cell or protoplast.

14. The concept of variety has accordingly always been broad in nature. It embraces a number of categories with widely differing methods of reproduction and degrees of genetic uniformity. There is no absolute dividing line between a population and a variety; the two merge imperceptibly into each other, and the one or the other expression will be used depending primarily upon the purposes of the person using the expression.

15. The purpose for which the notion of variety is most frequently used is one in which a plant genotype or group of plant genotypes is described and distinguished from another plant genotype or group of plant genotypes.

16. One can describe a variety only by observing its components through a complete life cycle from seed to seed or from one lot of vegetative propagating material to another. A variety might be described by seed, leaf, flower or pod characteristics or perhaps by the biochemical characteristics of the harvested product. A picture can be built up over a period but cannot all be observed at the same time.

17. The practical question which arises is how to describe and distinguish one variety from another under practical circumstances, given that the physical appearance of the individuals within a variety in each of its various growth stages may differ from one environment to another, varying with season,

location, fertility and other growing conditions. Questions of this nature have concerned agricultural and horticultural botanists in modern times, particularly in the context of the trade in seeds and the necessity to identify definitively by variety specific lots of seed or plant material, both under storage condition but also as a growing crop or plant in the field. A specialized scientific art of increasing sophistication was developed in this context by traders, botanists and governments.

18. The fact that governments were able in 1961 to create the International Convention for the Protection of New Varieties of Plants was in a large measure due to the specialized knowledge developed in the preceding 50 or so years. In order for a system of protection for plant varieties to operate in practice, first the subject matter of the rights must be precisely defined, and secondly the protected variety must be readily identified under practical circumstances to meet the standards of proof required in the courts in proceedings against infringers. The technical criteria imposed by the UPOV Convention are specifically designed to meet this need. The requirement of distinctness is linked with the requirements of homogeneity and stability. Unless a variety is sufficiently uniform, that is unless it reaches the level of uniformity appropriate for its mode of reproduction, it is not possible to identify a sufficient number of characteristics typical of the variety so as to readily distinguish it from other varieties. Unless a variety is stable in its distinction features from one generation to another it will not have a fixed identity to which a grant of rights can attach.

19. Over the 27 years of existence of the UPOV Convention, the body of scientific art concerned with the identification of varieties has expanded dramatically. The UPOV Guidelines for the Conduct of Tests for distinctness, homogeneity and stability of new varieties of plants, the practical know-how on the conduct of tests held in the national offices of UPOV member States and the steadily growing data banks held by such offices constitute the major source of knowledge of the art concerned with the systematic botany of the major cultivated plants in the world.

B. The Nature of Plant Breeding

20. Genes are the building blocks of varieties but the characteristics that one sees in a given plant (the plant's "phenotype") are not necessarily directly related to the genotype. The observed characteristics result from a chain of physico-chemical reactions and interactions initiated by genes but leading through complex chains of events, controlled or modified by other genes and the external environment, to the final phenotype. To a greater or lesser degree the functioning of any gene whether naturally present within the plant or introduced by genetic engineering depends on the genotype of which it is a part and on the external environment to which it is exposed.

21. Some single genes control a single qualitative characteristic, e.g. certain genes for dwarfness in wheat. The characteristics that are of greatest interest to plant breeders and users, for example yield, are those which vary continuously and are controlled by very large numbers of genes.

22. When two plants are crossed, their respective gene complements re-combine and their progeny segregate in subsequent generations. It has been calculated that if two wheat plants of two hypothetical very similar varieties (so similar in fact as to be unlikely to exist in practice; the varieties are assumed to differ in only 21 gene pairs) are crossed, the process of segregation, if

allowed to continue through the number of generations necessary to produce a population of individuals expressing all the potential combinations of genes present in the two parents would number 4,398,046,511,104 individuals of which only two would be the same as the parental types. At typical planting rates this population would occupy 50 million acres or an area five times the size of Switzerland.

23. In nature, the full range of genetic variability is rarely expressed. Vast numbers of individual plants will have defects which prevent survival; they may be susceptible to disease, drought, heat, cold or other factors present in their environment. Nature places specific selection pressures upon the vast potential for genetic variability. Only genotypes able to resist drought will survive in a drought stricken environment and the local population of a plant will consist entirely of drought survivors. However, within the genomes of the plants in the population, there will remain great reservoirs of potential variability for the generation of alternative plant forms if the selection pressure for drought resistance is removed or if cross pollination occurs with plants from another population.

24. Man in turn has placed specific selection pressure upon particular plant species. He needs, for example, to harvest his crop at a particular time so that the only individuals which survived from a primitive wheat population were those which set viable seed which remained on the plant at harvest time.

25. The roots of modern plant breeding lie in the early years of the 19th century when man began systematically to select superior plants from within the available range of genetic variability. Since that time, and prior to the unravelling of the structure of the DNA molecule, great progress was made in understanding the genetics of crop plants. Plant breeding became a highly organized activity, drawing upon knowledge from related sciences, where genetic diversity was created by all available means and selection pressure applied to select individuals meeting very specific selection criteria.

26. Since the most important features of plant varieties such as the harvested yield are frequently the net result of the activity of large numbers of genes which have played a role at one time or another in the development of the plant either directly or through interaction with other such genes and since there may be some twenty or more such important features, the task of the breeder is to create a vast range of variation and to select individuals that express the optimal combination of the desired characteristics. A large proportion of his work consists in crossing individuals, which express the desired features to a high degree, with other such individuals, in order to concentrate the desired genes giving an ever better expression of the whole range of desired characteristics in the latest varieties. Quantum leaps occur (yield improvements in new varieties of 5 - 10% are not uncommon) but any significant improvement in any characteristic which is not matched by an excessive deterioration in the expression of some other desirable characteristic will still represent progress for the plant breeder and the user.

27. The dramatic contrast between varieties in use 50 years ago and those used at the present time results from incremental progress and quantum leaps by many individual breeders over many years where later breeders have used the varieties of their predecessors as the basis for the next step up in performance.

28. The activity of the plant breeder is not different in essence from the pressure placed by the natural environment upon a species of plant, e.g. the drought resistant population considered earlier. The plant breeder's activity

speeds the selection process very greatly but he is still, in effect, putting pressure on a population to move it in a desired direction. This is a core activity for a plant breeding program but can be supplemented in some instances so as to enable speedier progress.

29. The plant breeder by the manipulation of selection pressure moulds the vast and complex structure of the plant genotype into forms which progressively approach his pre-specified ideal. The integration of an extraneous single gene into this structure would be the equivalent, perhaps, of positioning a single nut or bolt into an off-shore drilling platform and, of course, some nuts and bolts are more important to the structure than others. The great technical achievements of genetic engineering are concerned, in effect, with methods for introducing or removing nuts, bolts and components from plant structures. It is generally agreed that within the foreseeable future progress in the improvement of plant structures (i.e. of plant varieties) will continue to be achieved by exploiting the innate ability of plants, in the course of their reproduction, to assemble genes in fresh combinations. The new technologies will typically insert specific genetic factors into the structures which have been thus developed.

III. AN HISTORICAL REVIEW

A. Early Attempts to Apply Patent Protection to Plant Varieties - Problems Involved

30. The conditions for obtaining patent protection for an invention are the following:

(a) there must be an invention;

(b) patent protection must not be excluded for the category of invention under consideration;

(c) the conditions of patentability (novelty, inventive step (non-obviousness), industrial applicability) must be fulfilled;

(d) the invention must be described in a sufficiently complete and precise way for a person skilled in the art to reproduce it, i.e. there must be an "enabling disclosure."

31. Doubts concerning the patenting of plant varieties arose in different ways in different countries and involved the following issues:

(i) that, according to an opinion maintained in particular during times of food shortages, monopoly rights in relation to food production were undesirable;

(ii) that the modification of living matter was a "product of nature," a "mere discovery" or "essentially biological";

(iii) that plant varieties were not industrially applicable;

(iv) that the creation of a new plant variety did not involve an inventive step; it was sometimes considered to be obvious to a person skilled in the art that the progeny of a cross between variety A and variety B might include examples with improved yield;

(v) that, in contrast to inanimate matter, living material could not be fully described and even when described living matter could not be independently reproduced by a person skilled in the art without access to the actual living material, the subject of the invention.

32. Until the 1960s, patents were granted in relation to plants in some States, e.g. Belgium, France, Germany (Federal Republic of) and Italy, but the subject remained one of legal controversy and uncertainty. In other countries, patents for plant varieties were expressly excluded from patent protection by statute and by legal interpretation in decided cases. Uncertainty arose particularly from the difficulties which existed when the patent doctrine of exhaustion of rights was applied to self-replicating material. The fact that patent rights are exhausted when goods subject to a patent are placed into the market was, according to one opinion, considered to have the effect of nullifying the benefits of the patent when such goods freely reproduce.

B. The Plant Patent Step

33. Notwithstanding widespread doubts but taking into account requests by interested plant breeders, the Congress of the United States of America opened the patent system to plant varieties by the provisions of the Plant Patent Act of May 23, 1930.

34. The Act granted protection only to varieties of plants propagated by vegetative means (excluding, however, tubers) and since varieties of such plants reproduce themselves precisely they are relatively amenable to description. Furthermore the Act relaxed the normal patent law requirement of full description in requiring only that the description be "as complete as is reasonably possible." Only one claim was permitted and that was to the plant shown and described. The scope of the right granted was defined as the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced. In its present form, in the United States Patent Code (35 USC), Section 161 provides that a plant patent may be granted to "whoever invents or discovers and asexually produces any distinct and new variety of plant, including cultivated sports, mutants and hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state."

35. Of the three general requirements for patentability, distinctness replaces industrial applicability in the case of plant patents, but novelty and inventive step (non-obviousness) are still required. The inventive step (non-obviousness) requirement has presented particular problems. In *Yoder Bros v California-Florida Plant Corporation*, the Court of Appeal thought that in this context the non-obviousness requirement was designed "to ensure that minor improvements will not be granted ... protection" and to limit protection to a new variety that "adds significant improvements." A subsequent Senate Patent Committee view was that it was "immaterial whether the new characteristics are inferior or superior to those of existing varieties. Experience has shown the absurdity of many views held as to the value of new varieties at the time of their creation." The difficulty of applying the non-obviousness criteria means that in practice it is largely ignored; President Johnson's Commission on the US Patent System expressed concern that the criterion of non-obviousness was not applied in the granting of plant patent applications.

C. The Plant Breeders' Rights Step

36. The United States of America novel concept of a plant patent was not widely followed in other countries. Only Cuba, the Republic of Korea and South Africa introduced a plant patent based on similar principles. Attempts continued in the post-war years to persuade industrial property and patent circles to provide protection for new plant varieties on a coherent and consistent basis, but without success. However, in 1961 the International Convention for the Protection of New Varieties of Plants (the UPOV Convention) was adopted. To a large extent the initiative for this measure originated in agricultural circles and, whilst in many respects it is modeled on industrial property principles, it took the form of a sui generis protection specifically designed to provide for the nature of plant material and of new plant varieties.

36. A particular feature of the UPOV Convention is that it specifies in unusual detail the minimum content of the laws that prospective member States should enact if they were to adhere to the Convention. This has provided a high degree of harmonization in breeders' rights laws. The UPOV Convention introduced a form of protection for new plant varieties based upon novelty, distinctness, homogeneity and stability. The Convention contains in Article 2(2) the following definition of the term "variety:"

"For the purposes of this Convention, the word "variety" applies to any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs 1(c) and (d) of Article 6."

Article 6(1)(c) provides that

"The new variety must be sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation."

while Article 6(1)(d) provides that

"The new variety must be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle."

37. It should be noted that the Convention in no sense attempted a total definition of the concept of variety. It simply stated that, for the purpose of protection under the Convention, the word variety "applies" to certain very broad descriptions of plant material which are sufficiently homogeneous and stable. Plant material of varieties which are not homogeneous and stable to the extent required by the Convention are not protectable under the Convention but may nonetheless still be considered representative of a "variety." When the Convention was revised for the second time in 1978, the definition of variety was removed.

