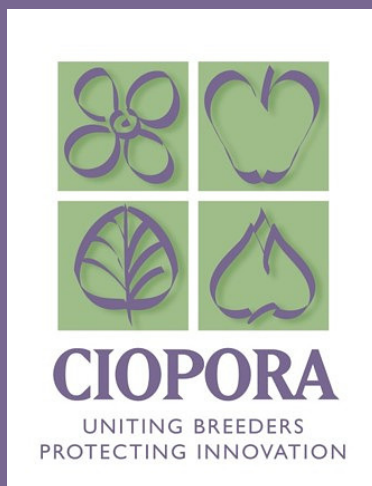


2017



CIOPORA POSITION PAPERS ON PBR AND PATENTS

Minimum Distance

The Scope of the Right

Essentially Derived Varieties

Breeders' Exemption

Exhaustion

General PBR Matters

Patents for Plant-Related Inventions

CIOPORA
Position Papers on
PBR

2014-2017

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INTRODUCTION

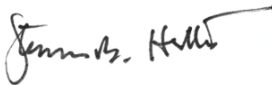
CIOPORA, the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants, was founded in 1961 with the objective of representing individual breeders and breeding companies in the strengthening of IP protection for plant innovations. Today, CIOPORA brings together plant breeders, title-holders, national breeder associations, IP lawyers, patent attorneys and Intellectual Property consultants from all over the world, whose joint efforts are aimed at the development, improvement and harmonization of national and international regulations of Plant Variety Protection (PVP).

CIOPORA published its first formal positions on IP with the CIOPORA Green Paper in November 2002. This paper recapitulated what CIOPORA members viewed to be the main deficiencies of the UPOV Convention, explained the practical difficulties encountered by breeders when applying for rights and in the daily exploitation of their protection titles, and expressed the views of breeders of vegetatively-reproduced plants as to what an optimum system of PVP should be.

Since 2012, CIOPORA and its members have been working to identify the cornerstones of IP Protection for vegetatively reproduced ornamental and fruit varieties, including their weaknesses and loopholes. During the CIOPORA Annual General Meeting (AGM) in 2014, the association approved the first of its official Position Papers, on Minimum Distance, The Scope of the Right, Breeders' Exemption and Exhaustion; the position on General PBR Matters was approved the following year during AGM 2015. In 2016, CIOPORA approved its position on Essentially Derived Varieties (EDV) and, in autumn 2017, the association voted on the approval of its Position on Patents for Plant-Related Inventions.

In this book, you can review each of the seven Position Papers in their entirety. Each of the positions demonstrate the desire of CIOPORA members to have a more effective protection, including enforcement, for their innovations with clearer international regulations and increased harmonisation.

Ornamental and fruit species account for more than 60 percent of all plant breeders' rights titles and plant patents granted, worldwide; CIOPORA has been representing the views of the breeders of these plants for over 55 years. The CIOPORA Position Papers on PBR and Patents serve as the blueprint for the future of these efforts.



Steve Hutton
President



Dr. Edgar Krieger
Secretary General



Andrea Mansuino
Past President
2011-2017

1

CIOPORA POSITION ON MINIMUM DISTANCE/DISTINCTNESS

as approved by its Annual General Meeting on 2 April 2014 in
The Hague, The Netherlands

KEY STATEMENTS

- **CIOPORA demands a sufficient minimum distance between varieties for an effective Plant Variety Right.**
- **Since new varieties are bred, selected and introduced mainly for commercial targets, the requirement “clearly” should be seen as a judgmental and evaluative requirement, and should not end in a simple search of a botanical difference.**
- **The requirement “clearly distinguishable” should be assessed on characteristics important for the crop concerned; in this regard, new important characteristics may be taken into consideration. Accordingly, a new type of characteristics (“relevant for the determination of clearly distinguishable”) should be included into chapter 4.8 of TG/1/3 and the test-guidelines should determine for each characteristic whether it is considered relevant for the determination of “clearly distinguishable”.**
- **The relevant authorities should have the continuing obligation to take into consideration additional characteristics proposed by applicants, if such additional characteristics are important for the determination of “clearly distinguishable”.**
- **Differences in unimportant characteristics only should not lead to a clearly distinguishable variety.**
- **In order to be clearly distinguishable, the distance between two varieties in regard to their important characteristics must be**

sufficiently broad. Particularly in regard to pseudo-qualitative characteristics and quantitative characteristics a difference of only one note in general should not be considered as a sufficiently broad distance. The decision should be made on a crop by crop basis.

- **Varieties with the same note in the UPOV test-guideline for a given characteristic should not be considered to be clearly distinguishable with respect to that characteristic. The possibility to search for a difference in a subsequent growing trial if such difference was not clear in the first properly performed examination should be eliminated.**
- **The possibility of randomized “blind” testing in case of doubts over the distinctness of a candidate variety should also be eliminated. In case of a doubt over distinctness, the candidate variety cannot be considered to be clearly distinguishable from the reference variety.**
- **The decision on which characteristics are relevant for the determination of “clearly distinguishable”, on how many of such characteristics must differ from each other and on the distance between such characteristics should be made on a crop-by-crop basis by a panel of experts, including representatives of the breeders of the crop concerned.**

Full Text:

Minimum distance

CIOPORA demands a sufficient minimum distance between varieties for an effective Plant Variety Right.

The TRIPS agreement requires that a ‘sui generis’ system for the protection of plant varieties is effective. One of the most important requirements for effective PBR protection is a sufficiently broad minimum distance between varieties. An insufficient distance between varieties results in multiple weaknesses of the protection:

- The exclusive right of the breeder of the first variety is weakened. The exclusive right is mainly determined by the scope of protection. If

PBR protection is granted for other very similar varieties, these other varieties are considered to be clearly distinguishable from the first variety, and thus fall out of the scope of the right of the first variety.

- The purpose of IP protection to support the commercial interest of the innovators is disregarded by not differentiating between important and unimportant characteristics.
- The obligation of the breeder to maintain his protected variety true-to-type is at risk if no tolerance is allowed. The breeder will potentially not be able to fulfill his obligation to maintain the variety true to type, if already very minor differences lead to a new variety.
- A fair examination of candidate varieties is not given anymore, because the environmental variation of the phenotypic appearance of the reference varieties compared to the previous years and to the year of their initial examination makes it extremely difficult for the examination offices to judge if the reference variety is still the one which has been granted protection – particularly in species where no living reference collection exist.
- The enforcement of PBR is very difficult, because very soon a plant runs out of the scope of protection if the plant differs from the variety description in only one or two minor characteristics.
- The phenotypic variation within a variety, caused by environmental influences or by cultivation methods, is larger than the variation tolerated between two separate varieties. This makes it very difficult to identify a plant in the production and trade chain.

In today's reality, based on the UPOV 1991 Act, even a very small difference between two varieties makes the varieties clearly distinguishable in the eyes of the examination offices. Based on a pure botanical approach, all characteristics of a species are considered to be equally essential. In contrast to the UPOV 1978 Act, no differentiation is made anymore between characteristics important or unimportant for a variety. As a consequence, even a difference in one unimportant characteristic can make a variety clearly distinguishable from another variety in the eyes of the examination offices.

This systematical and inbuilt narrowing of the distances between varieties is supported by UPOV even more, by allowing for example randomized

blind tests if doubts exist over the distinctness of two varieties.

This pure botanical approach runs contrary to the legal character of intellectual property protection and devaluates the requirement of “clearly distinguishable” in Article 7 of the UPOV 1991 Act to a sole measurement of a difference in at least one characteristic in the meaning of Article 1 (vi) of the UPOV 1991 Act (definition of variety).

As a result, the initial improvement of the UPOV 1991 Act compared to the UPOV 1961 and 1978 Act, aiming at a better control of “varieties, which are not clearly distinguishable from the protected variety” (Article 14 (5) (a) (ii) of the 1991 Act) has been impeded by this botanical approach.

Taking into consideration the weaknesses resulting from too small minimum distance and from the undifferentiated evaluation of important and unimportant characteristics, CIOPORA requires the following changes in the DUS examination:

- Since new varieties are bred, selected and introduced mainly for commercial targets, the requirement “clearly” should be seen as a judgmental and evaluative requirement, and should not end in a simple search of one botanical difference.
- The requirement “clearly distinguishable” should be assessed on characteristics important for the crop concerned; in this regard new important characteristics may be taken into consideration. Accordingly, a new type of characteristics (“relevant for the determination of clearly distinguishable”) should be included into chapter 4.8 of TG/1/3¹, and the test-guidelines should determine for each characteristic whether it is considered relevant for the determination of “clearly distinguishable”.
- The relevant authorities should have the continuing obligation to take into consideration additional characteristics proposed by applicants, if such additional characteristics are relevant for the determination of “clearly distinguishable”.

