

ESSENTIALLY DERIVED VARIETIES (EDV)

Position of CIOPORA

January 2008

In November 2002 the CIOPORA GREEN PAPER on PLANT VARIETY PROTECTION has been published. Within Chapter 3.4 of the Green Paper CIOPORA expressed the view of breeders of asexually reproduced ornamental and fruit varieties on Essentially Derived Varieties (EDV) and Dependency. Today, an increasing number of cases and ongoing discussions in the industry regarding essential derivation make a comprehensive commentary of the EDV concept by the breeders necessary.

17 years ago the concept of Essentially Derived Varieties has been incorporated into the UPOV 1991 Act, after more than 40 years of great efforts by breeders, inter alia represented by CIOPORA. In order to strengthen the rights of the breeders and in particular to give to the breeders of original genotypes an additional source of remuneration and to provide an effective protection against plagiarism, a system of "Plant Variety Right specific dependency", based on "essential derivation", has been developed.

It is a common understanding among the UPOV members that it is up to the breeders to determine when there is essential derivation between varieties.

Therefore, CIOPORA, as the international organisation representing breeders of asexually reproduced ornamental and fruit varieties, who hold ca. 70% of the Plant Breeders' Rights titles under the UPOV regime, determines in this paper the conditions under which an asexually reproduced ornamental or fruit variety should be considered as EDV of another variety. CIOPORA encourages all parties concerned to accept the determinations and thresholds given and to find on that basis amicable solutions in order to avoid costly court proceedings with an unpredictable outcome.

I. Introduction

1. The Basics

- a) The concept of "Essentially Derived Varieties" is a mixture of technical (describing) and legal aspects.
- b) Whether a variety has to be considered to be an "initial variety" or is "essentially derived" from another variety is, in the first approach, a pure technical fact.
- c) An essentially derived variety remains an EDV forever and an initial variety remains an initial variety, irrespective of the protection status. An initial variety itself cannot be an essentially derived variety and vice versa.
- d) The legal aspect of "essentially derived varieties" deals with the notion of "dependency" of an essentially derived variety from an initial variety, i.e. with questions of the scope of rights and infringement.
- e) Only if the initial variety enjoys protection, the title-holder of this variety can prevent everybody else from exploiting any essentially derived variety thereof, irrespective whether the essentially derived variety itself is protected or not. If the initial variety is not or not anymore protected, no case of dependency exists, and the owner of the initial variety cannot claim any control on essentially derived varieties thereof.

2. The EDV-concept as a true extension of the breeders' right and a temporary limitation of the breeders' exemption

- a) The title-holder of a protected variety can exclude all others from carrying out any of the acts mentioned in Article 14 (1) (a) of the UPOV 1991 Act, that is production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, stocking for any of these purposes of propagating material (and in some cases also harvested material) of his variety.

The UPOV 1991 Act has incorporated in Article 14 "Scope of the Breeder's Right" the subparagraph (5) "Essentially derived and certain other varieties" with the aim to strengthen the breeders' rights. The right of the breeder to exclude others from the acts mentioned before no longer covers only the protected variety itself, but also varieties that are *essentially derived* from the protected variety. The EDV-concept, therefore, constitutes a true extension of the breeders' right. It is applicable not only in the relationship between the title-holder of an initial variety and the breeder of an EDV thereof, but is applicable between the title holder and everybody who wishes to exploit the EDV.

- b) On the other hand the EDV-concept also is linked to the so-called *breeders' exemption*. The breeders' exemption provides that the breeder's right shall not extend to acts done for the purpose of breeding other varieties and, unless such other varieties are essentially derived varieties, to the exploitation of such other varieties. Therefore, the EDV-concept does not constitute a limitation of the free access to germplasm, but it constitutes a temporary limitation of the exploitation of varieties, if they are EDV.

CIOFORA strongly supports the breeders' exemption within the temporary limits determined by the EDV-concept.

3. What is the EDV-concept aiming at?

The EDV-concept is aiming at protecting Initial Varieties and the exclusive right of the title holder to exploit these Initial Varieties.

In the sector of asexually reproduced ornamental and fruit varieties, the EDV-concept therefore is of particular importance for the following two groups of varieties:

- a) varieties which are solely based on the genome of the initial variety and where the genomic structure is highly conserved, e.g. spontaneous and induced mutants¹, GMO and apomicts², and
- b) varieties resulting from crossing and selecting, including the initial variety, being predominantly derived from the initial variety and being destined for circumventing the exclusive right to exploit the initial variety (plagiarism or *me-too-varieties*).