38. The Convention introduced a concept novel to industrial property which was not found in the same way in the plant patent legislation of the United States of America and other countries. Article 7(1) provided that

"Protection shall be granted only after examination of the new plant variety in the light of the criteria defined in Article 6. Such examination shall be adapted to each botanical genus or species having regard to its normal manner of reproduction or multiplication."

This physical testing of actual materials contrasts with the paper examination which is characteristic of the patent system. Under Article 7(2), the competent authorities of each country are empowered to ask the breeder "to furnish all necessary information, documents, propagating material or seeds."

39. The combination of the features of distinctness, uniformity and stability plus the requirement of an objective physical examination of each candidate for protection, addressed head on the difficulty in describing living material which had hitherto preoccupied industrial property circles when addressing the protection of plant varieties. The objective examination system provided an opportunity for all candidate varieties to be examined in accordance with a uniformly applied system of classification when enquiring into distinctness. The requirement of homogeneity also facilitated precision in the definition of the protected subject matter while the requirement of stability ensures that the protected subject matter could continue to exist in the identified form. The requirement for a growing test ensures that varieties of relevance for distinctness (existing varieties and other new varieties) will be grown alongside each other under the same environmental condition when assessing distinctness so as to minimize phenotypic differences in order that reliable conclusions can be drawn concerning distinctness.

40. The thoroughness of distinctness testing, and in particular the efforts made to limit environmental effects, provides applicants with confidence that it will be possible to grow the protected variety alongside alleged infringing samples of seed so as to provide evidence of infringement.

41. The difficulties arising from exhaustion of right in the patent system in relation to self-replicating living material do not arise in the plant breeders' rights system, since the right accorded to the breeder is in effect the exclusive right to produce reproductive or vegetative propagating material of his variety for commercial marketing and to offer for sale and to market such material. Each time that his variety is reproduced his right revives to cover the sale and marketing of the reproduced material.

42. The scope of the right envisaged by the UPOV Convention differs in important respects from the patent right. Under patent law, subject to the concept of exhaustion of right, every commercial utilization of the subject matter of an invention is covered by the protection. With plant breeders' rights only the production for commercial marketing and the offer for sale of reproductive material of the protected variety is subject to the protection. The harvested material is not covered by the protection, and where a farmer reproduces the variety on his farm, not for the purposes of commercial marketing but in order to use the material for his own purposes on his own farm, this also falls outside the scope of protection. This is the so-called farmer's privilege. It is also notable that the architects of the UPOV Convention, although widely separated in time and space from the U.S. legislators responsible for the Plant Patent Act, adopted one important provision in common with their U.S. forebears. The protection afforded by the UPOV Convention is for the variety, the physical reality and not for an inventive idea concerning the breeding of a variety. There is no possibility of making claims. Under the provisions of the Plant Patent Act the only claim permitted is for the variety. Both legislative provisions recognize that a variety must exist physically if it is to exist at all. The UPOV Convention exhaustively determines the scope of protection and should be contrasted with the patent system which allows inventors to specify the scope of protection by the free formulation of claims.

43. A further feature of the UPOV Convention is that the Convention expressly provides that the authorization of the breeder is not required in order to use the new variety as an initial source of variation, i.e. as a parent in the creation of other varieties or for the marketing of such varieties. This contrasts with a possible position under patent law where the second variety might be "dependent" upon the first variety.

44. Article 2 of the UPOV Convention provides that, whilst the rights to be created by a UPOV member State could be provided in the form of a patent or of a plant breeders' right, only one of such forms could be provided for any one and the same botanical genus or species.

45. In relation to novelty, the Convention requires that distinct varieties should not have been marketed or offered for sale with the agreement of the breeder in the State where the application is filed or for longer than four years in the territory of any other State. Insofar as this rule is more generous than the corresponding rules in the patent system, it recognizes the particular nature of plant material (physical release of plant material is essential if a person is to have access to a variety; it is not necessary to base novelty on publication) and the extensive testing required to ascertain adaptation to the conditions in any geographical area. The Convention adopted rules for national treatment and priority which were broadly similar to those adopted by the patent system. To aid users of varieties, the Convention requires that a denomination be given to a variety prior to a grant of rights.

D. Exclusions from Patenting

Historical Developments

46. The deliberations which led to the UPOV Convention took place in Paris between 1957 and 1961 and included eminent specialists in both plant breeding and industrial property. Certain of the specialists in industrial property were also involved contemporaneously in work which led to the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (adopted in 1963) (hereinafter referred to as the "Strasbourg Convention") and the European Patent Convention (adopted in 1973). Delegates to the Lisbon Diplomatic Conference (1958) to revise the Paris Convention for the Protection of Industrial Property (hereinafter referred to as "the Paris Convention"), aware that a system for the protection of new plant varieties outside the framework of the Paris Convention was emerging, were asked to extend the benefits of patent protection to new plant varieties. They decided to take no action on the question. Article 2 of the Strasbourg Convention and Article 53(b) of the European Patent Convention should be considered in the light of the above. When the Strasbourg Convention was concluded in 1963 under the auspices of the Council of Europe, Article 2 of the Convention provided that the Contracting States were not bound to provide for the grant of patents in respect of plant or animal varieties or essentially biological processes for the production of plants or animals (with the exception of microbiological processes and the products thereof). When the European Patent Convention was concluded in 1973, the Munich Diplomatic Conference made use of the freedom under the Strasbourg Convention and excluded the grant of European patents for these particular categories of inventions in Article 53(b) EPC, which provides that European patents are not to be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals (with the exception of microbiological processes and the products thereof). The European Patent Convention entered into force in 1977 and is

presently in force in the following 13 States: Austria, Belgium, France, Germany (Federal Republic of), Greece, Italy, Liechtenstein, Luxembourg, Netherlands, Spain, Sweden, Switzerland, United Kingdom. These States provide for the same (or practically the same) exclusion also in their national laws.

47. An exclusion of plant varieties from patenting also exists in the national laws of the following States, namely Algeria, Bahamas, Barbados, Brazil, Bulgaria, China, Colombia, Cuba, Cyprus, Denmark, Ecuador, Finland, German Democratic Republic, Ghana, Israel, Kenya, Malaysia, Mexico, Nigeria, Norway, Peru, Poland, Portugal, Romania, South Africa, Soviet Union, Sri Lanka, Thailand, Uganda, United Republic of Tanzania, Yugoslavia; together with the members of the African Intellectual Property Organization (OAPI) that is Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Gabon, Mali, Mauritania, Niger, Senegal and Togo. Section 112 of the WIPO Model Law for Developing Countries, published in 1979, contains the following provision in paragraph (3): "The following even if they are inventions within the meaning of subsection (1), shall be excluded from patent protection: ... plant or animal varieties." Rule 39 of the Regulations under the Patent Cooperation Treaty establishes "that no International Searching Authority shall be required to search an international application if and to the extent to which its subject matter is ... plant or animal varieties."

Reasons for the Exclusion of Plant Varieties under the European Patent Convention

48. The two reasons put forward to explain the exclusion of plant varieties from patenting in the European Patent Convention are first that a special system of protection for plant varieties already existed in a number of countries and that it was considered that this system should remain as the only applicable system for plant varieties, and second that at the time of the creation of the European Patent Convention it was considered that granting patents for biological inventions could create legal and administrative difficulties and the newly created European system should not be burdened with such difficulties.

Interpretation

49. Doubts have grown up as to the interpretation to be given to the wording of Article 53(b) EPC. In particular, the question has been raised whether the wording which excludes from protection plant varieties means that all plant inventions are excluded or whether there are some plant inventions that are somehow not covered by the exclusion.

50. There is a significant body of opinion that the exclusion of plant varieties means that only plant varieties per se are excluded from patentability. This opinion relies on the Ciba-Geigy case ((1984) OJ EPO 112) in which a Technical Board of Appeal of the European Patent Office held that Article 53(b) prohibits only the patenting of plants or their propagating material in the genetically fixed form of a plant variety. The view has been expressed that it is inherent in the decision that an individual trait or characteristic of a plant should be patentable. Furthermore it has been stated that the approach and policy of the decision have been followed by at least one national patent office, since the Federal Intellectual Property Office of Switzerland has adopted a practice statement which provides that product claims relating to whole plants or their propagating material (seeds, tubers, cuttings, etc.),

but in which no variety is specified, that is, claims containing characters that are valid for several varieties (for example, a whole genus), are not excluded from patenting under Swiss patent law. It will have to be further examined whether the Ciba-Geigy decision can be taken this far. The case concerned an application for a patent under the European Patent Convention which had claims for plant propagating material (including seed) treated with certain chemical agents. The invention claimed the treatment of propagating material in a certain way; it was essentially a technical one and in no way involved the phenotype or genotype of plants. Reversing the decision of the Examining Division, the Technical Board of Appeal held that such an invention was not unpatentable as a result of Article 53(b), which was not surprising since the invention in question bore no relationship whatsoever to plant varieties or biological processes for the production of plants. The Technical Board of Appeal stated that Article 53(b) prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety. However, that statement was obiter dicta since the Board did not have to deal with exactly what is prohibited by Article 53(b) but rather with whether the specific inventions claimed were excluded subject matter.

51. The view that Article 53(b) only excludes from patenting plant varieties per se and that other plant inventions are not excluded is the narrow interpretation of this Article. Such an interpretation can be supported on the grounds that exclusions from patent protection are to be considered as exceptions from a general principle and, according to general rules of interpretation, any exception from a principle requires a narrow interpretation. On the other hand, a broad interpretation of Article 53(b) can be supported on the grounds that patents should be considered in themselves as an exception from the general principle that technology may be freely used, and therefore exceptions from patenting should be construed broadly. In any event, the rules of interpretation of statutory provisions require first the ascertainment of the purpose and objectives of the provision; only thereafter does one examine whether a provision constitutes the general law or the exception. If it is assumed that Article 53(b) only excludes plants in the genetically fixed form of a plant variety but does not apply to individual plants or parts of plants or to categories of plants higher than that of variety, the following problems arise:

(a) plant breeders may find it impossible to distinguish between a plant and a variety; frequently a plant is totally representative of a variety;

(b) if a characteristic which is common to a group of varieties or to a whole species or botanical family is an acceptable claim in a patent relating to a plant, the provisions excluding plant varieties (the European Patent Convention uses the plural) from patenting would be meaningless in a situation which involves more than one variety but would only be applicable to a single variety; the question arises whether such a conclusion is logical and acceptable;

(c) parts of plants are in effect propagating material since it is possible in many cases to reproduce a whole plant from them by appropriate techniques; since a patent claim for all callus or all cells would clearly not be allowed, protection sought will invariably be for the callus or cell-line of a particular plant; it is the protection of the particular plant that is important and for this protection is available under the plant variety protection system.

52. Concerning the protection of genetic components or genes (DNA-sequences as agents of genetic information), these are in one sense plant material. On the other hand, genetic components being chemical compounds have an identity independently of particular plant material. Since mere components do not contain the genetic code for a complete plant they can in no sense be regarded as representative of a plant variety. It seems to be well established that genetic components are not excluded from patenting as a result of the plant varieties exclusion. In a number of countries it has been held that genetic components can be protected by patents.

E. The Industrial (Utility) Patent Step

53. The provisions of Article 2 of the UPOV Convention are such that UPOV member States remained free if they so wished to grant patents for varieties of any botanical genus or species for which they did not grant plant breeders' rights. Patents were granted for plant varieties on this basis in France, Germany (Federal Republic of) and Italy but the practice was limited because of uncertainty concerning the application of the patent system to plant varieties, in particular because of doubts concerning the enforceability of patents for reproduceable material, as a result of the doctrine of exhaustion of right.