¹ TG/1/3: “General Introduction to the examination of Distinctness, Uniformity and Stability and the development of harmonized descriptions of new varieties of plants.”

- Differences in unimportant characteristics only should not lead to a clearly distinguishable variety.
- In order to be clearly distinguishable, the distance between two varieties in regard to their important characteristics must be sufficiently broad. Particularly in regard to pseudo-qualitative characteristics and quantitative characteristics a difference of only one note in general should not be considered as a sufficiently broad distance. The decision should be made on a crop by crop basis.
- Varieties with the same note in the UPOV test-guideline for a given characteristic should not be considered to be clearly distinguishable with respect to that characteristic. If a difference was not clear in the first properly performed examination, the possibility to search for a difference in a subsequent growing trial, according to chapter 5.2.3.2.4 of TGP/9, should be eliminated.
- The possibility of randomized “blind” testing according to chapter 6.4 of TGP/9 in case of doubts over the distinctness of a candidate variety should also be eliminated. In case of a doubt over distinctness, the candidate variety cannot be considered to be clearly distinguishable from the reference variety.
- The decision on which characteristics are relevant for the determination of “clearly distinguishable”, on how many of such characteristics must differ from each other and on the distance between such characteristics should be made by a panel of experts, including representatives of the breeders of the crop concerned.

CIOPORA suggests that these changes, which first have to be included into the general UPOV TGP documents, should afterwards be included into the single UPOV test guidelines gradually, species by species, by the Technical Working Parties and the Technical Committee, taking into consideration the input of the breeders.

The changes should not have retroactive effects for varieties which are already on the market or for which protection has been granted.

2

CIOPORA POSITION ON THE SCOPE OF THE RIGHT

as approved by its Annual General Meeting on 2 April 2014 in
The Hague, The Netherlands

KEY STATEMENTS

- **CIOPORA requests UPOV and its member countries to harmonize the definition of propagating material world-wide.**
- **Propagating material should include any material of a plant from which, whether alone or in combination with other parts or products of that or another plant, another plant with the same characteristics can be produced.**
- **CIOPORA requests the clarification that propagating material that (in a technical sense), has been harvested is considered exclusively as propagating material. Only material of a variety which is not capable, by any means, of producing another plant with the same characteristics should be considered to be harvested material in the legal sense.**
- **CIOPORA requests that harvested material should be protected directly and per se.**
- **CIOPORA requests that products that are obtained directly from material of a protected variety should be protected directly and per se.**
- **CIOPORA requests to include into the scope of rights the use of propagating material for the production of harvested material.**
- **CIOPORA requests that the EDV concept is clarified and**

implemented in a sufficiently broad way.

- **CIOPORA requests that the concept of varieties, which are not clearly distinguishable from the protected variety, will be restored and its meaning be sufficiently broadened, by establishing a sufficiently broad minimum distance between varieties.**
-

Full Text:

The scope of the Right

1. The protected material

According to Article 14 (1) of the UPOV 1991 Act the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder: (i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing and (vii) stocking for any of the purposes mentioned in (i) to (vi), above.

According to Article 14 (2) of the UPOV 1991 Act the acts as listed above shall apply also to harvested material, including entire plants and parts of plants, that has been obtained through the unauthorized use of propagating material of the protected variety, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

Additionally, according to Article 14 (3) of the UPOV 1991 Act, the UPOV members may – optionally - provide that the acts as listed above apply also to products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

Although the terms are key terms in the UPOV system, the UPOV Acts do not include a definition of “propagating material” and “harvested material”.

As a consequence of the absent definition of propagating material in the UPOV Acts, many of the UPOV member states have a – to some extent significant - different definition for propagating material. As a consequence, one and the same material of a variety is considered in one country to be propagating material, while in another country it is considered to be harvested material. This causes confusion in the international trade and runs contrary to the aim of UPOV to harmonize the IP protection for plant varieties.

CIOPORA requests from UPOV and its member countries to harmonize the definition of propagating material world-wide. Propagating material should include any reproductive or vegetative material of a plant from which, whether alone or in combination with other parts or products of that or another plant, another plant with the same characteristics can be produced.

Additionally, CIOPORA requests the clarification that propagating material that (in a technical sense) has been harvested is considered exclusively as propagating material. Only material of a variety which is not capable, by any means, of producing another plant with the same characteristics should be considered to be harvested material in the legal sense.

Harvested material and products directly obtained from propagating or harvested material should be covered directly and without limitations.

Harvested material of protected vegetatively reproduced ornamental and fruit varieties needs to be protected directly and per se, without the restrictions and conditions as given in the current UPOV 1991 Act. Given the large number of countries with an increasing production and export of horticultural products, but without effective IP protection for plant varieties, the restricted protection of harvested material causes a lot of confusion, uncertainties and the severe risk of wide loopholes, which can

make the protection for vegetatively reproduced ornamental and fruit varieties ineffective.

Protecting directly and per se harvested material is to the benefit of the honest growers and producers, too. They pay royalties anyway and suffer from unlicensed propagation and production of harvested material. Particularly imports of fruits from countries with limited or no protection can be controlled more effectively if the harvested material is protected directly.

Taking into consideration the fast-growing amount of processed products, such as fruit juice, being processed in many parts of the world and being imported into other countries, products that are obtained directly from material of a protected variety must be protected directly and per se, too, as far as vegetatively reproduced ornamental and fruit varieties are concerned.

CIOPORA, therefore, requests that harvested material and products that are obtained directly from material of a protected variety should be protected directly and per se.

2. The acts which require the authorization of the title holder

According to Article 14 of the UPOV 1991 Act the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

- (i) production or reproduction (multiplication),*
- (ii) conditioning for the purpose of propagation,*
- (iii) offering for sale,*
- (iv) selling or other marketing,*
- (v) exporting,*
- (vi) importing and*
- (vii) stocking for any of the purposes mentioned in (i) to (vi), above.*

In the horticultural industry the cut-flowers, fruits and plants are the main

added-value products. The use of propagating material for the production of such products is one of the most important acts in the production chain. Therefore, it needs to be included within the scope of rights in order to allow the title-holders to license said acts.

Even under a broad concept of “propagating material”, as it is described above, the use of propagating material for the production of harvested material needs to be covered by the scope of the right.

CIOPORA strongly requests to include into the scope of rights the use of propagating material for the production of harvested material.

3. Varieties which fall under the scope of the protected variety

According to Article 14 (5) of the UPOV 1991 Act the authorization of the title holder is also required for acts listed in paragraphs (1) to (4) of this Article in regard to:

- (i) varieties which are essentially derived from the protected variety,*
- (ii) varieties which are not clearly distinguishable from the protected variety and*
- (iii) varieties whose production requires the repeated use of the protected variety.*

In its ‘Green Paper’, CIOPORA articulated its appreciation about the extension of protection manifested in Article 14 (5) and expressed its hope that this Article corrects the existing loophole in regard to “cosmetic breeding”. As a precondition to the closing of this loophole, CIOPORA mentioned: “These new provisions oblige the authorities in charge of the examination of distinctness to be more rigorous when evaluating the minimum distances between varieties for the grant of a title of protection.”

However, in practice it turns out that the inclusion of Article 14 (5) does not keep its promises to better protect existing protected varieties. The EDV-concept is still heavily disputed and some circles try to limit this concept as far as even possible. Regarding varieties which are not clearly distinguishable from the protected variety it turns out that in today’s reality

the provision of Article 14 (5) (ii) of the UPOV 1991 Act is devoid of meaning, as even a very small difference between two varieties makes the varieties clearly distinguishable in the eyes of the examination offices (see also the CIOPORA Position Paper on Minimum Distance of 2 April 2014). Only the extension to “repeated use” seems to work, but this is not of importance for vegetatively reproduced ornamental and fruit varieties.

CIOPORA, therefore, requests that the EDV concept is clarified and implemented in a sufficiently broad way (see the CIOPORA Position Paper on EDV of 2016, page 12).

Additionally, CIOPORA requests that the concept of varieties, which are not clearly distinguishable from the protected variety (Article 14 (5) (ii)) will be restored and its meaning be sufficiently broadened, by establishing a sufficiently broad minimum distance between varieties (see also the CIOPORA Position Paper on Minimum Distance of 2 April 2014).

