

UPOV Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy

Essentially Derived Varieties: Challenges of the past and opportunities for the future?

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Plant variety right protection

- A system that fits rather nicely with the demands of many breeders:
 - Access to material for further breeding
 - Protection for a specific variety which will be commercialised, hence a fair quid pro quo
 - Relatively low cost
 - Does not have a prohibitively wide scope

EDVs: The Law

- Art. 14(5) [Essentially derived and certain other varieties] **(a) The provisions of paragraphs (1) to (4) shall also apply in relation to**
 - **(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 in accordance with Article 7 from the protected variety and
 - (iii) varieties whose production requires the repeated use of the protected variety.
- (b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when
 - **(i) it is predominantly derived from the initial variety, 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 variety,**
 - **(ii) it is clearly distinguishable from the initial variety 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 variety.**
- (c) 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 engineering.

Criteria

All three criteria must be fulfilled

- There are no clear definitions of:
 - predominantly derived
 - clearly distinguishable
 - Essential characteristics
 - Conforms to the initial variety

Examples of breeding techniques that may result in EDV:

- 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 engineering

How does it work?

- If the normal protection requirements (novelty, distinctness, uniformity and stability) are fulfilled, the breeder of an essentially derived variety is granted a plant variety right and may thus assert all rights resulting from variety protection against any third party.
- However, the marketing of the derived variety requires the authorization of the breeder of the initial variety, from which it was essentially derived. The result is that the "breeder" who desires to commercially exploit an essentially derived variety requires the permission of the owner of the initial variety, and is thus dependent on the initial variety, so as to provide the developer of the initial variety some of the reward for his "efforts" to create the initial variety which was depended on for the creation of the new variety.

Why EDVs?

- Plant breeding is an incremental and iterative process. Plant breeders use and build upon the work of previous plant breeders and rely on existing plant varieties for the initial source of genetic variation.
- Common plant breeding techniques include
 - targeted selection (where plant breeders cross two closely related parents, each with a different desirable characteristic, and then select the progeny that has both of those characteristics) and
 - induced mutations (where the aim is to stimulate an increase in the frequency of mutation events through radiation or chemical induction).
- The incremental and iterative nature of plant breeding is accommodated in the UPOV Convention, with the so-called breeder's exemption allowing protected varieties to remain available to plant breeders developing new plant varieties

Why EDVs?

- However, the breeder's exemption has, in combination with other provisions of the UPOV Convention, caused troubles for plant variety rights holders and concerns for UPOV Members and breeder organisations.
- Leading in to the Diplomatic Conference of 1991, there were concerns among plant breeders and UPOV Members that when combined with the low threshold of distinctness and limited infringement provisions in UPOV 1978, the breeder's exemption allowed, or even encouraged, copying and plagiarism in plant breeding.
- The combination of which resulted in an unfair advantage to second and subsequent plant breeders and weakened plant variety protection.

Why EDVs?

- The existence of a full breeder's exemption is not easy to reconcile with an effective protection for the innovation activity in new plant varieties.
- We understand that access is a paramount principle underlying the PBR system
- However, a basic economic principle underlying virtually all IP rights is that in the absence of any enforceable kind of right, market players will have no incentive to invest in new innovative activity.
- Even though the full breeder's exemption does not take away all enforcement options for the plant variety right holder, it does in effect take away any possibility to enforce his/her right against any third party who wishes to use the protected variety to develop a competing variety on the basis of the protected variety.
- Effective protection is de facto limited to enforcement against third parties who deal with the protected variety as such or with parts thereof

Why EDVs?

- Relatively small changes can have enormous impact on initial variety right holder
 - “In the field of plant species, this question of principle is of considerable economic importance, particularly in the horticultural and floral sphere where any new variety — whether it be a mutation or a creation - can become a best-seller overnight and capture a market share as large as that held” by the original plant variety right holder (EC Pitica/Kyria case)
- That reality calls for some form of effective enforcement of IP rights, absent of which incentives to innovate might vanish

Why EDVs?