54. Some specific reference should be made to the position in the United States of America, which had created in 1970 a system of plant variety protection for sexually reproduced plants on principles which were broadly similar to the principles of the UPOV Convention and which complemented the plant patent provisions of the Patent Law for varieties which were reproduced asexually. Some plants, however, can be reproduced either sexually or asexually so that in certain cases there existed the possibility to protect a plant variety by both a plant patent and a plant variety protection certificate. This situation conflicted with the provisions of Article 2 of the UPOV Convention and was considered to render the United States of America ineligible for UPOV membership. When the UPOV Convention was revised in 1978, Article 37 provided that, during the period for which the revised Convention was open for signature, any State which provided protection for one and the same species in the different form provided in Article 2(1), could continue to do so if it made an appropriate reservation prior to signing or ratifying the Convention. The United States of America made such a reservation at the time of its signature of the Convention. The period during which the revised Convention was open for signature having expired and no further reservations having been made this option is not available to other States.

55. Paragraph (2) of Article 31 of the UPOV Convention provides that, where a reservation has been made by a State and protection is sought under patent legislation, the State may apply the patentability criteria and the period of protection of its patent legislation to varieties protected in this way.

56. Following upon a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office of August 9, 1985, in re Hibberd, the United States of America now grants "utility" patents as well as plant patents and plant variety protection for plant varieties. This decision is in line with the Chakrabarty decision of the United States Supreme Court, according to which an invention is not precluded from patent protection under Section 101 because it consists of living matter, the test for patentable subject matter in the United States of America being whether the invention is the result of human intervention. However, problems in a number of areas seem

to remain. In particular, the application of the exhaustion of right principle generally to self-replicating material requires clarification, as well as the rights of patent owners in relation to farm-saved seed, the so-called "farmer's privilege." Whether the research exemption operates so as to totally forbid the use of a patented variety as a parent in a breeding program or whether it operates only to forbid the commercialization of a resulting new variety also seems to require clarification. Moreover, little experience exists on the application of the requirement of non-obviousness to plant varieties, and problems may arise with the breadth of claims for plant varieties. Since there is no existing body of art within the patent system a tendency exists to grant patents with wide claims; this problem is likely to diminish as applicants and examiners gain experience and the patent documentation concerning the state of the art of plant varietal development is built up. However, the development of new plant varieties is an established field of technology. Documentation concerning the state of the art exists primarily within the UPOV plant variety protection system. This particular example of a perceived problem with the application of patents to plant varieties does highlight the desirability of protecting plant varieties on the basis of uniform criteria.

Biotechnological Development - Implications

57. The unravelling by Watson and Crick of the structure of the DNA molecule (the chemical which makes up the nucleus of the cell and of other cell parts imparting genetic information) and the development of techniques for adding or removing DNA, or "genes," from the cells of living organisms has revolutionized biology and created the potential for major industrial developments. New genes can be added to plants artificially without resorting to the normal plant reproduction process and can be transferred not only from other plant species where cross fertilization was hitherto impossible but can also be transferred from plants to micro-organisms or animals or vice-versa. Other developments in the field of tissue culture permit individual cells of living organisms to be multiplied in vitro and for whole plants to be generated from such cells. The walls of individual cells of differing species can be dissolved and cells persuaded to merge, permitting the exchange of cell materials. Where plants can be regenerated from the merged cells there arises the possibility of new species based upon the cell and nuclear materials inherited from both parent species. A cross between a tomato and a potato and a chimaera based upon a goat and a sheep are often referred to as examples, but examples only, of what is now possible.

58. It is no longer necessary when describing living material to rely solely on the examination of morphological or physiological features of the various growth stages of the complete organism. It is possible to describe certain features of living material, typically however limited to qualitative features encoded by a single gene, by reference to the actual chemical composition of certain genes or gene products which are totally uninfluenced by environment.

59. Accordingly it is claimed that the difficulties in providing a complete description of living material are no longer of concern; that in many instances, for example with genetic engineering, inventions are reproduceable and that developments in this field clearly satisfy the requirement of inventive step or non-obviousness. Since the doctrine of exhaustion of right remains a difficulty with reproduceable living material it is suggested that this question should be clarified in patent laws (see draft suggested solution No. 10 in WIPO document BioT/CE/IV/3).

60. It is further claimed that any remaining lack of definition in description or disclosure should be remedied by extending the use of deposit (designed for micro-organisms) to higher forms of life including plants. The impossibility of making an enabling disclosure in the plant field would then be remedied by substituting a deposit. It should be noted, however, that deposit substitutes for an enabling disclosure; it does not amount to a description and to that extent much of the original difficulty remains.

IV. THE CURRENT DEBATE

A. Perceived Problems for Biotechnological Inventors and Plant Breeders in Relation to the Protection of Innovations in the Plant Field

61. The UPOV Convention was created in 1961 after a long period of uncertainty in both patent and agricultural circles concerning the desirability and feasibility of granting property rights in new plant varieties. The rights granted represented, after intense debate, a balance between the interests of plant breeders and the public interest in providing an incentive to encourage their activities and the interest of farmers and growers whose freedom to produce and sell new varieties was curtailed and the interests of the consumer who was deemed to be harmed by excessive monopoly rights at the most fundamental point in the food chain, i.e. at the level of the primary producer.

62. Accordingly, the UPOV Convention, instead of conferring upon the breeder the extensive rights to exploit his variety, including the final product arising from the growing of his variety, which might be granted by the patent system, required only of its member States that they create as a minimum an exclusive right in favor of the breeder to produce reproductive or vegetative propagating material of his variety for the purposes of commercial marketing and to offer for sale and to market such material.

63. The Convention provided expressly that a new variety should be freely available as an initial source of variation for the purpose of creating other varieties. This provision also contrasted with the possible position if patents were to be granted for varieties since it is to be assumed that in that event the later variety would be dependent upon the earlier variety; however, this provision did reflect the widely held view amongst agriculturists that there was almost a moral requirement that germplasm be freely available to contribute to the next incremental step in breeding performance. The provision also reflected a basic practical reality of plant breeding that, where a variety is used as a parent in a plant breeding program, the progeny of the cross will not necessarily owe their features in any strongly identifiable way to one particular parent. This would not be true of all plant breeding procedures but will frequently be true in the case of a simple cross. Transgressive segregation frequently causes features to appear in progeny which are not found in either parent.

64. The nature of the breeders' exclusive rights as defined in Article 5(1) of the UPOV Convention are such that the production of reproductive or vegetative propagating material by a grower, not for the purposes of sale but for further use on his own holding, falls outside the breeder's right (this is the so-called "farmer's privilege"; it does not exist in all UPOV member States).

65. The breeders' rights are exercisable in relation to the protected "variety," that is the specific plant material which comprises the variety with the particular combination of characteristics which it expresses. It is

not possible to claim a monopoly for a characteristic taken in isolation, as might be the case were a patent to be granted for a plant variety. This also reflects plant breeding reality in that a characteristic in conventional plant breeding terms has no independent existence. An individual characteristic, along with a host of other characteristics, exists only in the particular combination presented by the variety, while the breeder may have limited or no knowledge concerning the genetic factors governing its inheritance. Each new combination of characteristics qualifies for an independent title of protection.

66. In 1961, there was limited interest in industrial circles in plant breeding and seed marketing, and this fact is probably reflected in the relative disinterest in protection for plant varieties which had existed in patent circles. The Convention and the national laws based upon its provisions which were subsequently enacted have had a dramatic effect upon the level of plant breeding and commercial activity in relation to the development of new plant varieties. The impact of these developments upon agricultural and horticultural productivity has been widely documented.

67. The achievements of genetic engineering and tissue culture technology and the prospects for further development changed the public perception of the seed and plant breeding industries and accentuated significantly an existing trend towards concentration. Significant additional investments in the new technologies have been made within the industry but also by organizations outside the industry who have seen technology as the basis for entry to the industry.

68. The financial risks associated with investments in plant breeding and biotechnology and the significant investments involved have led to criticism, from organizations accustomed to operating within the patent system, of the tightly defined scope of industrial property protection available under the UPOV Convention in its present form, of the exclusions from patenting of plant varieties and of essentially biological processes for the production of plants which exist in many patent laws and also of the intrinsic difficulty of patent laws to effectively protect inventions for self-replicating living matter, particularly where the self-replicating living matter is the material put into commerce.

Particular Features of the Availability of Protection for Inventions Concerning Plants which have Attracted Criticism

(a) The Limited Scope of Protection Available under the Plant Breeders' Rights System

69. Although the UPOV Convention allows the granting of more extensive rights than the minima prescribed in the Convention, member States have not availed themselves of this possibility except in the limited cases of cut flowers and fruit trees, presumably because they felt that the UPOV protection formula provides an adequate incentive for plant breeders appropriately balanced with the interests of other groups. It is, however, criticized that protection limited to reproductive material and not extending to the product of the variety is inadequate to protect both the products of classical plant breeding and the broad range of novel inventions which can be anticipated upon the full deployment of the new technologies. Plant varieties expensively transformed to produce particular proteins or other materials will not be adequately protected if any farmer can produce the variety freely and sell the new final

product without constraint. The "farmer's privilege" severely restricts both the total market available for sales of an improved variety (a large percentage of the potential demand will be satisfied by on-farm seed production) and the fact that the farmer has the freedom to produce his own seed (he can clearly do so very cheaply) severely restricts the profitability of the limited proportion of the demand for seed which is in fact satisfied by purchased seed.

70. So long as there is no transfer of property in seed of a protected variety, business organizations, offering an on-farm mobile seed cleaning service or offering a custom cleaning service on their own premises, are thought to be able under many laws to profit from the freedom which farmers possess to produce seed for their own purposes. Similarly, a fruit grower, for example, can buy one specimen of a new variety of tree and could use that as the basis of further tree propagation to plant a complete orchard but the breeder's sole chance to profit would be on the sale of the original single tree. The fruit grower could continue to profit permanently from sales of fruit of the variety.

71. The limitation of protection to the variety in its entirety and the non-availability of protection for an isolated characteristic of the variety is claimed by some (but disputed by others) to discourage breeding designed to introduce totally new features into plant varieties.

(b) The Breeder's Exemption

72. The breeder's exemption, according to which any variety can be used as a source of initial variation in the production of other varieties, is seen by some as a major drawback of the UPOV protection (see Article 5(3) of the UPOV Convention). The exemption does not only mean that the variety can be used as a parent in a crossing program (as indicated above, this freedom is widely supported) but that the variety itself can be re-selected by the removal of a deviant fraction and provided this fraction when isolated is clearly distinguishable by one or more important characteristics from the totality of the original variety it is entitled to a separate and independent title of protection. Similarly, if a new variety is subjected to a process such as back-crossing or perhaps is transformed by genetic engineering so as to introduce what is effectively a single new gene, the product of this step will, if it satisfies the distinctness rules, be entitled to an independent title of protection free of all obligation to the original breeder.

(c) Doubts Concerning the Exercise of Patents for Genes Incorporated into Plant Varieties

73. The UPOV Convention confers a positive right to produce and sell the new plant variety (see Article 1(1) "The purpose of this Convention is ... to ensure to the breeder ... a right the content and condition of exercise of which are defined hereafter and Article 9." "The free exercise of the exclusive right accorded to the breeder ... may not be restricted otherwise than for reasons of public interest."). These provisions when read together with Article 5(3), the research exemption, whereby any variety may be freely used as an initial source of variation, give rise to the question of whether patents for genes which have been incorporated into a plant variety should be enforceable.

(d) The Exclusion of Plant Varieties and Essentially Biological Processes for the Production of Plants from Patenting in the European Patent Convention and in Many National Laws

74. The view is taken that this exclusion, where it exists, negates the possibility of using the patent system to protect plant varieties in cases where new plant varieties otherwise would fulfill the patentability criteria. The opportunity to take advantage of the possibly wider protection afforded by the patent system is thus denied. A further problem is that the actual wording of the exclusion leaves many uncertainties particularly in view of the impact of the new technologies. Attempts to interpret the exclusion in a restrictive sense have been made (see paragraphs 49 to 51 above).