3

CIOPORA POSITION ON ESSENTIALLY DERIVED VARIETIES

as approved by written procedure in May/June 2016

KEY STATEMENTS

- **CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.**
- **CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.**
- **The degree of the phenotypic similarity and the number of phenotypic differences between the EDV and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.**
- **Predominant derivation is given if material of the Initial Variety has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.**
- **The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.**
- **CIOPORA maintains that mutants and GMOs – as far as they**

are distinct from the Initial Variety – are EDVs, whenever they retain a very high genetic conformity to the Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

- **CIOPORA maintains that the outcomes of repeated back-crossing – as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.**
- **CIOPORA recognizes that there is a realistic possibility that with advancing technologies it might become possible to create independent varieties by new methods, in particular genetic engineering.**

Full Text:

1. Essentially Derived Varieties

According to Article 14 (5) (a) of the UPOV 1991 Act, varieties, which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, fall under the protection of the protected variety.

According to Article 14 (5) (b), a variety shall be deemed to be essentially derived from another variety (“the initial variety”) when

- (i) *it is predominantly derived from the initial variety¹, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety²,*

¹ Predominant derivation means that the variety can only be essentially derived from one variety.

² The expression of the essential characteristics that result from the genotype or combination of genotypes is not a synonym for “phenotype”, because phenotype is to a high degree influenced by the environment. The expression of genotype is in fact a chemical process in the cell, through which a part of the genotype (“gene”) codifies a certain trait. Such trait is the direct expression of the genotype.

- (ii) *it is clearly distinguishable from the initial variety³ and*
- (iii) *except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety⁴.*
- (iv) *Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering⁵.*

2. The current EDV-concept under the UPOV 1991 Act

Very reason for the introduction of the EDV concept in the UPOV 1991 Act was to strengthen the breeders' right, particularly by creating a balance between biotechnology inventors and traditional breeders and by bringing mutations under the scope of protection of their Initial Variety. The wording of the EDV provision (14 (5) (a) of the UPOV 1991 Act) gives room for interpretation as to what are the requirements of an EDV.

CIOFORA has tried to clarify the current EDV concept by establishing a detailed position on EDV in January 2008.

CIOFORA notes that some want to limit the EDV concept to varieties, which can be distinguished from the Initial Variety by a very limited number of characteristics (typically by one). Such interpretation limits the EDV concept as far as even possible and does not achieve UPOV's objective to create a balance between biotechnology inventors and traditional breeders and to bring mutations under the scope of protection of their Initial Variety. Taking into consideration that an EDV per definition must be clearly distinguishable from the Initial Variety, which requires as a minimum a difference in one characteristic, under such

³ For the concept of "clearly distinguishable / distinct" refer to the Position Paper on Minimum Distance.

⁴ This sentence does not add to clarity, but is superfluous.

⁵ This list indicates the intention of the authors that mutations and GMOs and varieties resulting from backcrossing (where the Initial Variety is obviously used as recurrent parent) are typical examples of EDV.

interpretation only varieties which have exactly one difference compared to their Initial Variety could be considered to be an EDV. This approach does not support innovation.

3. The desired EDV concept

CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.

Such objective approach shall be based on the genetic conformity of the varieties concerned. Phenotypic components shall be taken into consideration only as far as the distinctness of the respective varieties is concerned.

Particularly the entanglement of dependency and plagiarism is a mistake in the conception of the EDV provision. Plagiarism is not a question of derivation or dependency, but rather a question of Minimum Distance and direct infringement. If a variety in its phenotype very much resembles a protected variety, it is not clearly distinguishable from the protected variety, and its commercialization is a direct infringement, irrespective whether the new variety is (essentially) derived from the protected variety or not.

Additionally, phenotype is, by definition, what results from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two. The degree of phenotypic similarity is the result of a subjective evaluation, strongly influenced by variations based on environmental and judgmental factors.

Finally, the wording of the UPOV 1991 Act with regard to the requirement and level of phenotypic conformity between an Initial Variety and its EDV is unclear and contradictory. In Article 14 (5) (b) (i) a general conformity seems to be required, while Article 14 (5) (b) (iii) provides that the EDV must conform to the Initial Variety in the expression of the essential characteristics, except for the differences which result from the act of

derivation⁶.

CIOPORA, therefore, maintains that Article 14 (5) (b) (i) of the UPOV 1991 Act does not establish phenotypic similarity as a pre-condition for EDV (because the interaction with the environment is not taken into account), but specifically and expressly refers to genotype⁷.

CIOPORA, therefore, is of the opinion that close phenotypic similarity must not be a precondition for a variety to be considered to be an EDV. However, a close phenotypic similarity can be an indication for essential derivation.

Instead, CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.

The degree of phenotypic similarity and the number of phenotypic differences between the dependent and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.

3.1 Distinctness

An EDV shall be phenotypically distinct from its Initial Variety. For the assessment of Distinctness the Position Paper of CIOPORA on Minimum Distance of 2 April 2014 shall apply.

3.2 Predominant derivation

An EDV shall be predominantly derived from its Initial Variety.

⁶ Contrary to that, in the PVR law of the European Community (Regulation 2100/94) and some other countries, this contradiction does not exist, since the phrase “while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety” of Art. 14 (5) (b) (i) has not been included in Art. 13 (6) (a) of Regulation 2100/94. Nevertheless, Regulation 2100/94 has been accepted by UPOV as being in line with the UPOV 1991 Act.

⁷ Obviously, at the time when the UPOV 1991 Act was drafted, genotype could not be described other than in relation to its expression.

Predominant derivation is given if material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety, has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.

A variety can only be predominantly derived from one variety, as Article 14 (5) (b) (i) UPOV 1991 Act stipulates the EDV must be predominantly derived from the Initial Variety.

The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.

CIOPORA maintains that mutants and GMOs – as far as they are distinct from the Initial Variety – are EDVs, whenever they retain a very high genetic conformity to the Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

CIOPORA maintains that the outcomes of repeated back-crossing – as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.

4. Burden of proof

For the sake of establishing the existence of an EDV the following requirements are to be fulfilled:

- Distinctness
- Use of Material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety (derivation),
- Very high degree of genetic conformity (predominant derivation)

With regard to the burden of proof it is up to the plaintiff (holder of the Initial Variety) to prove distinctness and the very high degree of genetic conformity, as defined above. Proving the necessary degree of genetic

ESSENTIALLY DERIVED VARIETIES

conformity establishes also a prima facie evidence that material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety has been used. Nevertheless, a close phenotypic similarity may also call for an assessment of the degree of genetic conformity by the parties or the court.

An EDV is dependent on its protected Initial Variety. As a consequence, the commercialization of the EDV requires the authorization of the title holder of the Initial Variety during the duration of its protection.

4

CIOPORA POSITION ON BREEDERS' EXEMPTION

as approved by its Annual General Meeting on 2 April 2014 in
The Hague, The Netherlands

KEY STATEMENTS

- **CIOPORA supports a breeders' exemption that contains the use of commercialized plant material of protected varieties for further breeding.**
- **CIOPORA requests that the commercialization of any variety, which falls under the scope of a protected variety, shall require the authorization of the title holder of the protected variety.**
- **The breeders' exemption should read: The breeder's right shall not extend to acts done for the purpose of breeding other varieties.**

Full Text:

Breeders' exemption

According to Article 15 (1) (iii) of the UPOV 1991 Act the breeder's right shall not extend to acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14 (5) apply, acts referred to in Article 14 (1) to (4) in respect of such other varieties.

The breeders' exemption is imbedded in the UPOV PBR system since its beginning. It is a unique feature in IP protection systems. The underlying

BREEDERS' EXEMPTION

rationale for the breeders' exemption was that without unrestricted access to existing genetic variation advances in breeding would be hampered.

The current breeders' exemption consists of two components:

- The free use of protected plant material for further breeding
- The - limited - commercialization of the new breeding result.

The free use of protected plant material for further breeding is the component of the breeders' exemption which has not changed since the beginning of the UPOV system.

