

“Origin and goal of the EDV principle
in UPOV and its importance in the
use of new breeding technologies”

22 March 2023 – Huib Ghijsen
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Short introduction

- Educated both as lawyer (2001) and agricultural engineer (1971)
- Independent legal counselor since 2009
- Previously, IP manager for Bayer Bioscience 2000-2009
- Chairman Technical Working Party Agricultural Crops 1994-1996
- Technical Expert for the Dutch Board of Plant breeder's Rights 1991-2000
- Breeder at Barenbrug Holland 1971-1991
- Proposed by the International Association of Horticultural Producers (AIPH) as speaker on this seminar, aiming a mutual understanding within UPOV about origin and goal of the EDV principle. Urgent in the use of NBT's and growers do need security about access to new varieties. They need seed on right time, in right quantity of right quality.

The revision of the UPOV 1978 Convention to 1991

- The EDV provision originates from the revision of the UPOV 1978 Convention to the present 1991 Convention.
- One of the important aims of the revision: to improve and to extend the scope of protection.
- The revision started in 1987 with the collection of comments and proposals from the 16 member states, observer states and non-governmental organizations from breeders, biotech companies and patent holders
- It took 4 years with extensive deliberations which have been recorded in the meeting papers accessible on the UPOV website and very valuable to understand the meaning and scope of the EDV provision

The revision of the UPOV 1978 Convention to 1991

The concept of dependency was felt necessary because of:

- much discussion about plagiarism
- (too) small varietal distances, and
- the upcoming biotechnology providing means to add additional characteristics to conventionally bred varieties

(Plant breeders were concerned that a new variety, taking 15 years of hard work and investment could be hijacked by inserting a new gene)

The concept of essential derivation

In the October 1988 CAJ meeting the following text was proposed to define an essentially derived variety:

" If a variety is essentially based upon the material of a single protected variety the owner of the right in the protected variety may demand *equitable remuneration* to be paid in respect of the commercial exploitation of the new variety."

- ✓ It was also established that the crossing of two protected varieties was the classic case for when the breeder's exemption should apply.
- ✓ Although in the case of backcrossing also two varieties are involved, the effect is that a particular characteristic can be transferred into a protected variety. Therefore dependency should also apply to varieties created by backcrossing.

The concept of essential derivation

The selection from the initial variety of a:

- Mutant (natural or induced) same
- soma clonal variant genetic
- variant (off type) structure
- genetic modification as INV

* (repeated) back-crossing → measuring genetic similarity of EDV-INV

The concept of essential derivation

After the 4th meeting with International Organizations, October 1989,
3 text alternatives for the Rights of the owner of the INV were discussed in the 25th
meeting of the CAJ:

If a variety is essentially derived from a protected variety, *the owner of the right* in the protected variety,

[1] may *exercise* his rights on the essentially derived variety

Supported by all delegations

[2] shall be entitled to *equitable remuneration* in respect of the commercial exploitation of the new variety.

Supported by a few delegations only

[3] may *exercise* his rights on the essentially derived variety .

However, where the new variety shows a substantial improvement over the protected variety, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.

Not supported by any of the delegations!

The concept of essential derivation **Element of substantial improvement was rejected**

[3] “may *exercise* his rights on the essentially derived variety”

“However, *where the new variety shows a substantial improvement over the protected variety*, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety”

It was considered that its interpretation gave rise to many difficulties, and the concept of "a substantial improvement" was foreign to the protection of new varieties of plants

Not anyone of the member state delegations in 1989 supported alternative 3!

The concept of essential derivation

Rejection of alternative 3 and support for alternative 1:

- the value of the added trait(s) does not have consequences for the dependency.
- In other words: if the trait(s) added is/are considered to contribute a substantial improvement to the derived variety, that variety will still remain essentially derived from the initial variety, or
- the value of the added trait(s) does/do not make any difference for the dependency.

The concept of essential derivation

- In CAJ October 1989 , there seems to be general agreement on the fact that the following conditions should be met for dependence:
- The derived variety must retain *almost the totality of the genotype* of the mother variety and be *distinguishable* from that variety by a very *limited* number of characteristics (*typically by one*).
- The derived variety must have been obtained using a plant improvement method whose *objective* is the achievement of the requirement above:
mutation, gene transfer, full backcrossing scheme, selection of a variant within a variety, etc.:

Further development of the formulation of essential derivation
Discussion on the Substantive Law in the IOM 5 October 1990 meeting

A variety shall be considered to be essentially derived from another variety ("the initial variety") when

- (i) it is predominantly derived, from the initial variety, (..) through methods which have *the effect of conserving the essential characteristics* that are the expression of the genotype (..) of the initial variety, such as the selection of a natural or induced mutant or transformation by genetic engineering etc.,
- (ii) it is clearly distinguishable from the initial variety in accordance with Article 7(3) and
- (iii) it conforms to the genotype (..) of the initial variety, apart from the differences which result from the method of derivation.

This is the basic text for the Diplomatic Conference where it is changed by 2 amendments and the drafting committee to the present text

(..) = “or combination of genotypes”

Further development of the formulation of essential derivation

How essential is an essential characteristic?

- There is no hierarchy between characteristics in the UPOV system
- The adjectives ‘essential’, ‘relevant’ and ‘important’ before the word ‘characteristic’ are synonyms, inconsistently used in the UPOV papers
- The term ‘essential’ - or ‘essentiels’ in French’ - has already been used in the first UPOV Convention of 1961
(La variété nouvelle doit être stable dans sa caractères essentiels)
- The characteristics must just be suitable to Describe, Define and Distinguish the varieties
- So a color mutant variety in an ornamental crop is an EDV, although the important, essential or relevant color characteristic has been changed!

Securing investment and partnerships

- Text UPOV'91 Convention was discussed in the same period as the EU Directive 98/44/EC for patenting of biotechnological inventions.
- If a party has a very valuable protected variety and another party has a very interesting patented characteristic, cooperation can be secured by the use of cross-licensing. This has also been advocated by UPOV.
- In the case that one party is not willing to cooperate, article 29 of EU CPVR Regulation 2100/94/EC and article 12 of the EU Biotech directive 98/44/EC provide the possibility of a compulsory cross license between breeding - and biotech companies.
- Although the requirements to obtain such compulsory license is complicated, it might support the ultimate cooperation between the parties.

Conclusions

1. The use / modification of an existing valuable genotype has the advantage that the unique and (proven) economically interesting combination of characteristics remain unchanged, from which the EDV will profit;
2. The text of essential derivation with the definition of an essentially derived variety has been extensively and cautiously discussed during 4 years with all interested parties;
3. Although it has been more than 30 years ago the result can still be applied, despite its complex character;
4. The dependency is unrelated with the economic value of the resulting EDV or the added characteristic(s);

Conclusions

5. The term ‘essential characteristics’ can be replaced by ‘relevant’ characteristics, meaning that the change of any characteristic by essential derivation will result in an EDV;
6. The role of IP rights in securing investment and partnerships in breeding is important for further progress and partnerships, while parties can secure their interests and investments in breeding technologies;
7. The breeder that uses targeted breeding techniques to create an EDV can choose upfront the most suitable parent variety. Preferably one for which he is able to reach a settlement with the PVR holder;
8. The principle of cross licenses serves the purpose of facilitating the mutual dependency of the holder of the patented (biotech) trait versus the holder of the original PVR protected variety.

Thank you !
Any questions ?



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