(e) Doubts Concerning the Meaning of the Expression "Microbiological" in Article 53(b) EPC and the Effect of the Exclusion of Plant Varieties upon the Claims for Plants or Plant Varieties as the Direct Products of a Microbiological Process

75. Article 53(b) of the European Patent Convention provides that the exclusion from patenting of essentially biological processes for the production of plants or animals does not apply to micro-biological processes or the products thereof. This exception to an exception was added to ensure that the protection of pharmaceutical products (particularly antibiotics) and processes based upon the use of micro-organisms should not fall within the exclusion. It could not have been envisaged at the time when the provision was drafted that a plasmid of Agrobacterium tumefaciens (a micro-organism) would be used to transfer genes into plants so as to create new varieties. Equally it seems unlikely that it was envisaged that plant cells fell within the field of microbiology which was concerned at that time exclusively with micro-organisms, and a plant cell is in no obvious sense a micro-organism. To the extent that a process is truly micro-biological, and if the product of the process is a plant variety, is the variety protectable by a patent or is this possibility excluded by the exception relating to plant varieties? The acceptance of claims for the production of plants (which are representative or "specimens" of a plant variety) would have the effect of wide-spread protection of plant varieties by process patents. Whilst this result did arise in the case of processes for the manufacture of pharmaceutical products, which were also the subject of exclusions in some national patent laws, a similar result with plants would seem in the opinion of some to run counter to the objective of Article 53(b) in excluding the grant of patents in respect of plant varieties.

(g) Doubts Concerning the Application of Patent Principles to Self-Replicating Living Material

76. What is the product obtained by a biotechnological process? Does it consist of the product of the process or does it extend to products obtained from the product by replication (cloning) and/or differentiation (plant from cell)? WIPO document BioT/III/2, page 30, reports on existing uncertainty in the patent field with respect to products obtained by replication and/or differentiation. The position in relation to plant varieties protected by breeders' rights is clear. The breeder's right potentially revives in relation to each replication.

(h) Doubts Concerning Exhaustion of Patent Protection

77. Would a patent granted in respect of a plant variety be exhausted after an initial sale? WIPO document BioT/III/2 reports on existing uncertainty in

patent circles. The position in relation to a variety protected by breeders' rights is clear. Each reproduction potentially revives the breeder's rights.

(i) Limited Application of the UPOV Convention to Botanical Species

78. The Convention may be applied to all botanical genera and species and member States undertake to apply the Convention to the largest possible number of botanical genera and species. There is, however, no mandatory requirement to apply the Convention to all botanical genera and species. The Convention's only mandatory requirement is the progressive application of the Convention to a minimum of twenty-four genera or species after eight years from accession to the Convention. Whilst most member States protect the species of major economic importance within their territories, this means that innovators in crops which are novel for a particular country have no certainty that they will be able to secure protection when they complete their work.

B. Problems Perceived by Plant Breeders in Relation to Patents for Plant Innovations

(a) General

79. The activity of plant breeding is concerned with the creation, using all available technology and scientific knowledge, of genetic diversity and selection within that diversity, using all available technologies. It is likely that recombinant DNA techniques, cell fusion, in vitro selection and so on will simply supplement earlier technologies. The whole field of technology concerned with plant innovation is a continuum. A new useful gene must be incorporated into the most advanced variety if it is to find a role in the market place. Any distinction between a group called plant breeders and other innovators in the plant field is accordingly artificial. However, since plant breeders as a group have historically had little familiarity with the patent system and for the time being still perceive problems in relation to patents for plants there remains some justification for identifying separately certain of their views.

(b) Legal Uncertainty

80. Plant breeding and varietal development is not a new field of technology. In considering any modification in relevant industrial property provisions, due regard should be given to the impact of the modifications upon the industry. The plant breeders' rights system is "user-friendly" and provides great legal certainty not only to its immediate users but to all parties involved in the relevant horticultural or agricultural production chain. A list of desirable features of an intellectual property rights system seeking to provide a high degree of legal certainty would include

- (i) that the subject matter of the right should be well defined;
- (ii) that the grantee of the rights and other interested parties (such as farmers, horticulturalists and consumers in the case of plant breeders' rights) should be able to rely upon the validity of the rights when granted;
- (iii) that the likelihood of a grant of rights can be confidently anticipated without excessive cost or delay.

The plant breeders' rights system emerges very well from a review based on these criteria. The examination system based upon guidelines and linked to an obligation to maintain the variety in its original form ensures that the subject matter of the right is well defined. Disputes concerning the validity of rights granted have been virtually non-existent. The rules for distinctness, homogeneity and stability are such that all products of original breeding are in practice protectable. The long-term nature of much plant breeding makes confidence in the eventual availability of protection an important element for plant breeders. The cost of the breeders' rights systems to applicants compares well with other forms of industrial property protection, particularly when account is taken of the total cost including the time and effort of searches and the professional support necessary to operate within other systems of protection. Plant breeders are appreciative of the above aspects of the UPOV system. The degree of legal certainty provided is important in production systems based upon thousands of licensed seed producers and traders.

81. The plant breeders' rights system performs a comparatively simple task in the sense that its property right attaches to something which exists physically. The patent system performs the much more complex task of granting property rights in relation to inventive ideas which are abstract in nature. This involves more complex thinking in terms of a system based on claims framed by an applicant, whose validity has to be determined and whose scope needs interpretation. The relative legal certainty provided by the plant variety protection system is valued by plant breeders who do not wish to see it diluted. The application of the criteria for patentability to plant varieties is considered as giving rise to uncertainty. For example, the history of the special plant patent for asexually produced plants has illustrated the great difficulty of applying the non-obviousness requirement to plant varieties.

82. The strength and legal certainty of the UPOV system lies in the fact that protection is based upon the consistent application of criteria designed to accommodate the specific art of variety identification. The provisions of the UPOV Convention which require the inclusion in its member States' laws of specific provisions, including the technical criteria of distinctness, uniformity and stability, has meant that plant breeders' rights are granted in most member States in a uniform way and with comparable legal certainty. The harmonization sought by the international patent system already exists in a large measure within UPOV. Some plant breeders are of the opinion that, if patents are granted for plant varieties or for parts of plants which amount, in effect, to plant varieties on the basis of totally different criteria to UPOV criteria, there might be effects upon the application of the criteria of the UPOV Convention, e.g. the distinctness rules, to applications for plant breeders' rights and that the legal certainty afforded by the UPOV system could thus be impaired. There would be a need for breeders to take into account information on patents and possible future patents (e.g. published patent applications), and this would create a financial burden for them. However, breeders in some countries (e.g. the United States of America) where patents are granted for plant varieties have to take into account patent documents anyway.

(c) Exhaustion of Right and Research Exemption

83. Doubts exist under the patent system concerning the application of the doctrine of exhaustion of right to plant varieties. Would farmers be entitled to reproduce a patented variety for their own purposes on their own land so as to negate the protection of a patent? The position is unclear. There are also doubts concerning the application of the research exemption of the patent system to plant varieties. According to one opinion, any use of a plant

variety other than for an enquiry to see "how it works" would be an infringement. According to another opinion, the use of varieties as parents is permitted, and only the commercialization of a resulting variety would constitute an infringement. Moreover, a significant body of the general public is opposed to any restriction upon the free use of germplasm.

(d) Patents for Genes

84. Whilst some plant breeders express reservations concerning any tendency to excessive monopoly, the granting of patents for genes (where the gene has been cloned and sequenced and is derived from a plant species or living organism other than the intended host species) does not create major problems for many plant breeders, notwithstanding the fact that such genes may control the expression of a plant characteristic. In this case the technology has created a clear division between the field appropriate for patents and that for breeders' rights. The gene can exist as a physical reality independently of any plant. In this respect it is quite different from "characteristics" which have no existence independently from the specific plant or plants in which they are expressed. However, general concern exists in relation to genes that are already known to be present in a crop species or which are present in existing varieties. Plant breeders could hardly accept that a person cloning and sequencing a gene of this nature could thenceforth claim a total monopoly on its use in the species concerned. This problem could perhaps be non-existent in practice since the general patent law might permit an examiner to limit the claims of a patent relating to such a gene to the use of the construct developed by the person cloning and sequencing the gene leaving breeders free to deploy the gene through traditional techniques, but the continuing doubts on the subject are of great concern to plant breeders.

(e) Time Scales

85. Plant breeding by its nature is time-consuming. The time-scale will vary with breeding methods for many crop species. The selection process, conducted in the environment in which the plant is to be grown, takes place during the years of segregation of the plant material prior to its achieving the degree of uniformity and stability that is required for the practical use of the selected material. The conditions of uniformity and stability of the UPOV Convention require that the end product must be developed before protection is available. This is not a cause of concern to plant breeders since they know that, until uniformity and stability is achieved, a specific unit of plant material capable of precise definition for the purposes of the granting and exercise of breeders' rights and for the assessment of performance in the field will not exist.

86. From the point of view of plant breeders, it is not sufficient for protection purposes to conceive an original and non-obvious idea concerning a variety, perhaps with a particularly desirable combination of characteristics. The nature of biological material is such (except to some degree in cases where genes have been cloned and sequenced) that, until plant material exists physically with such combination of characteristics, the "original and non-obvious idea" can only have the status of an objective of a breeding or research program. It is not possible to assume that the idea can be turned into reality. The fact that breeders' rights protection is only available when the objective has been achieved and is embodied in material which exists physically is entirely appropriate to the subject matter of plant variety protection. Furthermore, it is virtually impossible for two breeders working independently, in good faith, to breed the same variety, so that little prejudice arises from

the necessity of completing the breeding process before protection is available (priority is a rather minor question not of great practical importance in the breeders' rights system). In the patent system, however, it is not necessary that an invention be realized in final form prior to a patent application. It suffices if the description of the invention is such that a man skilled in the art can reproduce it. If patents are granted for plant varieties and if the deposit system is used to substitute for an enabling disclosure, patents could be granted in relation to plant material of a "variety" with claims to characteristics in circumstances where there is no certainty that a useful variety will emerge. Meanwhile it is possible that other breeders will be deterred or perhaps be prevented by injunction from developing a distinct variety which possesses the characteristics of the "variety" protected by patent. However, a dependency license, as proposed in Suggested Solution No. 11 in WIPO document BioT/CE/IV/3, would create an appropriate balance between the interests of the patent owner and other breeders under the circumstances referred to.

(f) Claims for Characteristics

87. The situation is further complicated if one recognizes that a patent permits claims so that the exclusive right would cover not just the claimed, not yet fixed, material but all future varieties with any characteristic claimed for the non-fixed material. Plant breeders would be placed in a position where a significant proportion of their efforts should be devoted to the discovery of "characteristics" per se rather than the finely balanced structure that constitutes the variety. Plant breeders selection fields frequently contain plants with interesting features but which are otherwise deficient in many respects. Patents for plant varieties would enable such a feature to be claimed in a patent application with no certainty that it could eventually be incorporated into a useful variety. Some plant breeders might claim that the existence of such patents could have the effect of inhibiting or perhaps of debarring other breeders from developing varieties which, whether by chance or design, incorporate the claimed feature.

(g) Impact upon the UPOV System

88. If patents were available for plant varieties, the impact upon the integrity and reliability of the UPOV system of items (b), (c), (e) and (f) would probably be negative. For distinctness purposes should plant variety protection offices take into account patent applications and patents only where a variety is specifically claimed but also patent applications and patents for plants and cell lines which are in fact varieties? Should consideration be given to the description of the variety or to the claims? How should plant variety protection offices react to descriptions which plainly have not respected the disciplines of the art of variety classification? What attention should be paid to deposited material in general or to deposited material which is not sufficiently uniform to be stable or a sound basis for classification? All these questions show how the work of plant variety protection offices would be rendered more difficult. But under the rules of the patent system, there should already exist, in principle, an impact of the plant variety protection system, namely the need to take into account all prior art even if it has been disclosed through that system. It may be questioned, however, to what extent patent offices have considered or availed themselves of data in plant variety protection offices when examining and granting patents in the plant field.