What has changed in the course of time is the limitation of the commercialization of the breeding result: while in the UPOV 1961 Act and 1978 Act (Article 5.3) the breeders' exemption was limited only when the repeated use of the protected variety is necessary for the commercial production of another variety, in the UPOV 1991 Act, Article 15 (1) (iii) in combination with Article 14 (5) was meant to limit the breeders' exemption to a greater extent - at least on paper - by prohibiting the free commercialization of three groups of varieties:

- (i) *varieties which are essentially derived from the protected variety (where the protected variety is not itself an essentially derived variety),*
- (ii) *varieties which are not clearly distinguishable from the protected variety and*
- (iii) *varieties whose production requires the repeated use of the protected variety.*

From a systematical point of view, the reference in Article 15 (1) (iii) to the varieties listed in Article 14 (5) (ii) and (iii) is incorrect: only varieties which are essentially derived from the protected variety are necessarily the result of breeding with the protected variety. Varieties which are not clearly distinguishable from the protected variety can be developed by using other material than the protected variety (e.g. the same parents of the protected variety), and varieties whose production requires the repeated use of the protected variety are usually the result of sexual reproduction of plants, but not of breeding work. The main reason for this systematical

error is obviously that UPOV on the one hand wanted to maintain the “traditional” possibility to commercialize varieties resulting from breeding with a protected variety, while on the other hand it wanted to further limit the breeders’ exemption by prohibiting the commercialization of two more types of varieties.

In order to have a systematically correct structure, the breeders’ exemption should be re-structured. Additionally, in order to adapt the PBR system to the current environment in modern breeding and to make it suitable for the challenges in the future, the breeders’ exemption should be fine-tuned.

Additionally, it should be clarified that the free use covers only material, which has been put on the market by the breeder or with his consent. Plant material, which for example has been handed over to an examination office for purposes of DUS examination, should not be freely available for further breeding. The same applies to material which has for example been propagated illegally or has been stolen from the breeder or obtained by another unlawful activity.

In conclusion, CIOPORA is in favor of the free use of commercialized plant material of protected varieties for further breeding, provided that the commercialization of the breeding results does not weaken the exclusive right in the protected innovation.

CIOPORA, therefore, supports a breeders’ exemption that contains the use of commercialized plant material of protected varieties for further breeding.

CIOPORA requests that the commercialization of any variety, which falls under the scope of a protected variety, shall require the authorization of the title holder of the protected variety¹.

Such varieties shall be:

- varieties which are not clearly distinguishable from the protected

¹ This solution is comparable with the “limited” breeders’ exemption in some Patent laws, such as the Unitary Patent in the EU and the Patent laws in Germany, France and Switzerland.

BREEDERS' EXEMPTION

variety

- varieties which are essentially derived from the protected variety
- varieties whose production requires the repeated use of the protected variety.

Therefore, for the sake of clarification and convenience, the second part of the current breeders' exemption (... and, except where the provisions of Article 14 (5) apply, acts referred to in Article 14 (1) to (4) in respect of such other varieties.) should be deleted and the breeders' exemption should read:

The breeder's right shall not extend to acts done for the purpose of breeding other varieties.

Such change of the wording of the breeders' exemption will correct its current structure and will, in combination with a clarification of the EDV concept and a broadening of the Minimum Distance strengthen the breeders' right.

5

CIOPORA POSITION ON EXHAUSTION

as approved by its Annual General Meeting on 02 April 2014 in
The Hague, The Netherlands

The 1991 Act of the UPOV Convention has introduced in its Article 16 the principle of “Exhaustion” of the PBR; a principle, which is known in all Intellectual Property Protection systems. The UPOV 1991 Act establishes exhaustion in form of national exhaustion¹. National exhaustion has the effect that products, which have been marketed by the title- holder or with his consent in the protected territory, fall in the public domain in this territory, so that the title-holder can exert his right to said products only once in this territory.

The exhaustion provision in the UPOV 1991 Act reads:

Article 16 Exhaustion of the Breeder’s Right

1. *[Exhaustion of right] The breeder’s right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 14(5), which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned, or any material derived from the said material, unless such acts*

¹ In contrast to this the concept of *international* exhaustion includes that a product, which has been marketed somewhere in the world by the title-holder or with his consent, falls into the public domain in the protected territory.

EXHAUSTION

- (i) *involve further propagation of the variety in question or*
 - (ii) *involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes.*
2. *[Meaning of “material”] For the purposes of paragraph (1), “material” means, in relation to a variety:*
- (i) *propagating material of any kind,*
 - (ii) *harvested material, including entire plants and parts of plants, and*
 - (iii) *any product made directly from the harvested material.*
3. *[“Territory” in certain cases] For the purposes of paragraph (1), all the Contracting Parties which are member States of one and the same intergovernmental organization may act jointly, where the regulations of that organization so require, to assimilate acts done on the territories of the States members of that organization to acts done on their own territories and, should they do so, shall notify the Secretary-General accordingly².*

On one side the exhaustion provision in the UPOV 1991 Act is very broad. It covers not only acts concerning the plant material marketed by the title-holder or with his consent, but also acts concerning any material derived from said material. On the other side it explicitly excludes specific acts from the exhaustion, namely the further propagation of the variety in question and the export of specified material into countries which do not provide for protection for the genus or species concerned.

² Here the principle of *regional* exhaustion, as practiced e.g. in the EU, is allowed, too.

CIOPORA is of the opinion that the exhaustion provision in the UPOV Act should be modernized and adapted to the current circumstances.

It is obvious and correlates to the exhaustion rules in other IP systems that the PBR in a territory in principle shall be exhausted for material, which has been marketed by the title holder or with his consent in the territory where the PBR is effective.

Taking into consideration the heterogeneous protection of plant varieties in the world and the capacity of propagation material to reproduce itself true-to-type, it is reasonable to limit the exhaustion of the PBR for the export of the propagating material³ into a country, which does not protect varieties of the plant genus or species to which the variety belongs.

As far as material is concerned, which is produced from the material marketed by the title-holder or with his consent (in the following “produced material”), the PBR should be exhausted only for produced material, if and to such extent its production has been licensed, and provided that the produced material is not subsequently used for other propagation or multiplication.

In the first instance it is a matter of the parties concerned (title-holder and licensee) to draft the scope of the license and to precisely describe the acts covered by the license. However, in that regard it can be assumed that, if for example the title-holder or his licensee sells apple trees to an apple grower without any specific agreement, the apple grower has been granted an unlimited implied license to produce and sell apples from these trees in the territory, where the PBR is valid. A cut-rose grower buying rose plants without a specific agreement has the implied right to produce cut-roses for the purpose of selling them – directly or via the trade chain - to end-consumers in the territory, where the PBR is valid.

Once more it shall be clarified that exhaustion of any PBR shall be strictly limited to the very territory where the PBR is in effect. The marketing of material in a protected territory shall trigger the exhaustion only for this very territory. Any import of said material or material produced from it

³ Propagating material as described in the position paper “Scope of the Right”.

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into another territory, where a (parallel) PBR exists, requires a separate authorization (license) of the respective title-holder. CIOPORA is opposed to any form of international exhaustion.

6

CIOPORA POSITION ON GENERAL PLANT BREEDERS' RIGHTS MATTERS

as approved by its Annual General Meeting on 28 April 2015 in
Hamburg, Germany

1. Genera and species to be protected

According to Article 3 of the UPOV 1991 Act a new member-country of UPOV shall provide protection at the date on which it accedes to this Act for at least 15 plant genera or species and, at the latest after 10 years after the accession, to all plant genera and species.

Countries, which are already bound by an earlier UPOV Act, shall provide protection at the date on which it accedes to the 1991 Act for all those plant genera and species, which are protected under the earlier Act and, at the latest after five years after the accession, to all plant genera and species.

Countries, which are bound by the UPOV 1978 Act, must provide protection only for at least twenty-four genera or species.

CIOPORA requires that all countries, which provide for PBR protection, shall cover all genera and species.

The limitation of the number of genera and species, for which PBR-protection is provided, makes the PBR legislation non-conform to Article 27 (3) b) of the TRIPS agreement, which requires an effective sui generis system for all plant varieties.

Such limitation is not justifiable and on the top not necessary anymore. In the past decades a high expertise in the examination of all kind of species

has been developed, and for most of the species, which are in commerce, exists a (at least national) test-guideline. The take-over of test-reports allows all Plant Breeders' Rights authorities to grant a title.

Therefore, the limitation of the number of protectable genera and species is no longer caused by technical limitation, but is used solely for political reasons, for the supposed benefit of growers in the country, who shall be continuously enabled to grow a species without contributing to the work of the breeders.

2. Conditions of Protection

2.1 Novelty

According to Article 6 (1) of the UPOV 1991 Act, a variety shall be deemed to be new if, at the date of filing of the application, propagating or harvested material of the variety has not been sold or otherwise disposed of to others within the territory earlier than one year before that date and outside the territory earlier than four years or, in the case of trees or of vines, earlier than six years before the said date.