- DNA technology allowed for speedier breeding and it made it arguably also easier for subsequent breeders to develop a derived variety
- A relatively small genetic variation could be sufficient to fulfil the requirements for a new PVR, whilst in effect the product would remain much the same
 - E.g., insect resistant orange subject to PVR, second breeder changes the leaf colour, all other features remaining identical. That would likely in itself suffice to obtain PVR protection for the second variety.
- That, together with the absence of a breeder's exemption in patent law made the latter more interesting to innovators and the legitimacy of the UPOV system came under pressure

Why EDVs?

- Patent law has become more “popular” as an IP right with means of effectively enforcing one’s rights
 - No full breeder’s exemption
 - Scope of protection of patents is potentially broader, covering also “equivalents” of the protected subject matter

How to implement EDV?

- That has been a very difficult issue for as long as the EDV concept exists. At least one reason why it has proven to be so difficult to implement is that the entire concept of EDV’s is “a hybrid concept: creating scientific, legal and pragmatic questions.” Another reason is also that the statutory text is notoriously difficult to understand.
- Rather opposite views exist on this issue.
 - Some have argued that the EDV concept should be interpreted very narrowly, i.e., that only those new varieties which have one or very few modifications from the initial variety can fall within the scope of protection of the right holder of the initial variety. In that context, reference is sometimes made to “plagiarism.”
 - Others argue that limiting the EDV protection mechanism to “plagiarism” would be tantamount to introducing no additional scope of protection whatsoever in any meaningful way.

UPOV Explanatory Notes

- 5. The phrase “while retaining the expression of the essential characteristics” requires that the expression of the essential characteristics conforms to and be derived from the initial variety.
- 6. The following might be considered in relation to the notion of “essential characteristics”:
 - (i) essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety;
 - (ii) characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user;
 - (iii) characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics;
 - (iv) essential characteristics may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS);
 - (v) essential characteristics are not restricted to those characteristics that relate only to high performance or value (for instance, disease resistance may be considered as an essential characteristic when the variety has susceptibility to disease);
 - (vi) essential characteristics may be different in different crops/species.

UPOV Explanatory Notes

- “9. The words “except for the differences which result from the act of derivation” do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by Article 14(5)(b)(i) and (iii). **The differences must not be such that the variety fails “to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety”.**
- 10. The examples given in Article 14(5)(c) make clear that the differences which result from the act of derivation **should be one or very few.** However, **if there are only one or few differences that does not necessarily mean that a variety is essentially.”**

How should the EDV system be implemented?

- UPOV Explanatory notes suggest narrow interpretation
- Others refer to “plagiarism” standard

How should the EDV system be implemented?

- My analysis based on intention of the legislature
- Rationale for UPOV 1991 -> strengthening rights for breeders
- Using the Vienna Treaty on the law of treaties as a means of interpreting UPOV 1991
 - -> above rationale
 - -> A proposal to limit the scope of the EDV concept to a “very limited number of modifications” during negotiations was rejected
 - -> plagiarism standard could not have been the intention of the legislature

How should the EDV system be implemented?

- Moreover, plagiarism is in fact not equivalent to only a small number of modifications if one studies the copyright system where it is derived from
 - -> plagiarism standard is incompatible with PBR system
 - -> another reason to conclude that plagiarism cannot be the standard for interpreting the EDV concept

Arctic® apple



- **View 1:** This is an EDV as it - except for the differences which result from the act of derivation - conforms to the initial variety in the expression of the essential characteristics. It is an example in Art 14.5 (c): a natural or induced mutant, [...] or transformation by genetic engineering.
- **View 2:** This is NOT an EDV as a variety cannot be declared an EDV whenever it contains an important characteristic which differentiates it from the initial variety and adds to the performance or value of the variety.

Interpretation of EDV concept: conclusions

- Plagiarism not tenable
- Intention of the legislature suggests broader interpretation, providing a de facto effective means of enforcing PBR against third parties
- Which test to apply then?

Which test to apply?