C. Impact of Currently Proposed Revisions of the UPOV Convention on the Perceived Problems

89. At its twenty-first ordinary session, held at Geneva on October 15 and 16, 1987, the Council of UPOV charged its Administrative and Legal Committee with the preparatory work for the revision of the UPOV Convention. That Committee discussed the subject at its twenty-second, twenty-third and twenty-fourth sessions held from April 18 to 21, 1988, October 11 to 14, 1988 and April 10 to 13, 1989, respectively. At its twenty-fourth session, the Committee based its discussions on a document of the UPOV Office CAJ/XXIV/2 which has since been revised and re-issued as document CAJ/...* The objectives of the revision are, in addition to the introduction of amendments designed to improve the working of UPOV as envisaged in Article 27(1) of the 1961 Text of the UPOV Convention, as follows:

- (a) to strengthen the right of the breeder, in particular through revision of Article 5;
- (b) to extend the practical scope of application of the plant variety protection system through revision of Articles 3 and 5;
- (c) to clarify a number of provisions on the basis of experience, in particular those of Article 6 and to adapt them to recent and prospective developments.

90. The proposals, which are the outcome of the discussions of this Committee, [have been endorsed] [have been endorsed with some amendments] by the Consultative Committee of UPOV and provide a general indication of the likely content of revision proposals which could, if the Council of UPOV so decides, be made the subject of a diplomatic conference to revise the UPOV Convention. Financial provision is proposed to be made in the UPOV budget for a Diplomatic Conference during the biennium 1990/1991.

91. The principal proposals, if implemented, would have the following effects upon the problems perceived by plant breeders and by biotechnological inventors in the field of plants.

Article 5

92. The present restriction of the breeder's right to commercial production and sale of reproductive or vegetative propagating material of the variety is proposed to be replaced by a right to exclude others from all reproduction or propagation of the variety (which right is not subject to exhaustion) and by a right (which is subject to exhaustion) to exclude others from offering for sale, putting on the market or using or importing or stocking material of the variety.

* A future document not yet determined.

93. Paragraph (4) of Article 5, as proposed to be revised, permits a member State to exempt acts from the scope of the new rights if this is necessary in the public interest and provided the exemption does not cause excessive prejudice to the legitimate interests of breeders. This paragraph recognizes inter alia that it is likely to be desirable to make provision for farmers in some States to continue to produce seed on their own farm for their own purposes but equally recognizes that such rights may not be equally appropriate for all species and that the precise provision that should be made should be tailored to suit a State's agricultural policy, the structure of its agriculture and other local situations such as the nature of its agricultural input industry, climate, plant health requirements, the need to provide effective incentives for plant breeding in a particular species and so on. The new broad right does meet the needs of plant breeders to secure a wider scope of protection and, in effect, places a burden on individual member States to justify any proposed exemptions.

94. Acts done for experimental purposes or for the purpose of breeding new varieties are expressly excluded from the ambit of the new rights, so that the existing breeders' exemption is, subject to the provision mentioned in paragraph 95, substantially preserved.

95. An important development is proposed in paragraph (3) of Article 5. It provides that where a variety is essentially derived from a protected variety, the owner of the protected variety may prevent all third parties not having his consent from exploiting the derived variety. In a possible proposed alternative, he would be entitled to equitable remuneration in respect of the commercial exploitation of the derived variety. This provision addresses the problem whereby, under the existing UPOV Convention, simple reselection or other manipulation, e.g. transformation by genetic engineering of individual characteristics, which enables a new variety to be clearly distinguished from the variety from which it is derived, forms the basis for an independent grant of protection. The objective of the provision is to reduce the attractions of breeding approaches totally based upon the "structure" of an existing variety and so to remove the most criticized aspect of the present breeder's exemption. The breeder's exemption remains in effect in all other respects so that varieties remain available as an initial source of variation in the breeding of other varieties but since the breeding of varieties by methods not involving "essential derivation" from another variety is time-consuming and expensive and since any resulting variety will not be reliant for its characteristics on any one parent variety, a period of de facto protection will exist before a breeder can experience competition based upon any element of his protected variety.

Article 4

96. The existing Article 4 provides that the Convention may be applied to all botanical genera and species and requires of member States only that their domestic laws apply the provisions of the Convention to five genera or species on accession to the Convention and within eight years from accession to a minimum of twenty-four genera or species. To meet the view that the protection afforded by the Convention was too narrow, the proposed revision makes mandatory provision for the application of the Convention to all botanical species. Exceptions would be allowed but only in limited circumstances.

Article 6

97. Paragraph 1(a) of this Article of the existing Convention provides that "whatever may be the origin, artificial or natural, of the initial variation from which it has resulted, the variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for." The practical application of this provision has established that the word "important" does not have its most obvious meaning for the lay person of "important in practical use" but instead means "important for the purposes of distinction," and accordingly adds little to the requirement for clear distinguishability. The combination of the requirement of clear distinguishability and the breeder's exemption created the situation where any clear difference between a new variety and an existing variety, even when it results from simple reselection of the existing variety, is the basis for an independent title of protection. This situation is proposed to be fundamentally modified by the dependency principle introduced by the proposed new Article 5(3).

D. Problems which will Remain Outstanding After a Revision of the UPOV Convention Implementing the Proposals for Revision Contained in Section C

98. Plant breeders have divided opinions concerning the desirability of patenting genes useful in plants and plant breeding processes but significant bodies of opinion are in favor of accepting these developments. The current revision proposals contain a so-called "collision-norm" in paragraph (5) of Article 5 which would have the effect of limiting the exercise of patent rights where a patented gene is incorporated into a plant variety.

99. The provision of the proposed new Article 5(3) would ensure that, where a patented gene is incorporated into an existing variety, the person incorporating that gene will not be able to commercialize the new variety free of obligation to the breeder of the existing variety. In view of the inclusion in the revision proposals of a collision norm, a breeder who incorporates a patented gene into his variety will be effectively able to freely market his variety subject perhaps to a pecuniary obligation to the breeder but otherwise free from constraint. Mutual dependence may not fully exist.

100. If a system of mutual dependence were to evolve it would then be a matter for further discussion whether a dependent party should be able in all circumstances to acquire a compulsory license under a dominant right. A patentee in relation to a gene of trivial commercial significance should perhaps not be able to compulsorily seek a license from a right holder for an expensively developed variety of importance in the market place. Conversely, a breeder of an unexceptional variety should perhaps not be in a position to force the grant of a license under a patent for a gene which is of great importance and may have been developed at exceptional difficulty and expense. The parties involved may be the best arbiters of what is reasonable between them and any interference with their freedom of contract should perhaps be limited to the protection of public rather than private interests.

101. The principal remaining issue unresolved by a revision of the UPOV Convention arises from the fact that plant variety protection is limited to the variety and that it is not possible to make claims other than to the variety. [The potential extension of protection to the product of the variety will cover a significant portion of the scope that might typically have been

the subject matter of claims.] The single outstanding area where the breeders' rights system would continue to limit the scope of protection but where an applicant might wish to make claims if patents were to be granted for plant varieties (whether represented by a plant, by plants or parts of plants or other plant material), concerns characteristics of plants or plant material.

102. The patenting of genes will involve the patenting of chemical sequences which govern the expression of particular characteristics in plants. The identity of such sequences is so precisely ascertained and their independent existence from the specific plant material in which they have been expressed is such, that these sequences fall conceptually in a totally different category from plant material which contains the genetic code for a complete plant.

103. Over time a principal objective of genetic engineers will be to increase the number, variety and combinations of genes where the sequences are known and which can therefore be made the subject of genetic engineering procedures. An increasing number of characteristics which can be linked precisely to chemical constituents of the plant genome will fall within the scope of patent protection. Other characteristics would not be protected per se but only as features of a particular plant variety. The objection to the patenting of characteristics is that in the absence of precise knowledge concerning the chemical sequences involved in the expression of a characteristic they have no existence independently from the plant material in which they are expressed. They will in most cases have resulted from normal plant breeding procedures or from manipulations of plant material involving the recombination of genes which are similar in their essence to conventional plant breeding procedures.

104. The concept of varietal development involves an attempt to improve the level of expression of any one or more of many characteristics. The concern is that the patenting of the characteristics of plants would permit any party establishing a higher level of expression of any one such characteristic in a plant, to make claims in relation to that characteristic which will block further development in that species. In the context of plant breeding, which involves continuous improvement by steps which will sometimes be large and sometimes small, this would be a non-sensical result.

105. The issue of claiming "characteristics" in this way seems to arise in circumstances where the claims in a product patent or in a process patent include what is in effect a claim to a "plant variety." "Plant variety" in this context is given the broad general meaning of plant breeding usage which is reflected in the definition set out in paragraph (iii) of the proposal for Article 2 in the UPOV Convention revision proposals, i.e. 'variety' shall mean any plant, grouping of plants or plant material which, by reason of its characteristics, is regarded as an independent unit for the purpose of cultivation or any other form of use.

106. Whenever a claim is made for a specific characteristic of a plant or of plant material of a variety, the problem arises of the potential creation of an unreasonably wide monopoly which makes little sense in the context of plant improvement and which does not arise as a result of technological advance. The question of protection of a variety as opposed to the monopolization of a characteristic was an issue in relation to conventional plant breeding at the time of the creation of the UPOV Convention in 1961. The true issue arising from technological advance since that time is the patenting of identified and sequenced genes. The UPOV system and patent system could accommodate this development if a system of reciprocal dependence were allowed to develop.

ANNEX I

I. Comparison Between Types of Protection under the Existing Legal Situation
Two Examples: Dwarf Wheat and Early Wheat

1. In order to ascertain the existing legal situation with respect to the interface between patent protection and plant variety rights, two theoretical examples have been chosen on which the considerations contained in this Annex will be based:

The first example (Example A) concerns the development of a variety of dwarf wheat, the claimed advantage of dwarf wheat residing in the fact that the plant is less likely to fall over. This enables the application of increased amounts of fertilizer with consequent increases in yield. The developer of the variety has identified within the wheat genome and cloned a particular single gene for dwarfness and developed an appropriate construct incorporating that gene. This development involves inter alia the identification and use of the precise chemical sequences which comprise the gene. The variety has been developed by using the construct to transform an existing variety. Subject to the provision of the relevant laws its developer might wish to claim protection alternatively or cumulatively for the whole plant, the plant variety, the gene (which can be considered as a chemical component) or the specific construct incorporating that gene.

The second example (Example B) concerns the development of a variety of early wheat, for example a variety that reaches maturity about two days earlier than a pre-existing otherwise equivalent variety. The advantage here is that the time required until the harvesting of such wheat is reduced and that the risks of adverse weather conditions are thus reduced. It is assumed that the early wheat variety has been developed by breeding procedures involving a cross followed by selection. Transformation by genetic engineering is not involved. A great number of genes control the expression of the earliness characteristic, they are not identified and the complexity of their interaction is assumed to be very great. Subject to the provisions of relevant laws its developer might wish to claim protection for the whole plant or the plant variety.

Four Types of Protection

2. For the examples of a dwarf wheat and an early wheat variety considered in this Annex, four types of protection are examined.

3. The first type of protection is patent protection for a gene. This type of protection is considered only for the example of a dwarf wheat variety because only in that example variety does an identified gene which has been cloned determine dwarfness (in practice a number of genes are known to exist which can act independently or cumulatively to confer dwarfness). The earliness of the second wheat variety is determined by the interaction of a great number of genes which are not identified or cloned and whose interaction is not understood.

4. The second type of protection is patent protection for the whole plant and for the process used for the creation of the short wheat variety. The variety was produced by genetic engineering using a process involving the incorporation of a gene for which a patent is granted. Each plant emerging from this process is distinct, uniform and stable and will reproduce itself precisely. The inventor claims the variety inter alia as the direct product of the process.

5. The third type of protection is patent protection for the plant variety, i.e. the creator claims in a patent application the dwarf wheat variety or the early wheat variety as a new product involving an inventive step; he claims the shortness or the earliness of his variety as a unique feature.

6. The fourth type of protection is a plant breeders' right for the new variety of dwarf wheat and the new variety of early wheat.