In order to avoid confusion because of different legal understanding of “sales”, **the triggering point for the start of the period of grace should be linked to the physical transfer of propagating material for commercial purposes.**

It also should be clarified that the physical transfer of material for testing purposes shall not harm the novelty of the variety, as long as the material remains under the supervision of the breeder. Additionally, the physical transfer of material of the variety, which has been produced from plants grown for test purposes and which is not used for further reproduction or multiplication, shall not be deemed to be exploitation of the variety, provided that the said material is transferred without variety identification.

Additionally, a variety should be considered as “disclosed” (i.e. no longer “new”) only where material, which is capable of producing new plants true-to-type, has been made accessible to the trade or to the

public by the breeder or by its successor in title or with its consent.

The marketing of harvested material, which is not capable of producing a new plant true-to-type (such as the majority of fruits) shall not trigger the period of grace, because it does not allow a continued utilization of the variety.

Additionally, the mere publication of a description of a variety should not be considered as a disclosure of that variety.

When the so called “period of grace” was perpetuated by the UPOV 1991 Act, the marketing of protected new plant varieties was more or less confined to a fairly limited number of countries. Today, as a consequence of globalization on the one hand, and because of the shift of production to new territories on the other hand, new plant varieties have to be tested in many more territories and the marketing plans have become far more intricate and time consuming. Therefore, the placing of a variety on the world markets stretches over a much longer period of time. Some varieties, which were supposed to be adapted to only very specific conditions, become demanded by the trade or by the public in an entirely different environment after a number of years. As consequence, the long period of time necessary for the proper launching of a variety does require a more adequate period of grace, especially for fruit trees, where a minimum 10-year period of grace would be more in line with the actual requirements of breeders.

Therefore, the period of grace should be extended for non-woody plants to six years and for woody plants to ten years.

Finally, for the calculation of the period of grace the time of quarantine should not be taken into consideration.

Transitional period for varieties of recent creation.

According to Article 6 (2) of the UPOV 1991 Act, a UPOV member which applies this Convention to a plant genus or species to which it did not previously apply this Convention or an earlier Act may consider a variety of recent creation existing at the date of such extension of protection to

satisfy the condition of novelty even where the sale or disposal to others took place earlier than the original time limits defined for novelty.

In order to compensate the disadvantages for breeders due to a late implementation of Plant Breeders' Rights in a country, countries should allow a sufficient "transitional period", during which breeders can apply for Plant Variety Protection for their varieties, even if these varieties do not meet the requirements for novelty anymore. This should happen also if a country, which is already a member to the UPOV 1978 Act, upgrades its PBR-law and accedes to the UPOV 1991 Act.

In this respect there should be the possibility for breeders – within a specified time after enacting the respective provision – to apply for all of their varieties, irrespective of how old they are. In return the duration of protection might be limited to the remaining duration of the respective Plant Breeders' Right in the first country of registration.

2.2 Reference collections (Use of DNA analysis for the set up)

In many crops reference collections are necessary in order to perform solid DUS examinations.

The maintenance of reference collections causes – particularly in fruit tree species - a significant part of the costs for the DUS examination.

Therefore, the composition of reference collections must be evaluated permanently and shall reflect the developments in breeding. Old varieties with no relevance for modern breeding and with no relevance for the phenotypic appearance of new varieties should be eliminated.

If such old varieties are maintained on the premises of the examination offices for other reasons, the cost for their maintenance shall not be included in the calculation of the cost of the DUS examination.

A tool to reduce costs in respect of reference collections may be molecular markers that are reproducible between laboratories. Molecular markers can be useful to generate a genetic conformity measure as additional information when planning DUS trials, to come

to an optimized setting of variety comparisons in DUS trials and for management of reference collections (UPOV option 2, UPOV documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add.).

Care must be taken that no phenotypically similar varieties are omitted from the comparative trials. To avoid appeal in later examination years, which unnecessarily expand the examination period, applicants and owners of reference varieties must be fully informed and consulted on beforehand about the composition of the trials.

Additionally, CIOPORA in general favours the idea of involving panels of experts from outside the examination offices to identify the reference varieties, which should be compared with the candidate varieties, if no permanent living reference collection exists.

However, it is indispensable that the process of selecting the experts is completely transparent and ensures a balanced participation of the international breeders' community in each panel, preferably in co-operation with the respective breeders' organizations.

2.3 Suitable Variety Denomination

According to Article 5 (2) of the UPOV 1991 Act a variety, for which an application for protection is filed, must be designated by a denomination in accordance with the provisions of article 20 of the UPOV 1991 Act.

The bars to the acceptability, by national PBR authorities of a member country of UPOV, of a denomination proposed by an applicant for plant variety protection are restrictively enumerated by the UPOV Convention. Therefore, UPOV member countries must not be more restrictive than the UPOV Convention itself as to what may constitute a valid denomination. In general, CIOPORA supports a high flexibility as to the names, words, codes or signs that are eligible for the identification of a variety.

Where applicants use fancy names or words, instead of codes, then the examining authorities should not only make a prior search within the lists of other existing variety denominations for the same or closely related species, but also within the list of prior trademarks filed for closely related products in the international class 31. This would save unnecessary

litigation with holders of trademark rights having priority over the applicant of plant variety protection¹. By using coded denominations applicants avoid potential opposition and delays in the application process due to “prior use” of an identical fancy denomination.

CIOPORA considers that the “re-use” of a variety denomination can be a source of confusion. In particular in perennial species, trees, shrubs, perennial herbs and garden roses, plants of a specific variety are maintained in public or private gardens for a long time, even if the variety is not “on the market” any more. In such cases the variety has not ceased to exist, but it is extremely difficult to discover this. Additionally, the possibility of such re-use seems to be needless. In case of using codes as denominations there is no trouble whatsoever. If a breeder wishes to use a fancy name as denomination, it should be easy for him to find a denomination that is not identical with the denomination of an “old” variety. CIOPORA considers the denomination of a variety as its permanent identifier, irrespective whether the variety is commercialized any more or not.

2.4 Formalities

The breeder’s right shall be granted according to Article 5 of the UPOV 1991 Act where the variety is new, distinct, uniform and stable. The grant of the breeder’s right shall not be subject to any further or different conditions, provided that the variety is designated by a denomination in accordance with the provisions of Article 20, that the applicant complies with the formalities provided for by the law of the Contracting Party with whose authority the application has been filed and that he pays the required fees.

The formalities provided for by the national PBR laws should not go beyond what is necessary to accomplish the application. The compliance with obligations based e.g. on the Convention on Biodiversity (CBD) shall not be considered to be a formality for the

¹ A variety denomination should be considered as absolute ground for refusal for a trademark where the use of such trade mark may be prohibited pursuant to the variety denomination.

grant of a Plant Breeders' Right.

3. The process of application and granting

3.1 Documents and forms used

- **Harmonization**
- **Electronic application**
- **PBR-CT system desired – one application – one DUS examination**

CIOPORA strongly supports the development of harmonized application forms and technical questionnaires and the set-up of technical tools for electronic applications, including a harmonized language regime.

The ultimate objective should be an optional system which would allow breeders to apply for their new variety on one application form (electronically) and choose the countries in which the application shall be accomplished. This should be combined with a DUS examination for the variety in a competent examination office and the take-over of the test report in the countries chosen.

The requirements and formalities for the certification of documents, such as the Power of Attorney, should be reduced to what is absolutely necessary.

3.2 Plant material requested

CIOPORA considers that the applicant for a plant breeders' rights certificate should be obliged to supply nothing but the material of the variety for which the application is filed.

In some countries, a practice has developed, on the part of plant variety rights' offices to routinely ask applicants to also furnish to the examination authority material of "comparative" varieties. While breeders are usually willing to cooperate when they are in a position to do so, this request should not be transformed into an obligation. Indeed the examination authority, alone, should have the responsibility of keeping whatever

collection of “varieties of common knowledge” it may consider as appropriate for the purpose of comparing the latter to the candidate variety.

As regards the phytosanitary condition of plant material requested from breeders by DUS examination offices, CIOFORA acknowledges that such material should be in good sanitary condition in order not to infect other material that is being grown by said authorities. The recently stricter measures imposed by some DUS examining offices against the presence of pests and viruses seem to be going beyond what is strictly necessary or reasonable for the purpose of the DUS examination. Additionally, if a breeder provides to an authority material that does not meet the sanitary standards, this should not automatically lead to the refusal of the application.

Sufficiently broad time limits and possible extensions should be provided for the supply of plant material of the candidate variety. This is especially necessary for varieties that originate from another hemisphere than the one where the Examination Office is located, particularly if long periods of quarantine exist.

If plant material has to be sent to an examination office at a fixed period of time, the period should be communicated to the breeders in due time.