- Any test must respect the rationale of the UPOV Convention and the intention of the legislature to provide a strong and effective IP right for breeders, whilst at the same time respecting other of the fundamental principles of the system
- Two tests for inspiration:
 - One based on the doctrine of equivalence
 - One test based on a liability regime

Test based on doctrine of equivalence

- Taking inspiration from the doctrine of equivalence test in patent law is an acceptable way forward.
 - First of all, as is the EDV concept, the doctrine of equivalence is also a hybrid concept “creating scientific, legal and pragmatic questions”.
 - Secondly, fundamentally the issue of establishing whether a plant variety is an EDV and establishing whether an allegedly infringing product is equivalent to a patented one, is very much the same if not identical kind of exercise/evaluation.
 - Thirdly, even though the argument has been raised that the EDV concept is special as the EDV needs to be distinct from the initial variety, creating an allegedly unique IP situation, I do not think that this is a situation which is much different from what happens under the doctrine of equivalence, as a patent on the allegedly infringing product does not necessarily take away the fact that it can still infringe an earlier patent.
 - I therefore think that it is an allowable argument to take at least inspiration from the doctrine of equivalence under patent law.

Test based on doctrine of equivalence

- “(ii) In deciding whether a variety is an EDV, one should ordinarily ask three questions:
 - a) Notwithstanding that it is not within the literal meaning of the relevant initial variety, does the derived variety achieve substantially the same result in substantially the same way as the initial variety, i.e. does it retain the essential characteristics of the initial variety?
 - b) If yes, would it be obvious to the person skilled in the art, knowing the initial variety, but knowing that the derived variety achieves substantially the same result as the initial variety with the exception of the derivation, that it does so in substantially the same way as the initial variety by using the essential characteristics of the initial variety?
 - c) If yes, would the skilled person studying the initial variety have concluded that the plant variety right holder for the initial variety nevertheless intended that strict compliance with the literal meaning of the relevant characteristics of the initial variety was an essential requirement of the plant variety right application?
- If the answer to the last question is no, then the derived variety is an EDV.

Test based on liability regime

- Jerome Reichman ->He has suggested a so-called liability system as a replacement for the patent system, which he argued was rather inefficient, as it grants too many patents which are only marginally different from what is already in the state of the art.
- His argument is that the quality of examination is low, leading to too many patents of questionable quality being granted. He refers in this context to "subpatentable innovation".
- Those patents put a burden on society, as patents can be enforced, and patent rights can be exercised, leading to potentially monopolistic pricing, which brings additional costs for society.
- His idea was to replace the system with a type of liability system, where inventors can claim some sort of exclusive right into their inventions, but they could not prevent third parties from using their inventions for further development. Third parties using the inventions for further development would then be liable to compensate the original inventor for the use of the invention.

Test based on liability regime

- I start again from a rather broad definition of what is an EDV, also as this is in line with the intention of the legislature, as set out earlier.
- All varieties which use the essential characteristics of the initial variety would be deemed to be EDVs.
- I also retain the concept that the developer of the initial variety obtains some sort of exclusivity in the new initial variety.
- All the developers of such EDVs would then be under an obligation to pay compensation to the initial variety right holder for the use of the initial variety in the development of their EDVs.

Test based on liability regime

- Such a system would catch multiple birds with one stone.
 - 1) It gives meaning to the EDV concept as laid down in the treaty.
 - 2) The developer of the initial variety receives compensation for the use of his variety.
 - 3) The developer of the initial variety is capable of sharing in the proceeds of the EDV which has been developed on the basis of the initial variety and which EDV will in many cases be in competition with the initial variety. By providing an obligation to give compensation to the initial variety right holder, the loss of profits which typically accompanies the entering into the market of the competing EDV can at least be compensated, introducing an element of fairness into the system.
 - 4) It respects the one of the fundamental principles underlying the PBR system that guarantees access to germplasm for further breeding.

Conclusion

- The rationale of the legislature in developing an EDV concept under the UPOV 1991 Convention was to strengthen the rights of breeders. That brings with it that a very narrow interpretation of the EDV concept is contrary to the intention of the legislature.
- A broader interpretation must be given to the EDV concept, so as to respect the intention of the legislature and provide adequate protection to breeders
- Various tests could be developed. I have provided two as an intellectual exercise, both of which could prove to be rather useful in taking the EDV concept forward and arrive at a UPOV system that is attractive to breeders in protecting their innovations whilst at the same time respecting some of the underlying fundamentals of the PBR system such as guaranteeing access

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- THANK YOU