Criteria of Protection

7. For each of the types of protection referred to above, the following criteria will be examined in relation to, first, a UPOV member State which excludes plant varieties and essentially biological processes for the production of plants from protection in its patent law (Appendix I), and, secondly, to a UPOV member State without such exclusions in its patent law (Appendix II)*:

- (a) application requirements
 - formal requirements (including fees);
 - substantive requirements (in particular, form of disclosure, including deposit);
- (b) categories of inventions or plant varieties excluded by law from protection;
- (c) conditions of protection (for patents: novelty, inventive step and industrial applicability; for plant breeders' rights: distinctiveness, homogeneity and stability); novelty grace period;
- (d) substantive examination;
- (e) international and regional treaties;
- (f) rights conferred;
- (g) limitations of the right (including exhaustion, farmer's privilege, research exemption and non-voluntary licenses);
- (h) duration of protection;
- (i) exercise of the right and possible defenses.

* It is to be noted that Appendix II does not reflect the special situation existing in the United States of America described in paragraphs 33 to 35 and 54 to 56 of this document.

8. A synoptic comparison of the types of protection for each criterion of protection is presented in Appendix I (concerning the situation in a UPOV member State excluding plant varieties and essentially biological processes from patent protection) and Appendix II (concerning the situation in a UPOV member State without the said exclusions).

9. The following paragraphs give some general explanations concerning the criteria of protection referred to in paragraph 7, above, drawing particular attention to differences between patents and plant breeders' rights.

10. Formal Requirements Concerning Applications for Protection. The application for a patent requires the filing of an application in writing with the industrial property office. In order to obtain a confirmation of the filing date, usually the identification of the applicant and a written description or drawing disclosing the invention is sufficient; under some laws, the payment of a filing fee and the presentation of a claim or claims is required for establishing a filing date. Other formal requirements (not required for establishing a filing date, but required for the further processing of the application) include the compliance with the principle of unity of invention.

11. The application for the grant of a plant breeders' right requires the filing of an application in writing with the plant variety rights office and the payment of a fee. It may be necessary for the application to be accompanied by a technical "questionnaire" concerning the breeding history of the variety and seeking descriptive information concerning the variety. The date of receipt of a valid application in the office becomes the effective date for priority purposes and thus the equivalent of the filing date of the patent system.

12. Substantive Requirements Concerning Applications for Protection. An application for a patent must disclose the invention for which protection is sought in a manner such that a person skilled in the art (an average expert) is enabled to carry out the invention. This requirement may be fulfilled, where the invention relates to certain biological material (namely the determining gene of dwarf wheat) by presenting a written description which is supplemented by a reference to a deposit of a sample of the gene in a recognized depositary authority.

13. An application for a plant breeders' right must in most countries be accompanied by a completed technical "questionnaire." The information contained in the replies to questions in the questionnaire is used by the office to assist in deciding upon an appropriate method of testing for the applicant's variety. Subsequent to the filing of the application, the applicant will in most UPOV member States be required to submit specific plant material of the variety suitable to establish in appropriate tests the distinctness, uniformity and stability of the variety. In the United States of America, the applicant is required to submit descriptive information to establish distinctness, uniformity and stability and is only exceptionally required to submit plant material.

14. Categories of Inventions or Plant Varieties Excluded by Law from Protection. The following 42 States provide for the exclusion of plant varieties from patent protection, namely Algeria, Austria, Bahamas, Barbados, Belgium, Brazil, Bulgaria, China, Colombia, Cuba, Cyprus, Denmark, Ecuador, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ghana, Greece, Israel, Kenya, Luxembourg, Malaysia, Mexico, Netherlands, Nigeria, Norway, Peru, Poland, Portugal, Romania, South Africa, Soviet Union, Spain,

Sri Lanka, Sweden, Switzerland, Thailand, Uganda, United Kingdom, United Republic of Tanzania and Yugoslavia. The same exclusion also exists under the European Patent Convention and the Convention establishing an African Intellectual Property Organization (OAPI). Japan and the United States of America are amongst the States which do not have an express exclusion of plant varieties from patent protection. Article 2(1) of the UPOV Convention does not require the general exclusion of plant varieties from patent protection but only requires that patent protection and plant breeders' rights protection should not both be granted for one and the same botanical genus or species. All UPOV member States are bound by Article 2(1) of the UPOV Convention with the exception of the United States of America.

15. An exclusion of essentially biological processes for the production of plants from patent protection is provided for in the following 40 States: Algeria, Austria, Bahamas, Barbados, Belgium, Brazil, Canada, Colombia, Cuba, Cyprus, Denmark, Ecuador, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ghana, Greece, Italy, Kenya, Luxembourg, Malaysia, Mexico, Mongolia, Netherlands, Nigeria, Norway, Peru, Poland, Portugal, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Uganda, United Kingdom, United Republic of Tanzania and Yugoslavia; and in the European Patent Convention and the Convention establishing OAPI.

16. The UPOV Convention in Article 4(2) provides only an obligation for "the progressive application of the provisions of this Convention to the largest possible number of botanical genera and species" and the minimum numbers of genera or species specified in Article 4(3)(b). In compliance with these provisions, UPOV member States have established lists of plant varieties for which plant breeders' rights are available. Such lists generally include all genera or species of economic importance in each member State. This means that for genera or species not included in these lists, plant breeders' rights are not available. In consequence, some national laws which otherwise exclude plant varieties from patent protection allow such a protection for varieties not included in the list of varieties for which plant breeders' rights are available. Under the laws of the United States of America, plant breeders' rights are available only for varieties which are sexually reproduced since for those which are asexually reproduced plant patents are available.

17. Conditions of Protection. A patent may be granted only for an invention which is new, involves an inventive step and is industrially applicable. An invention is new if it is not anticipated by the prior art on the date of filing (which usually includes everything made available to the public anywhere in the world and also patent applications filed and later published). Where the priority of a previous application in another member State of the Paris Convention is validly claimed, disclosures after the filing date of that application are not to be taken into account.

18. The conditions for the grant of a plant breeders' right are different: according to Article 6 of the UPOV Convention and national laws implementing that article, only varieties which are distinct, homogenous and stable can be protected by a plant breeders' right. In addition, the said convention and national laws require that the variety must be "new." However, in contrast to the concept of novelty under patent law which is based on a comparison with the existing "prior art," the condition of novelty under the UPOV Convention and the national laws for the protection of plant varieties requires that propagating material of the variety in question has not been put on the market for longer than a specified maximum period prior to the filing date. It should be noted that fulfillment of the distinctness requirement also involves the

concept of novelty and that the notion of a written disclosure being destructive of novelty has no relevance to a system based upon the physical plant material which cannot be reproduced without access to plant material of the variety.

19. Procedure for the Grant of a Title of Protection. A patent is granted after a formal examination and--in a number of countries--also after an examination as regards the substantive conditions of patentability (novelty, inventive step and industrial applicability).

20. A plant breeders' right is granted after a formal and substantive examination. The grant of such a right without substantive examination is not permitted for UPOV member States (Article 7 of the UPOV Convention).

21. International and Regional Treaties. In the field of patents, the basic international convention is the Paris Convention for the Protection of Industrial Property (99 member States), which was concluded in 1883 and last revised in 1967. The patent law harmonization treaty at present under preparation within the framework of WIPO is expected to significantly influence the conditions of patent protection in its Contracting States. As regards the deposit of micro-organisms, the provisions of the Budapest Treaty (22 member States) of 1977 applies. A system of filing of international applications with the preparation of international research reports and international preliminary examination reports is provided for under the Patent Cooperation Treaty (41 member States), which was concluded in 1970. Regional patents are granted in accordance with the European Patent Convention (13 member States) and the Convention establishing an African Intellectual Property Organization (OAPI) (13 member States) both of which, however, exclude plant varieties from patent protection. The protocol concerning the patents and designs under the African Regional Industrial Property Organization (14 member States) may be available; the protection conferred by it depends upon the national law in each member State.

22. As regards plant breeders' rights, there is one comprehensive international convention namely the UPOV Convention which was concluded in 1961 and revised in 1972 and 1978 (currently 18 member States). Poland, which has not yet (in March 1989) acceded to the UPOV Convention, has a law which is in conformity with the UPOV Convention and a number of States have such laws at an advanced stage of preparation. Argentina and Kenya have plant breeders' rights laws which do not conform with the requirements of the UPOV Convention.

23. Rights Conferred. A patent confers the right to prevent others from making, selling or importing the patented product or using the patented process. In addition, most laws provide that process patent protection extends to products directly obtained by the patented process so that the sale and importation of such products could also be prevented.

24. The UPOV Convention requires that a plant breeders' right granted in accordance with the Convention confer as a minimum the exclusive right to produce for the purposes of commercial marketing, to offer for sale and to market reproductive material of the variety. The right of the breeder is more extensive in the case of ornamental plants and cut flowers, and under Article 5(4) of the UPOV Convention it is provided that any member States may grant a more extensive right than the above minima extending in particular to the marketed product.

25. Limitation of the Right. The exclusive right conferred by a patent usually does not extend to acts committed for experimental purposes. Moreover, it does not extend to articles which have been put on the market by the owner of the patent or with his consent (principle of exhaustion). Certain laws provide non-voluntary licenses in the public interest. Some laws provide also non-voluntary licenses in cases of abuses or in cases of failure to work or insufficient working and in cases where an invention cannot be used without using another patented invention.

26. A plant breeders' right does not restrict the use of a protected variety as an initial source of variation in the creation of other varieties. It follows from the definition of the exclusive right that the production of seed which is not intended for the purposes of commercial marketing as such and which is not in fact marketed, is not prohibited (the so-called "farmer's privilege").

27. Duration of Protection. In the case of a patent, duration varies between 14 and 20 years from the filing date or is fixed at 17 years from the date of grant.

28. In the case of plant breeders' rights, the duration, counting from the date of grant, is a minimum of 18 years for vine and trees and a minimum of 15 years for other varieties. Some member States grant longer periods of protection.

[Appendices follow]

UPOV Member State Excluding Plant Varieties and Essentially Biological Processes from Patent ProtectionExample A: THE VARIETY OF SHORT WHEAT(1) Patent Protection for Gene(2) Patent Protection for the Whole Plant
(and the variety as the product of a
patented process)(3) Patent Protection for the
Plant Variety(4) Plant Breeders' Rights
for the Variety**(a) application requirements**

formal requirements (including fees)

filing of application with industrial property office

filing of application with industrial property office

filing of application with industrial property office

filing of applications with plant variety protection office

filing by foreigner normally requires representation by local representative

filing by foreigner normally requires representation by local representative

filing by foreigner normally requires representation by local representative

filing of applications by foreigner requires representation by a local agent or a local address for the service of documents

payment of official fees and, where applicable, fees for the representative

payment of official fees and, where applicable, fees for the representative

payment of official fees and, where applicable, fees for the representative

payment of official fees; the local agent is not usually a paid professional

substantive requirements (in particular, form of disclosure including deposit)

written description. since in this case the gene has been sequenced it is totally described by its chemical formula

written description of the process/variety (possibly supplemented by a deposit of plant material or seed) enabling a person skilled in the art to carry out the invention

written description (would be essential to supplement with a deposit in lieu of an enabling disclosure)

completion of a technical questionnaire and submission of plant material (the precise requirement varies with species)

(b) categories of inventions or plant varieties excluded by law from protection

gene may be considered to be a chemical product; some countries exclude chemical products from patent protection

whole plant may be considered as plant variety and thus be excluded from patent protection

the plant or variety as the product of a patented process may be considered to fall within the exclusion of plant varieties from patent protection

if the member State's international obligations are directly incorporated into the domestic law patent protection would not be available as a result of Article 2 of the UPOV Convention where the member State grants plant breeders' rights for the same genus or species if protection of the whole plant is considered to be protection of a plant variety

excluded from patent protection as a plant variety, unless the UPOV member State does not grant plant breeders' rights for wheat and the provisions of its law excluding the patenting of plant varieties permit patenting where breeders' rights are not available (all UPOV member States in fact protect wheat)

the position varies from State to State. species are protected only when protection is expressly extended to them. States tend to protect species of economic importance