3.3 Priority

The claiming of the UPOV priority and the Paris Convention priority should be harmonized so that it can operate smoothly between all countries that are parties either to the UPOV Convention or to the Paris Convention, irrespective of whether the plant variety protection system is by patents or by a sui generis system.

In that respect the term “breeder’s right”, used in the UPOV 1991 Act, should be replaced by the term “title of protection” and the latter should be the subject of a broad definition in article 1 of the 1991 Convention, covering both sui generis breeders’ rights and patents.

The texts of national or regional laws applying any given Act of the UPOV

convention should be harmonized.

3.4 The DUS examination

In general CIOPORA is of the opinion that an IP title for a plant variety should be based on a DUS examination conducted by a governmental or specialized private entity.

The quality of the DUS examination should be high and should be harmonized on a world-wide level. A quality assurance system should be established.

CIOPORA is of the opinion that governmental or private entities, which conduct DUS examinations, should not be active in breeding the crops on which they do the DUS examination.

The conduct of the DUS examination should be as reasonably close as possible to standard commercial growing conditions.

Taking into consideration the significant influence of the environment on the phenotype of plant material and as a consequence also on the result of the DUS examination, the DUS examination should be conducted in areas having the best climatic conditions for the growing of the respective species and the candidate variety.

The DUS examination should be as short as possible in the given environment.

3.5 Ownership of plants, DUS reports, DNA samples and analyses

The property in the plants, which are shipped to the examination offices, belongs to the breeder. The mere shipping of plants to the examination office for the purpose of a DUS examination or the planting of the material into the ground of the examination office cannot be seen as transfer of property. As a consequence, the examination office is not allowed to keep or forward the plant material or parts of it, including DNA samples, during and after the end of the DUS examination without the authorization of the owner of the material.

3.6 Take-over of existing test reports

The examination offices / PBR offices shall make available the DUS examination report to other PBR offices for a reasonable handling fee. The current price for the take-over of an examination report of 240 EUR, as proposed by UPOV and accepted by the UPOV members is too high.

In principle PBR offices should be obliged to take over existing DUS reports. Precondition for such take-over is that the quality of the DUS examination is harmonized on a high level. In any case take-over of DUS reports should be compulsory between examination offices, which operate under a common system and observe the same procedures.

3.7 Duration of the application process

- **The entire application process should be as short as possible. In general, the PBR title should be issued not later than six months after the DUS examination has been completed.**

4. Farmers' exemption

CIOPORA points out that the so called Farmers' exemption has been admitted by UPOV under strictly limited conditions only for seed species grown by farmers and not in the horticultural sector (see the Recommendation relating to Article 15 (2) published in the Final Draft of the 1991 Act of the UPOV Convention and the UPOV document CAJ/50/3, No. 10, 11 and 13).

Applying the farmers' exemption to vegetatively reproduced ornamental and fruit varieties makes a PBR law for such species totally ineffective, and thus is contrary to the UPOV 1991 Convention and the TRIPS Agreement.

5. Compulsory license

CIOPORA points out that according to Article 17 of the UPOV 1991 Act (Restrictions on the Exercise of the Breeder's Right) no UPOV member may restrict the free exercise of a breeder's right for reasons other than of

public interest, except where expressly provided in this Convention. Similar provisions can be found in Articles 30 and 31 of the TRIPS Agreement.

Taking into consideration the large assortment of all kinds of ornamental and fruit varieties, CIOPORA is of the opinion that in general there exists no public interest in the commercialization of a specific variety of such crops, so that the preconditions for a compulsory license usually are not given as far as ornamental and fruit varieties are concerned.

6. Duration of protection

The minimum compulsory duration of a plant variety right under the UPOV 1991 Act is 25 years for trees and vines and 20 years for all other species, according to Article 19 (2).

CIOPORA is in favour of extending the duration for PBR to 30 years for all species for the following reasons:

- the requirements to a new variety increase steadily, and new varieties in general are of higher value than older ones,
- the costs for breeding and research increase, while the average royalty payments for varieties decrease,
- the breeder invests in average 10 to 20 years before a new variety enters the market; alone the testing period and the period for building up elite mother plants lasts 5 - 10 years,
- the scope of protection is not entirely effective,
- the desire of the public to get free access to the variety is fulfilled to a huge extend already during the protection period.

Such an extension will have no consequences for the vast majority of varieties. The vast majority of varieties have a rather short commercial life due to the rapid exchange of varieties in the market. It is only the exceptional, long-living varieties which would benefit from such extension. For such varieties it is necessary to have sufficient period of protection, because they earn most of the return on investment for the whole breeding program of the breeder. Additionally, it is justified to say that because of their excellence these varieties deserve a longer protection.

7. Provisional Protection between application and grant

Article 13 of the UPOV 1991 Act [Provisional Protection] provides that each UPOV member shall provide measures designed to safeguard the interests of the breeder during the period between the filing or the publication of a PBR application and the grant of that right. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorization. A state may provide that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application.

Different to inventions, which as a general rule are not released to the public before the patent is granted, breeders start the exploitation of their new varieties often even before they apply for protection, namely within the period of grace. This is to the benefit of the growers, too, because growers usually aim to access new varieties as soon as possible in order to reap the benefits of the improved characteristics of such varieties.

In order to create a real incentive for breeders to launch their innovation at an early stage, the breeder of the new variety must be in the position to control the exploitation of his variety, i.e. to grant licenses and to stop “infringers”, even before the protection title is granted.

Article 13 of the UPOV 1991 Act provides the basis for such an effective provisional protection. However, it shows that most the UPOV members make use only of the least possible measure to protect the breeder, i.e. granting to the title-holder the right to an equitable remuneration to be paid by the persons, who use the variety between the publication of the application and the grant of the title.

Safeguarding the interest of the breeder, however, requires a stricter approach. First of all, in the national PBR laws the application for a PBR should be designed as a true object of property of the breeder, which can serve as a basis of contractual exploitation rights and for enforcement, including court proceedings against infringers.

Additionally, and consequently, the applicant of the PBR should be entitled to enforce his right already during the period between the publication of the application and the grant.

If the application has been withdrawn, is deemed to be withdrawn or is finally refused the rights listed above shall be deemed never to have existed. In this case benefits received are to be returned, unless otherwise agreed by the parties.

If a PBR law provides that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application, the publication of the application in the official gazette of the competent authority should be considered as a proper notification.

CIOPORA is of the opinion that according to the current provisions concerning the provisional protection plants, which have been produced in the period of provisional protection without the authorization of the applicant remain illegal, even if the producer has paid an equitable remuneration to the applicant or title-holder. This is particular important for fruit-trees, which are usually produced for a long-lasting use.

8. The use of the variety denomination

According to the Article 20 (7) of the UPOV 1991 Act [Obligation to use the denomination] any person who offers for sale or markets propagating material of a variety protected within the protected territory shall be obliged to use the denomination of that variety, even after the expiration of the breeder's right in that variety.

The variety denomination shall be the unique identifier of the variety. UPOV and its members should see to it that the denomination of a variety is the same in all member states of UPOV, with as little exceptions as possible. The best way to avoid different denomination for one and the same variety is the use of code denominations, as promoted by CIOPORA since long.

In order to provide for clarity and transparency in the business and towards the consumers the mandatory use of the variety denomination for each and any material of the variety is necessary.

Therefore, the use of the variety denomination should not only be obligatory in relation to propagating material, but also in relation to harvested material.

This should apply not only for the protected variety, but also for varieties according to Article 14 (5) (a) of the UPOV 1991 Act, namely EDV varieties which are not clearly distinguishable from the protected variety and varieties, whose production require the repeated use of the protected variety.

9. Cost of protection

The costs for the acquisition and maintenance of a Plant Breeders' Right should not be unnecessarily high².

Particularly the fees for the DUS examination of fruit tree varieties reach in some countries a level which forms a barrier for the breeders to apply for protection.

Maintenance fees should be meant to cover just the administration costs by Plant Variety Rights Offices, no more. In view of the shorter and shorter turnover of varieties they should be kept at a minimal flat rate.

10 Enforcement

10.1 Effective enforcement measures

According to Article 30 (1) (i) of the UPOV 1991 Act each Contracting Party shall provide for appropriate legal remedies for the effective enforcement of breeders' rights.

Additionally, Article 41 of the TRIPS Agreement provides that members of the WTO 'shall ensure that enforcement procedures are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including

² Countries, which have unnecessarily costly fees for the acquisition and maintenance of IP rights violate Article 62 (4) in combination with 41 (2) of the TRIPS Agreement.

expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringement. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays’.