II. The interpretation of the EDV-concept

1. When is a variety essentially derived from another variety?

Taking into account Article 14 (5) (b) of the UPOV 1991 Act CIOFORA is of the opinion that an asexually reproduced ornamental and fruit variety shall be deemed to be *essentially derived* from another variety (the initial variety) if it

¹ Mutants appear as variant individuals of the initial variety and can be selected as somaclonal variants after in vitro culture, variant individuals in clonal propagations of the initial variety and other procedures.

² Apomixis describes the asexual reproduction of plants through seed formation without fertilization, i.e. without the fusion of a male and a female gamete. The male gamete, if integrated at all, serves only to stimulate the division of a gametophytic, maternal cell to form a zygote, an embryo and a seed.

- a) is clearly distinguishable from the initial variety,
- b) is predominantly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety and
- c) except for the differences which result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

These three preconditions are of technical nature and shall be specified as follows:

- sub a) The EDV has to be *clearly distinguishable* from the initial variety. This requirement draws the line between an EDV and a variety which is not clearly distinguishable from the protected variety in the meaning of Article 14 (5) (a) (ii). Whereas the EDV is a discrete variety, which is eligible for PVR protection, a variety not clearly distinguishable from the protected variety is not a discrete one but falls automatically within the scope of the protected variety.

In this context, *clearly distinguishable* only is related to the phenotype of the respective varieties and not to their genotype. CIOPORA strongly supports this method to evaluate distinctness on the basis of a phenotypic comparison.

- sub b) The EDV must be *predominantly derived* from the initial variety or from a variety that is itself predominantly derived from the initial variety.

No general definition of "*predominantly derived*" exists. However, some general statements can be made.

- aa) A variety can only be considered to be predominantly derived from the initial variety, if material from the initial variety or from a variety, which itself is predominantly derived from the initial variety, has been used in the process of developing the EDV.
- bb) Additionally, 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.
- cc) Mutants, GMO and apomicts are not only *predominantly*, but *totally* derived from the initial variety. Such varieties are based solely on the genome of the initial variety and the genomic structure is highly conserved.
- dd) In regard to me-too-varieties it is unclear, in what case a variety, which results from crossing and selecting, is *predominantly* derived from one of its parents. This question has to be answered on the basis of the genome of the varieties in dispute and it is up to the breeders of the specific species to determine a threshold, above which predominant derivation exists in these cases. As long as no such thresholds exist, the parties involved in a dispute have to find solutions on their own or, if they fail to do so, the courts have to decide on the basis of expert opinions.

- sub c) Finally, the EDV must, except for the differences which result from the act of derivation, conform to the initial variety in the expression of the essential characteristics.

- aa) 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 derivation*. Contrary to that, in the PVR law of the European Community (Regulation 2100/94) and some other countries, this contradiction does not exist.
- bb) This contradiction in the UPOV 1991 Act must not lead to a narrow interpretation of the EDV concept, as it would make the whole EDV concept meaningless for asexually reproduced ornamental and fruit varieties. This can be illustrated by taking the example of a

colour-mutant: It clearly does not retain the essential characteristic “colour” of the initial variety and thus, applying the narrow interpretation, could not be considered an EDV, although as a mutant it is *the* typical example of an EDV which has been one of the main reasons for the introduction of the EDV-concept.

- cc) Therefore, a balanced interpretation of the EDV-concept must account also for the new tendencies in the development of new varieties, e.g. certain methods of developing new varieties, applying chemicals and other mutagens, which allow the development of plants which phenotypically differ significantly from the mother plant without altering the genome and its structure significantly. Thus, the balanced interpretation does not *per se* limit the number of phenotypic differences between the initial variety and an EDV thereof.
- dd) As far as asexually reproduced ornamental and fruit varieties are concerned, in general all phenotypic differences between mutants, GMO and apomicts on the one hand and their mother variety on the other hand result from the act of derivation. As a consequence, there exists no limit to the number of phenotypic differences between an initial variety and this type of EDV, because all the differences result from the act of derivation.
- ee) In regard to *me-too*-varieties, a variety which has been created by crossing and selecting, can only be considered to be an EDV if it – in addition to the two requirements mentioned under a) and b) above - retains all essential characteristics of the initial variety and only shows changes in insignificant characteristics.

In this regard, conformity to the essential characteristics shall be measured on the basis of the phenotype. However, out of the list of the botanical characteristics listed in the UPOV-guideline for a species, only such characteristics shall be taken into consideration which are *essential* for the exploitation of the variety (in contrast to the measurement of the DUS examination, in which all botanical characteristics out of the UPOV-guideline are taken into account, without making a differentiation between essential and non-essential characteristics).