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Appendix I, page 2

	(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(c) conditions of protection	novelty (with grace period in some countries)	novelty (with grace period in some countries)		novelty (grace period in some States)
	prior art effect of pending application before its publication	prior art effect of pending application before its publication		distinctness
	inventive step	inventive step	N	uniformity
	industrial applicability (is fulfilled through application in agriculture)	industrial applicability (is fulfilled through application in agriculture)	O T	stability
d) procedure for grant of title of protection	formal examination	formal examination	R	formal examination
	in some countries publication of application	in some countries publication of application	E	publication of application
	substantive examination	substantive examination	L E	growing tests with plant material and subsequent findings re distinctness, homogeneity and stability
	possibility of opposition	possibility of opposition	V A N	possibility of opposition
(e) international and regional treaties	availability of PCT	availability of PCT (might not be fully available if the whole plant is considered to be a plant variety)	T	are extensive arrangements for co-operation with the growing tests and with the exchange of the results of tests
	availability of European patent, ARIPO patent (depending on the national law of each ARIPO member State) and OAPI patent	availability of ARIPO patent (depending on the national law of each ARIPO member State) European patent and OAPI patent are not available if whole plant is considered as plant variety		

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Appendix I, page 3

	(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(f) rights conferred	produce and use the gene import, sell or otherwise distribute gene extension to plant containing gene in some countries extension to further generations of the plant the scope of protection is determined by the claims of the patent	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant the scope of protection is determined by the claims of the patent	N O T	produce for sale and sell reproductive material of the variety scope limited to the variety; no other claims
(g) limitations of the right (including exhaustion, farmer's privilege, research exemption and non-voluntary licenses)	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	R E L E V A N T	production not for the purposes of commercial marketing with no such marketing falls outside the breeders' right (farmer's privilege) the variety may be freely used as an initial source of variation in the creation of other varieties non-voluntary licenses or licenses of right in the public interest may be non-voluntary licenses for abuses of right or because of non-working in some States
h) duration of protection	14 to 20 years from filing date or 17 from date of grant	14 to 20 years from filing date or 17 from date of grant		varies with species/country. Convention minima are 18 years for vine/trees and 15 years for others
i) exercise of the right and possible defences	if infringing acts are committed by owner of plant breeder's right granted for a variety that includes the patented gene the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law	if infringing acts are committed by owner of plant breeder's right granted before or after the filing of the patent application, the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law		the infringer of a plant breeder's right cannot invoke a patent as a defence for the acts committed by him because a patent does not confer a right to commit certain acts but only a right to prohibit certain acts

UPOV Member State Excluding Plant Varieties and Essentially Biological Processes from Patent Protection

Example B: VARIETY OF EARLY WHEAT

(1) Patent Protection for Gene

Patent protection for the gene does not arise. The genes have not been identified or sequenced

(2) Patent Protection for the Whole Plant (and the variety as a product of the patented process)

filing of application with industrial property office

filing by foreigner normally requires representation of local representative

payment of official fees and where applicable, fees for the representative

written description of the process/variety (possibly supplemented by a deposit of plant material or seed) enabling a person skilled in the art to carry out the intention

whole plant may be considered as plant variety and thus be excluded from patent protection

if the member State's international obligations under Article 2 of the UPOV Convention are directly incorporated into the domestic law patent protection will not be available where the member State grants plant breeders' rights for the same genus or species if protection of the whole plant is considered to be protection of a plant variety

(3) Patent Protection for the Plant Variety

filing of application with industrial property office

filing by foreigner normally requires representation of local representative

payment of official fees and where applicable, fees for the representative

written description (would be essential to supplement with a deposit in lieu of an enabling disclosure)

undoubtedly excluded from patent protection as a plant variety

(4) Plant Breeders' Rights for the Variety

filing of applications with plant variety protection office

filing of applications by foreigner requires representation by a local agent

payment of official fees. the local agent is not usually a paid professional

completion of a technical questionnaire and submission of plant material (the precise requirement varies with species)

the position varies from State to State. species are protected only when protection is expressly extended to them. States tend to protect species of economic importance

(a) application requirements

- formal requirements (including fees)

N
O
T

- substantive requirements (in particular, form of disclosure including deposit)

R
E
L
E
V

(b) categories of inventions or plant varieties excluded by law from protection

A
N
T

(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as a product of the patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(c) conditions of protection	novelty (with grace period in some countries)	N	novelty (grace period in some States)
N	prior art effect of pending application before its publication	N	distinctness
O	inventive step; unlikely to be fulfilled in this case	O	uniformity
T	industrial applicability (is fulfilled through application in agriculture)	T	stability
R		R	
(d) procedure for grant of title of protection	formal examination	E	formal examination
L	in some countries publication of application	L	publication of application
E	substantive examination	E	growing tests with plant material and subsequent findings re distinctness, uniformity and stability
V		V	
A		A	possibility of opposition
N	possibility of opposition	N	
T		T	are extensive arrangements for co-operation with the growing tests and with the exchange of the results of tests
(e) international and regional arrangements	availability of PCT (might not be fully available if the whole plant is considered to be a plant variety)		
	availability of ARIPO patent (depending on the national law of each ARIPO member State)		
	European patent and OAPI patent are not available if whole patent is considered as plant variety		

(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(f) rights conferred	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant		produce for sale and sell reproductive material of the variety
(g) limitations of the right (including exhaustion, farmer's privilege, research exemption and non-voluntary licenses)	the scope of protection conferred by the claims of the patent exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	N O T R E L E V A N T	scope limited to the variety; no other claims the variety may be freely used as an initial source of varieties in the creation of another variety production not for the purposes of commercial marketing with no such marketing falls outside the breeders' rights (farmer's privilege) non-voluntary licenses or licenses of right in the public interest non-voluntary licenses for abuses of right or because of non-working in some States
(h) duration of protection	14 to 20 years from filing date or 17 from date of grant		varies with species/country. Convention minima are 18 years for vine/trees and 15 years for others
(i) exercise of the right and possible defences	if infringing acts are committed by owner of plant breeder's right granted before or after the filing of the patent application, the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law		the infringer of a plant breeder's right cannot invoke a patent as a defence for the acts committed by him because a patent does not confer a right to commit certain acts but only a right to prohibit certain acts

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APPENDIX II

UPOV Member State without Exclusions

Example A: THE VARIETY OF SHORT WHEAT

	(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(a) application requirements				
- formal requirements (including fees)	<p>filing of application with industrial property office</p> <p>filing by foreigner normally requires representation of local representative</p> <p>payment of official fees and, where applicable, fees for the representative</p>	<p>filing of application with industrial property office</p> <p>filing by foreigner normally requires representation of local representative</p> <p>payment of official fees and, where applicable, fees for the representative</p>	<p>filing of application with industrial property office</p> <p>filing by foreigner normally requires representation of local representative</p> <p>payment of official fees and where applicable, fees for the representative</p>	<p>filing of applications with plant variety protection office</p> <p>filing of applications by foreigner requires representation by a local agent</p> <p>payment of official fees; the local agent is not usually a paid professional</p>
substantive requirements (in particular, form of disclosure including deposit)	<p>written description. since in this case the gene has been sequenced it is totally described by its chemical formula</p>	<p>written description of the process/variety (possibly supplemented by a deposit of plant material or seed) enabling a person skilled in the art to carry out the invention</p>	<p>written description (would be essential to supplement with a deposit in lieu of an enabling disclosure)</p>	<p>completion of a technical questionnaire and submission of plant material (the precise requirement varies with species)</p>
(b) categories of inventions or plant varieties excluded by law from protection	<p>gene may be considered to be a chemical product; some countries exclude chemical products from patent protection</p>	<p>whole plant may be considered as plant variety and if the member State's international obligations under Article 2 of the UPOV Convention are directly incorporated into the domestic law patent protection will not be available where the member State grants plant breeders' rights for the same genus or species</p>	<p>if the member State's international obligations under Article 2 of the UPOV Convention are directly incorporated into the domestic law patent protection will not be available where the member State grants breeders' rights for the same genus or species</p>	<p>the position varies from State to State. species are protected only when protection is expressly extended to them. States tend to protect species of economic importance</p>

	(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Utility Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(c) conditions of protection	novelty (with grace period in some countries) prior art effect of pending application before its publication inventive step industrial applicability (is fulfilled through application in agriculture)	novelty (with grace period in some countries) prior art effect of pending application before its publication inventive step industrial applicability (is fulfilled through application in agriculture)	novelty (with grace period in some countries) prior art effect of pending application before its publication inventive step industrial applicability (is fulfilled through application in agriculture)	novelty (grace period in some States) distinctness uniformity stability
(d) procedure for grant of title of protection	formal examination in some countries publication of application substantive examination possibility of opposition	formal examination in some countries publication of application substantive examination possibility of opposition	formal examination in some countries publication of application substantive examination possibility of opposition	formal examination publication of application growing tests with plant material and subsequent findings re distinctness, homogeneity and stability possibility of opposition
(e) international and regional arrangements	availability of PCT availability of European patent, ARIPO patent (depending on the national law of each ARIPO member State) and OAPI patent	availability of PCT (might not be fully available if the whole plant is considered to be a plant variety) availability of ARIPO patent (depending on the national law of each ARIPO member State) European patent and OAPI patent are not available if whole patent is considered as plant variety	PCT not available in the case of a plant variety availability of ARIPO patent (depending on the national law of each ARIPO member State) European patent and OAPI patent are not available	are extensive arrangements for co-operation with the growing tests and with the exchange of the results of tests

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	(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Utility Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(f) rights conferred	produce and use the gene import, sell or otherwise distribute gene extension to plant containing gene in some countries extension to further generations of the plant the scope of protection is determined by the claims of the patent	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant the scope of protection is determined by the claims of the patent	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant the scope of protection conferred by the claims of the patent	produce for sale and sell reproductive material of the variety scope limited to the variety; no other claims
(g) limitations of the right (including exhaustion, farmer's privilege, research exemption and non-voluntary licenses)	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege) acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights non-voluntary licenses or licenses of right in the public interest non-voluntary licenses if invention is made by other person which depends on patented invention non-voluntary licenses for abuses of right or because of non-working	production not for the purposes of commercial marketing with no such marketing falls outside the breeders' right (farmer's privilege) the variety may be freely used as an initial source of variation in the creation of other varieties non-voluntary licenses or licenses of right in the public interest non-voluntary licenses for abuses of right or because of non-working in some States
(h) duration of protection	14 to 20 years from filing date or 17 from date of grant	14 to 20 years from filing date or 17 from date of grant	14 to 20 years from filing date or 17 from date of grant	varies with species/country. Convention minima are 18 years for vine/trees and 15 years for others
(i) exercise of the right and possible defences	if infringing acts are committed by owner of plant breeder's right granted for a variety that includes the patented gene the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law	if infringing acts are committed by owner of plant breeder's right granted before or after the filing of the patent application, the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law		the infringer of a plant breeder's right cannot invoke a patent as a defence for the acts committed by him because a patent does not confer a right to commit certain acts but only a right to prohibit certain acts

UPOV Member State without Exclusions

Example B: THE VARIETY OF EARLY WHEAT

(1) Patent Protection for Gene

Patent protection for the gene does not arise. The genes have not been identified or sequenced

(2) Patent Protection for the Whole Plant (and the variety as the product of a patented process)

filing of application with industrial property office

filing by foreigner normally requires representation of local representative

payment of official fees and where applicable, fees for the representative

written description of the process/variety (possibly supplemented by a deposit of plant material or seed) enabling a person skilled in the art to carry out the intention

whole plant may be considered as plant variety and if the member State's international obligations under Article 2 of the UPOV Convention are directly incorporated into the domestic law patent protection will not be available where the member State grants plant breeders' rights for the same genus or species

(3) Patent Protection for the Plant Variety

filing of application with industrial property office

filing by foreigner normally requires representation of local representative

payment of official fees and where applicable, fees for the representative

written description (would be essential to supplement with a deposit in lieu of an enabling disclosure)

whole plant may be considered as plant variety and if the member State's international obligations under Article 2 of the UPOV Convention are directly incorporated into the domestic law patent protection will not be available where the member State grants plant breeders' rights for the same genus or species