The enforcement of plant variety protection depends largely on the scope of rights. This is why a sufficiently broad scope of the PBR is priority in all countries concerned.

Additionally, in order to be effective, a Plant Breeders’ Rights law must be accompanied by effective enforcement tools. Such enforcement tools should contain at least

- Civil measures
 - (i) provisional measures, to grant access to premises of a probable infringer, to prevent or stop an infringement of the breeder’s right, and/or to preserve evidence, e.g. to collect samples of infringing material;
 - (ii) measures to allow a civil action to prohibit the committing, or continuation of the committing, of an infringement of the breeder’s right;
 - (iii) measures to provide adequate damages to compensate the loss suffered by the holder of the breeder’s right and to constitute a deterrent to further infringements;
 - (iv) measures to allow destruction or disposal of infringing material;
 - (v) measures to provide payment by the infringer of the expenses of the holder of the breeder’s right (e.g. court fees and attorney’s fees);
 - (vi) measures to require an infringer to provide information to the holder of the breeder’s right on third persons involved in the production and distribution of infringing material.

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- Customs measures
 - (i) measures to allow suspension by the customs authorities of the release into free circulation, forfeiture, seizure or destruction of material which has been produced in contravention of the breeder's right;
 - (ii) measures to allow the suspension by the customs authorities of the release of the infringing material destined for exportation.

- Administrative measures
 - (i) provisional measures to prevent or stop an infringement of the breeder's right, and/or to preserve evidence (e.g. collect samples of infringing material from greenhouses);
 - (ii) measures to prohibit the committing, or continuation of the committing, of an infringement of the breeder's right;
 - (iii) measures to allow destruction or disposal of infringing material;
 - (iv) measures to require an infringer to provide information to the holder of the breeder's right on third persons involved in the production and distribution of infringing material;
 - (v) measures to allow the forfeiture, seizure of material which has been produced in contravention of the breeder's right;
 - (vi) measures for authorities responsible for the testing and certification of propagating material to provide information to the holder of the breeder's right regarding propagating material of his varieties;
 - (vii) administrative sanctions or fines in the case of a breach of the legislation on breeders' rights or of a non-compliance with provisions on, or misuse of, variety denominations.

- Criminal measures
 - (i) Criminal actions and penalties in cases of willful or negligent violation of the breeders' right

CIOPORA is of the opinion that national legislation, which does not include at least the measures as listed above, does not fulfill the requirements of Article 30 (1) (i) of the UPOV 1991 Act and of Article 41 of the TRIPS Agreement. The consequences are particularly severe and damaging for small and medium sized enterprises.

10.2 Affordable cost of enforcement

The enforcement of IP Rights must be affordable for all title holders, particularly for small and medium sized enterprises. Too high costs form a practical barrier for enforcement, particularly for companies which do not have high financial reserves.

CIOPORA requests that infringers of IP rights shall be obliged to compensate all reasonable costs incurred by enforcement proceedings.

10.3 Specialized Courts

Plant Breeders' Rights law is – due to the specifics of the material incurred – difficult and to judge about such cases it needs special knowledge.

Thus, it is advisable to direct Plant Breeders' Rights court cases to selected courts, which are specialized in Plant Breeders' Rights law or at least to courts that already are established for patent infringement cases because of similar experience in industrial property. This guarantees a unitary and qualified case law.

10.4 Use of molecular techniques for the enforcement

The effective enforcement of IP rights is of utmost importance for breeders. CIOPORA supports the elaboration of a standard *modus operandi* of DNA analysis as an additional tool to improve the enforcement of IP rights; molecular markers are then very useful for variety identification³.

Particularly in regard to the harvested material of fruit varieties, such as

³ See the CIOPORA position "The use of molecular techniques for plant variety protection", approved by the AGM 2011 in Rome.

GENERAL PBR MATTERS

apples or grapes, DNA analysis is the only way to prove or at least to provide a prima facie proof that the harvested material belongs to a protected variety, because in most fruit species it is not possible to produce a true-to-type plant from the harvested material.

6

CIOPORA POSITION ON PATENTS FOR PLANT-RELATED INVENTIONS

as approved by vote in September 2017

KEY STATEMENTS

- **It is the opinion of CIOPORA that, as a matter of principle, plant related inventions should not be treated so differently that they are essentially deprived of patent protection.**
- **CIOPORA supports the view that the mere discovery in nature of existing plant material with interesting characteristics would not, as such, be patentable.**
- **It is the position of CIOPORA that technical processes containing technical steps, even when combined with biological steps, are patentable, particularly if the technical step constitutes the essence of the invention, provided the processes are new and inventive**
- **CIOPORA is of the view that the so-called “new plant breeding techniques” of inter alia oligonucleotide directed mutagenesis (ODM), zinc finger nuclease (ZFN) technology, transcription activator-like effector nucleases (TALENs), CRISPR/Cas systems, cisgenesis, intragenesis and reverse breeding are all processes which contain a technical step that by itself (i.e. without crossing) introduces or modifies a trait in a plant’s genome and are therefore not essentially biological processes.**
- **A DNA sequence from a plant that is publicly available, such as**

in its natural environment, shall not be considered to be novel as such. However, the use of such DNA sequences isolated from their original plant genome for a given novel function can in principle be patentable.

- **CIOPORA is of the opinion that patent protection should be available for novel traits, biological material and plants comprising such traits, provided that the further requirements for patentability are fulfilled. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.**
- **CIOPORA is in favor of a breeders' exemption, both in plant variety rights and patent law, allowing plant breeders to use protected plant material for the purpose of breeding or discovering and developing a new plant variety. However, the subsequent commercialization of a plant comprising the patented invention should require the authorization of the patent holder.**
- **It is important for ornamental / fruit breeders to secure quick and efficient access to patented technology under fair, reasonable and non-discriminatory ("FRAND") terms. To this end, CIOPORA supports the establishment of a licensing platform and dispute resolution mechanism.**

Full Text:

Plant breeding in the fruit and ornamental sectors is tantamount to constant innovation, both in terms of breeding methods and of plant material with unique characteristics resulting from said methods. The means used to achieve such innovation are not limited to traditional plant breeding based on crossing and selecting. Innovation is also increasingly achieved through the use of biotechnology and advanced breeding techniques based on DNA markers or genome editing.

Whereas our industry has, for decades, relied on the availability of *sui generis* plant variety rights under the UPOV Convention or similar protection mechanisms such as the U.S. Plant Patent system, investments into modern breeding technologies and the ever-increasing use of sophisticated biotechnological tools call for an effective protection of

inventions in that area, in order to add value to the entire chain. Neither of the aforementioned systems, however, are designed to fully protect such inventions, as their scope is limited mainly to the protection of propagating material of plant varieties, respectively asexually reproduced plants, and therefore do not cover any plant related inventions beyond the plant variety / plant level. In general, the (utility) patent system can effectively protect such inventions.

CIOPORA is, however, of the opinion that an inevitable rise in the use of patents to protect plant related innovations beyond the variety level should not negatively affect the access to and availability of protected plant material for further breeding purposes. This principle has been inherent to our industries from the outset under the so-called “breeders’ exemption” and should continue to apply, regardless of the means of protection chosen. However, CIOPORA is adamant that a sufficient incentive is vital to foster innovation.

1. Patentable subject matter

a) Patent protection should be available for plant related inventions, as it is for other inventions

CIOPORA has always supported the strong protection of industrial property in all fields of research including biotechnology¹. CIOPORA, therefore, is of the opinion that in general all inventions which fulfill the requirements for patentability (novelty, industrial application, non-obviousness / inventive step) should be patentable.

This position resonates with the universally acknowledged principle, enshrined in the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”), that patents should be available for any invention, whether products or processes, in all fields of technology, without discrimination as to the field of technology, provided that they are new, involve an inventive step and are capable of industrial application.

It is the opinion of CIOPORA that, as a matter of principle, plant related

¹ See e.g. the CIOPORA Green Paper, page 52.

inventions should not be treated so differently that they are essentially deprived of patent protection.

b) Inventions should have technical character to be patentable

CIOPORA supports the basic principle underlying the patent system that, for something to be considered an “invention”, it must have some form of technical effect or character.

For the ornamental and fruit breeding industries, the most relevant effect of this principle is that mere discoveries and aesthetic creations are not considered to have technical character and therefore are not considered patentable.

DISCOVERIES

CIOPORA supports the view that the mere discovery in nature of existing plant material with interesting characteristics would not, as such, be patentable. This is similar to the situation under PBR laws, where protection is only open to varieties that have (at least) been “discovered and developed”; mere discovery is not enough.