As up to now no clear differentiation between essential and non-essential characteristics of asexually reproduced ornamental and fruit species exists, this may be decided on a crop-by-crop basis by the respective breeders. As long as no such differentiation exists, the parties involved in a dispute have to find solutions on their own or, if they fail to do so, the courts have to decide on the basis of expert opinions.

2. Conclusion

As a consequence from the explanations before it can be concluded that in the area of asexually reproduced ornamental and fruit varieties all mutants, GMO and apomicts as well as *me-too-varieties* have to be considered as EDV.

III. The proof of the existence of an EDV

The major challenge of breeders of asexually reproduced ornamental and fruit varieties is to find a practicable solution to prove that a variety is an EDV from another variety.

Usually it is the responsibility of the plaintiff to submit to the court and prove all facts which he bases the claim on. In EDV cases this is particularly difficult with regard to the question whether the supposed EDV is “predominantly derived” from the initial variety.

CIOFORA submits for the two groups of EDV in the area of asexually reproduced ornamental and fruit varieties the following solution:

1. Mutants, GMO and apomicts

In an EDV dispute concerning a mutant, a GMO or an apomict it is very difficult, if not impossible for the plaintiff to prove that the supposed EDV belongs to this group of varieties, as he usually is not able to gain access to internal information of the defendant. On the other side it is rather easy for the defendant to prove that his variety does not belong to this group of varieties but results from crossing and selection.

Therefore, there should be a shift of burden of proof if the plaintiff submits facts that reasonably indicate that the supposed EDV is a mutant, a GMO or an apomict.

- a) CIOPORA is of the opinion that such facts that indicate the existence of mutants, GMO and apomicts in general shall be based on a comparison of the genome of the two varieties in dispute. If the plaintiff on the basis of a reliable DNA-analysis submits to the court and proves a Jaccard Similarity Coefficient between 0.90 and 1.00 between his initial variety and the supposed EDV, he has furnished a *prima facie proof* that the supposed EDV belongs to the group of varieties mentioned before. In this case, the defendant has to prove that his variety is no mutant, GMO or apomict from the initial variety or from a variety that is essentially derived from the initial variety.
- b) However, this threshold does not mean that varieties, which range within the threshold, are automatically EDV. If a variety retains e.g. 93% of the genome of another variety, but has been created by way of crossing and selection, it obviously does not belong to the group of mutants, GMO and apomicts. The threshold in this group only serves for the purpose of shifting the burden of proof, not for establishing whether a variety is an EDV or not.
- c) On the other hand the threshold also does not mean that varieties, which are below it, are excluded from being an EDV. If e.g. a mutant retains only 88% of the genome of the initial variety, it has nevertheless to be considered to be an EDV. However, there is no shift of burden of proof, so that the plaintiff would have to fully prove that the supposed EDV is a mutant of his initial variety.
- d) The threshold of 0.90 has been chosen by CIOPORA because it turns out in the field of asexually reproduced ornamental and fruit varieties that this value is a good general separator between mutants, GMO and apomicts on the one hand and varieties, which result from crossing and selection on the other hand. However, if it turns out that the threshold does not fit to a given species, it is up to the breeders of this species to agree on a different threshold. As long as no such crop-specific thresholds exist, CIOPORA strongly submits to use the general threshold of 0.90 for the shift of burden of proof in EDV cases concerning mutants, GMO and apomicts.
- e) If the defendant uses his breeding records in order to prove that his variety is not a mutant, GMO or apomict of the initial variety one should evaluate this evidence critically. More valuable evidence might include material which the defendant presents from the varieties he claims to be the parents of the supposed EDV. In this case it can be explored by way of a DNA analysis whether these varieties could be the parents of the new variety or not.

2. Me-too-varieties

In an EDV dispute concerning a *me-too-variety* it is very difficult, if not impossible for the plaintiff to prove that material from his initial variety has been used in the process of developing the supposed EDV.

Therefore, CIOPORA suggests: if the plaintiff submits and proves to the court a genetic conformity higher than the threshold above which predominant derivation exists³ and a strong phenotypic conformity between his protected initial variety and the supposed EDV⁴ the defendant has to prove that he has not made use of the initial variety or a variety that is essentially derived from the initial variety.

END OF THE DOCUMENT⁵

³ See chapter II.1. sub b) dd)

⁴ See chapter II.1. sub c) ee)

⁵ In cases of translation the English version does prevail