(4) Plant Breeders' Rights for the Variety

filing of applications with plant variety protection office

filing of applications by foreigner requires representation by a local agent

payment of official fees; the local agent is not usually a paid professional

completion of a technical questionnaire and submission of plant material (the precise requirement varies with species)

the position varies from State to State. species are protected only when protection is specifically extended to them. States tend to protect species of economic importance

(a) application requirements

- formal requirements (including fees)

N
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- substantive requirements (in particular, form of disclosure including deposit)

(b) categories of inventions or plant varieties excluded by law from protection

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(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(c) conditions of protection	<p>novelty (with grace period in some countries)</p> <p>prior art effect of pending application before its publication</p> <p>inventive step; unlikely to be satisfied?</p> <p>industrial applicability (is fulfilled through application in agriculture)</p>	<p>novelty (with grace period in some countries)</p> <p>prior art effect of pending application before its publication</p> <p>inventive step; unlikely to be satisfied?</p> <p>industrial applicability (is fulfilled through application in agriculture)</p>	<p>novelty (grace period in some States)</p> <p>distinctness</p> <p>uniformity</p> <p>stability</p>
(d) procedure for grant of title of protection	<p>formal examination</p> <p>in some countries publication of application</p> <p>substantive examination</p> <p>possibility of opposition</p>	<p>formal examination</p> <p>in some countries publication of application</p> <p>substantive examination</p> <p>possibility of opposition</p>	<p>formal examination</p> <p>publication of application</p> <p>growing tests with plant material and subsequent findings re DUS</p> <p>possibility of opposition</p>
(e) international and regional arrangements	<p>availability of PCT; might not be fully available if the whole plant is considered to be a plant variety</p> <p>availability of ARIPO patent (depending on the national law of each ARIPO member State)</p> <p>European patent and OAPI patent are not available if whole patent is considered as plant variety</p>	<p>availability of PCT; not fully available in the case of a plant variety</p> <p>availability of ARIPO patent (depending on the national law of each ARIPO member State)</p> <p>European patent and OAPI patent are not available if whole patent is considered as plant variety</p>	<p>are extensive arrangements for co-operation with the growing tests and with the exchange of the results of tests</p>

(1) <u>Patent Protection for Gene</u>	(2) <u>Patent Protection for the Whole Plant (and the variety as the product of a patented process)</u>	(3) <u>Patent Protection for the Plant Variety</u>	(4) <u>Plant Breeders' Rights for the Variety</u>
(f) rights conferred	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant	produce and use plant variety import, sell or otherwise distribute plant in some countries extension to further generations of the plant	produce and sell reproductive material of the variety
N			
D			
T	the scope of protection conferred by the claims of the patent	the scope of protection conferred by the claims of the patent	scope limited to the variety; no other claims
(g) limitations of the right (including exhaustion, farmer's privilege, research exemption and non-voluntary licenses)	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege)	exhaustion for further generations if accepted under applicable law (exhaustion for further generations would result in farmer's privilege)	the variety may be freely used as an initial source of varieties in the creation of another variety
R			
E			
L	acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights	acts committed for experimental purposes relating to the subject matter of the patented invention are not covered by the rights	
E			
V			
A	non-voluntary licenses or licenses of right in the public interest	non-voluntary licenses or licenses of right in the public interest	non-voluntary licenses or licenses of right in the public interest
N			
T	non-voluntary licenses if invention is made by other person which depends on patented invention	non-voluntary licenses if invention is made by other person which depends on patented invention	
	non-voluntary licenses for abuses of right or because of non-working	non-voluntary licenses for abuses of right or because of non-working	may be non-voluntary licenses for abuses of right or because of non-working in some States
(h) duration of protection	14 to 20 years from filing date or 17 from date of grant	14 to 20 years from filing date or 17 from date of grant	varies with species/country. Convention minima are 18 years for vine/trees and 15 years for others
i) exercise of the right and possible defences	if infringing acts are committed by owner of plant breeder's right granted before or after the filing of the patent application, the question arises whether the said owner can invoke a positive right granted to him to commit certain acts under the plant variety law		the infringer of a plant breeder's right cannot invoke a patent as a defence for the acts committed by him because a patent does not confer a right to commit certain acts but only a right to prohibit certain acts

ANNEX II

EXAMPLES AS A BASIS FOR DISCUSSION OF ASSUMED SITUATIONS
UNDER PROVISIONS OF BOTH PATENT AND BREEDERS' RIGHTS LAWS
WITH INDICATIONS OF POSSIBLE CONSEQUENCES

The approach is to assume for each situation changes in either or both patent law and breeders' rights law. This approach highlights the fact that an optimal system may require adjustments within both the breeders' rights and the patent fields.

"Possible consequences" are not necessarily considered by the International Bureau of WIPO or the Office of UPOV to be the consequences of particular changes but are mentioned solely as a basis for discussion.

First Assumed Situation: No change concerning the patent system; changes concerning the plant breeders' rights system.

Changes

1. Availability of plant breeders' rights for all botanical species.
2. Extension of the scope of plant breeders' rights protection to cover all reproduction and, subject to exhaustion, the selling, marketing, using or the importing or stocking of material of a protected variety.
3. Extension of the exclusive rights concerning a protected plant variety to varieties essentially derived from the protected plant variety.
4. Retention of Article 2 of the UPOV Convention so as to forbid the granting of patents and plant breeders' rights for the same species; introduction of a collision norm to the effect that no acts concerning a variety for which a right has been granted in accordance with the provisions of the UPOV Convention shall be prohibited on the basis of some other industrial property right.

Possible Consequences

1. Plant breeders (for all species) will have a more satisfactory protection than at present; the protection for plant varieties would be similar to that available under the patent system. In relation to the exclusive right of reproduction the problem of exhaustion would not arise; claims for characteristics would not be possible.
2. The plant breeders' rights system and the legal certainty enjoyed by rights held would remain unimpaired; none of the practical problems for the plant breeders' rights system resulting from the granting of protection for plant varieties on differing criteria in two systems would arise.
3. The fact that patent protection is not available in some countries for plant varieties might, to some extent, discourage enterprises investing in research with respect to the creation of plant varieties by genetic engineering methods; however, these enterprises will be able to obtain patent protection for newly created genes, although the said protection may suffer from uncertainties in respect of extension to future generations and the freedom to exercise rights under patents would be restricted by the collision norm (i.e. no prohibition of the exercise of rights under the UPOV Convention on the basis of some other industrial property right).

Second Assumed Situation: No change concerning the plant breeders' rights system; changes concerning the patent system.

Changes

1. Removal of any exclusion of plant varieties and essentially biological processes for the protection of plants from patent protection.
2. Extension of process patents for the production of plant varieties to plant varieties.
3. Extension of process patents for the production of living matter to products derived from the materials initially obtained by the patented process, whether such derivation is through replication or differentiation or through both replication and differentiation carried out in any sequence.
4. Extension of patent protection for products that consist of, or contain, genetic information as an essential feature of the invention to any matter containing the patented product or obtained from the patented product, provided that the said genetic information is contained and expressed in the said matter.
5. Limitation of the exhaustion principle in relation to acts committed with respect to material obtained through multiplication of a product constituting living matter (with the exception of multiplication that is a normal consequence of the fact that the product has been put on the market).
6. Dependency licenses in favor of owners of plant breeders' rights who, in order to develop a protected plant variety, have to carry out an activity which is within the scope of protection of a patent.

Possible Consequences

1. The fact that patent protection is available for plant varieties may encourage enterprises investing in research with respect to the creation of plant varieties by genetic engineering methods. Moreover, these enterprises will be able to obtain patent protection for newly created genes, and the said protection will extend to future generations, subject to the possibility of dependency licenses for the creators of new plant varieties.
2. The availability of patents for plants and for plant varieties will enable innovators to make claims in relation to characteristics of plants and thus to secure a wide scope of protection in relation to a species or, in appropriate cases, to complete taxa of a higher order in circumstances where the DNA sequences controlling the expression of the characteristic are unknown; this could remove areas of the genetic variability within a species from access to other innovators.
3. Protection available within the plant breeders' rights system for the activity of building "genetic structures" would be unsatisfactory; owners of breeders' rights would be vulnerable to plagiaristic breeding approaches in the absence of a dependency principle in the breeders' rights system.
4. The legal certainty provided by the fact that plant varieties can only be protected within one common system according to common criteria, will no longer exist. A patent documentation concerning plant varieties will have to be established.

Third Assumed Situation: changes concerning both the patent system and the plant breeders' rights system as in the first and second assumed situations but not addressing problems resulting from the interface between the two systems.

Changes

All changes mentioned in the first and second assumed situations.

Consequences

1. Innovators (in all species) will have more satisfactory protection than at present.
2. The fact that patent protection is available for plant varieties may encourage enterprises investing in research with respect to the creation of plant varieties by genetic engineering methods. Moreover, these enterprises will be able to obtain patent protection for newly created genes, and the said protection will extend to future generations, subject to the possibility of dependency licenses for the creators of new plant varieties.
3. The availability of patents for plants and for plant varieties will enable innovators to make claims in relation to characteristics of plants and thus to secure a wide scope of protection in relation to a species or, in appropriate cases, to complete taxa of a higher order where the DNA sequences controlling the expression of the characteristic are unknown; this could remove areas of the genetic variability within a species from access to other innovators.
4. The legal certainty provided by the fact that plant varieties can only be protected within one common system according to common criteria will no longer exist. A patent documentation concerning plant varieties will have to be established.

Fourth Assumed Situation: changes concerning both the patent system and the plant breeders' rights system and the provision of solutions to problems resulting from the interface between the two systems.

Changes

1. All changes mentioned in the first assumed situation, the collision norm is not introduced.
2. Maintaining the exclusion from patenting of "plant varieties," both "as such" and as the direct product of a patented process.
3. Provided that as stated in paragraph 2 patent protection is not available for plant varieties, extension of process patents for the production of living matter to products derived from the materials initially obtained by the patented process, whether such derivation is through replication or differentiation or through both replication and differentiation carried out in any sequence.
4. Extension of patent protection for products that consist of, or contain, genetic information as an essential feature of the invention to any matter containing the patented product or obtained from the patented product, provided that the said genetic information is contained and expressed in the said matter and provided that as stated in paragraph 2 patent protection is not available for plant varieties.
5. Limitation of the exhaustion principle in relation to acts committed with respect to material obtained through multiplication of a product, not being plant varieties, constituting living matter (with the exception of multiplication that is a normal consequence of the fact that the product has been put on the market).
6. Recognition of the mutual dependency of breeders' rights and patents, for example, where a patented gene is incorporated into a protected plant, with the consequence that the protected plant could not be marketed without the consent of both patent and plant breeders' rights owners.

Consequences

1. The fact that improved plant breeders' rights protection is available for plant varieties and that improved patent protection is available for other innovations involving plants may encourage enterprises investing in research with respect to innovation generally in the field of plants. Such enterprises will be able to obtain patent protection for genes and deploy such protection in relation to plant varieties which incorporate the gene. Plant breeders will be protected by the extension of plant breeders' rights protection to cover "essentially derived" varieties where varieties are transformed by the incorporation of a simple genetic factor by genetic engineering.
2. The improved patent protection would eliminate most of the problems which have been foreseen arising in connection with biotechnological inventions; the plant breeders' rights system and the patent system would be completely complementary.

3. The plant breeders' rights system and the legal certainty enjoyed by rights holders would remain unimpaired; none of the practical problems for the plant breeders' rights system resulting from the granting of protection for plant varieties on differing criteria in two systems would arise.

4. Patents would be unavailable for "characteristics" of plant varieties, but only in cases where the genetic sequences responsible for the characteristic have not been identified; where such sequences have been identified, they could be patented as such. This distinction, together with the improvements referred to in paragraph 2, above, would increase the legal certainty of the patent system in respect of inventions in the plant field.

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