However, as soon as the biological material in question is isolated from its natural environment or if it can be produced by means of a technical process, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (“Biotech Patent Directive”) allows it to be patented.

Decisions from Australian² and US³ courts in the so-called Myriad cases have cast doubt on that principle, as it was held that DNA sequences isolated from naturally occurring biological material are not patentable subject-matter, as the mere fact that they are isolated from their natural surroundings does not take away the fact that they are essentially a discovery.

CIOPORA acknowledges the existence of these decisions and their effects in Australia and the US. CIOPORA also acknowledges the common

² D’Arcy v Myriad Genetics (2015) HCA 35.

³ Association for Molecular Pathology v Myriad Genetics 135 S. Ct 2107 (2013).

European Patent practice in that genetic material, removed from its natural environment, should have a described function to be patentable.

CIOPORA is of the opinion that DNA sequences isolated from naturally occurring biological material as such are to be considered discoveries and therefore not patentable subject-matter. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.

CIOPORA is of the opinion that plants, that contain such DNA sequences by nature, i.e. without human interference such as crossing and selection, should not be patentable, but be regarded as discovery.

AESTHETIC CREATIONS

It is CIOPORA's position that the mere fact that a plant serves an aesthetic purpose does not render such plant unpatentable.

It is CIOPORA's position that, to the extent that plants are produced by means of a technical process, which links the aesthetic effect to a technical effect, such plants should not be excluded from patentability

c) **Breeding methods and essentially biological processes**

A process consisting solely of crossing and selecting plant material is generally considered to lack any technical teaching and therefore is not considered patentable. In that regard, TRIPS provides the possibility to exclude from patentability so-called "essentially biological processes for the production of plants ... other than non-biological and microbiological processes".

In Europe, under the European Patent Convention ("EPC"), this principle was confirmed by the 2010 decisions from the European Patent Office's Enlarged Board of Appeal in cases G1/084 ("Tomato I") and G2/075 ("Broccoli I"). CIOPORA supports the findings of that Board that pure breeding processes consisting of crossing and selection are excluded from

⁴ EBoA 9 December 2010, G1/08.

⁵ EBoA 9 December 2010, G2/07.

patentability.

It is the position of CIOPORA, however, that technical processes containing technical steps, even when combined with biological steps, are patentable, particularly if the technical step constitutes the essence of the invention (e.g. if a human-technical intervention or step enables or assists the crossing or selecting), provided the processes are new and inventive, it being understood that when a process contains the steps of crossing and selection, the mere fact that the selection step is inventive, does not make the process a technical one. Providing patent protection only for the technical step is in most cases insufficient because the scope of protection does not cover the breeding process and breeding result and the technical step in many cases can easily be circumvented.

It is CIOPORA’s opinion that, as far as the EU is concerned, this is in line with both the EU legislator’s definition of an “essentially biological process” as a process consisting **entirely** of natural phenomena such as crossing or selection⁶, and the Commission’s initial intention⁷ to provide patent protection for processes in which human intervention consists of more than selecting an available biological material and letting it perform an inherent biological function under natural conditions.

In any event, CIOPORA is of the view that the so-called “new plant breeding techniques” of inter alia oligonucleotide directed mutagenesis (ODM), zinc finger nuclease (ZFN) technology, transcription activator-like effector nucleases (TALENs), CRISPR/Cas systems, cisgenesis, intragenesis and reverse breeding are all processes which contain a technical step that by itself (i.e. without crossing) introduces or modifies a trait in a plant’s genome and are therefore not essentially biological processes within the meaning given to that term by the Enlarged Board of Appeal in the Tomato and Broccoli I cases.

d) Patentability of plant material

The value of innovation in the plant breeding sector manifests itself most

⁶ Article 2(2) of the Biotech Patent Directive.

⁷ 1988 Commission Proposal for a Council Directive on the legal protection of biotechnological inventions

ostensibly in the plant material resulting from the application of the chosen breeding method. Innovation can e.g. reside in the development of a new plant variety, the identification and introgression of new specific characteristics or traits or the fabrication of gene construct to carry foreign genetic material.

GENETIC MATERIAL/DNA SEQUENCES

A DNA sequence from a plant that is publicly available, such as in its natural environment, shall not be considered to be novel as such. However, the use of such DNA sequences isolated from their original plant genome for a given novel function can in principle be patentable.

TRAITS

The presence of a specific trait in a plant can e.g. be the result of genetic modification, mutations (induced or naturally occurring) or the identification of existing traits in different environments (native traits). Traits often constitute the main component of innovation and considerable investment is made in the area of trait research. However, once a variety with such a trait is made available on the market, the trait may be relatively easily transferable to other varieties⁸.

Accordingly, sufficient protection for trait innovation should be in place. Such protection is currently only available under the patent system. However, in many countries the availability of patents for plant product innovations is made dependent, by either legislators, courts or administrative bodies, on the manner in which the traits in question were created (GM, man-made traits, native traits).

CIOPORA is of the opinion that patent protection should be available for novel traits, biological material and plants comprising such traits, provided that the further requirements for patentability are fulfilled. The use of DNA sequences isolated from their original plant genome for a given function can in principle be patentable.

⁸ With the transfer to a different genetic background, even if PVP protection for a variety comprising the trait is in place, the trait itself escapes the protection provided by the PVP today.

CIOPORA takes note of the 1 July 2017 changes to the EPC Implementing Regulations excluding from patentability plants and animals exclusively obtained by an essentially biological breeding process.

It is the opinion of CIOPORA that, legally, the binding Tomato II / Broccoli II decisions⁹ of the European Patent Office's Enlarged Board of Appeal provide the only correct interpretation on this matter, as was also confirmed by the Dutch court of The Hague in the radish cress case.¹⁰

To the extent that products obtained from essentially biological processes were to become unpatentable in the future, CIOPORA calls upon the legislator to strengthen the plant variety rights system so that such products, provided they are plant varieties, at least receive sufficiently strong protection under that system.

2. The research and breeders' exemptions

CIOPORA calls for a worldwide harmonized **research exemption** which allows research on the patented invention including for the purpose of improving the invention. The mere use of the patented invention as a research tool (research "with") should not be permitted. The research exemption should apply for plant related inventions in the same way as for any other inventions.

Additionally, CIOPORA is in favor of a **breeders' exemption**, both in plant variety rights and patent law, allowing plant breeders to use protected plant material for the purpose of breeding or discovering and developing a new plant variety. However, the subsequent commercialization of a plant comprising the patented invention should require the authorization of the patent holder. However, any commercial use of a plant variety which no longer contains the patented characteristics should be automatically exempted from infringement.

3. Quality of patents

In order to guarantee high-quality patents, the requirements for

⁹ Enlarged Board of Appeal decisions of 25 March 2015 in cases G 2/12 and G 2/13

¹⁰ District court The Hague, 8 May 2013, [2013] BIE 276.

patentability must be strictly observed. In fact, a stricter examination and scrutiny must take place in order to avoid that sub-patentable developments obtain patent protection. Particularly, a too lenient approach to the requirement of non-obviousness and inventive step damages the reputation of the patent system.

In order to provide for high-quality, fast, cost-effective and transparent examination and opposition procedures, the patent offices and patent courts must be well equipped in regard to both staff and equipment.

4. Information about and access to patents

For plant breeders, it is important to know whether the material used for further breeding purposes is patented and, if so, which patents relate to which plant varieties. To increase transparency in this area, and in view of the increasing amount of patents in the ornamental / fruit sectors, CIOPORA calls for the establishment of an online database with as broad coverage as possibly feasible allowing breeders to verify, per variety / trait, whether a patent is in place.

Furthermore, it is equally important for ornamental / fruit breeders to secure quick and efficient access to patented technology under fair, reasonable and non-discriminatory (“FRAND”) terms. To this end, CIOPORA supports the establishment of a licensing platform and dispute resolution mechanism.

However, it is crucial that costs for any IP Protection do not prevent breeders and inventors, particularly small and medium sized enterprises, from making use of the protection systems.

ABOUT CIOPORA

CIOPORA is the International Association of Breeders of Asexually Reproduced Ornamental and Fruit Varieties. Breeders of such varieties account for two-thirds of all Plant Variety Rights (PVR) titles in the world. Since the association's foundation in 1961, CIOPORA has represented these breeders in all matters of Intellectual Property (IP) Protection and has worked to foster an environment throughout the world in which the creativity and innovation of these breeders can flourish. CIOPORA is a member-based, nonprofit Swiss organization with its administrative office in Hamburg, Germany.

CIOPORA: Uniting Breeders, Protecting Innovation.

For more information, visit www.ciopora.org