

Research Article**Essential derivation of Varieties and the imminent challenges to Indian Plant Breeders**

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Abstract

To get the protection for essentially derived variety, the initial variety must be a protected first, because the dependence can only exist in relation to protected variety. While determining whether a variety is EDV or not, it is to be noted that, an EDV can be directly derived from the initial variety or from any variety that itself is predominantly derived from the initial variety. Hence there can be "cascade" of derivations. In determining the cascade of derivation, it should be noted that each EDV shall only be dependent on one, the protected initial variety; a cascade of dependence shall not exist. This principle of dependence has been introduced to better protect the breeder of the initial variety and not those having made just derivations. More recently, based on the general opinion of its members, ISF moved to the definition of only one threshold that would divide the scale of conformity into two parts: below the threshold there would be no presumption of essential derivation, above the threshold there would be presumption of essential derivation and the burden of proof of non predominant derivation would fall on the breeder of the putative essentially derived variety. The threshold will certainly vary from species to species, depending on the existing genetic variability within the species and the established breeding procedures. To eliminate the 'copycat breeding' or 'cosmetic breeding', the concept of 'essential derivation' was included in the revised UPOV convention Act (UPOV, 1991). This paper therefore focuses on the imminent challenges to the breeders and the responsibilities they need to shoulder to respect and promote the IP and plant variety protection in India to usher in an era of incentives and benefit sharing for the plant breeders.

Key words: Essentially derived variety, UPOV, plant variety protection

Introduction

The plant Breeder's Rights (PBRs) provide incentives to breeders to develop superior planting material thereby ushering in seed & feed, Food & fodder and livelihood & economic security through enhanced productivity through provision of improved hybrids and varieties through conventional breeding, Marker assisted breeding or through biotechnological means.

The Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV & FRA) was legislated in lieu of article 27.3(b) of Trade-Related Intellectual Property Rights (TRIPS) agreement under General Agreement on Trade and Tariffs (GATT), World Trade Organization (WTO, 1994). It integrates the rights of breeders', researchers' farmers' and communities, and takes care of the concerns for equitable sharing of benefits. The PPV & FRA provides protection

for all plant varieties, including the "essentially derived varieties" (EDVs). The PPV & FR Act 2001 also allows the registration of traditional varieties or farmers' varieties [Section 14]. Registration of the variety grants PBR on the variety, which allows exclusive legal right to the PBR-holding farmers to produce and market its seed [Section 28]. Farmers are awarded PBRs by the Act on their recognition as more farmers are eligible for registration as farmer's varieties. Hence the farmer is placed on equal footing as that of a breeder.

The Plant Breeders and Researcher's Rights

Main objective of the PPV&FR Act 2001 is to promote the availability of high quality seed and planting material to farmers for accelerated agricultural development. The act tries to achieve this objective by ensuring adequate availability of seeds of registered varieties to farmers at reasonable cost. Access to seed by farmers is important for availing the benefits of scientific crop improvement while allowing exclusive right to the PBR-holder on commercial production and marketing of seeds of the

variety at reasonable prices. The primary purpose of registration of a plant variety under this Act is to establish exclusive commercial right on the variety. Commercial demand arises from the capability of the variety for better agronomic performance.

The cause of benefit sharing arises from a declaration made by the breeder that the pedigree of a new variety has material that belongs to someone or it may have certain traditional varieties or traditional knowledge sourced from certain regions/communities. However, there can be situations where the breeder of a new variety may not disclose the correct identity of parental varieties or knowledge. This lapse may arise either from an honest ignorance on the identity and origin of the parental varieties or a dishonest suppression of parental variety identity. Under such circumstances if such parental varieties belonged to other breeders or other organizations or one or more rural communities, they may be denied the opportunity for benefit share due from the new variety.

The communities concerned also may not have the capability to detect such use of their varieties or traditional knowledge in the breeding of a new variety. Under such situations, any third party who has a reasonable knowledge on the possible identity of the traditional varieties or knowledge used in the breeding of the new variety, is eligible to prefer a claim for compensation on behalf of the concerned local or tribal community [Section 41 (1)]. The third party could be an NGO, an individual, a government or private institution. Such compensation claims are to be submitted to the PPVFR Authority by such third party. The authority on verification of the veracity of the claim shall admit the same and decide on the compensation to be awarded. The awarded compensation will be remitted in the National Gene Fund by the PBR-holder. The National Gene Fund shall disburse the compensation to the party who made the claim. A good understanding of plant varieties and professional skill in plant breeding science will help in detecting many of such eligible cases for compensation.

The legislation provides that for the purpose of research, any person can use such variety for conducting experiment or research as an initial source of variety for the purpose of creating other varieties. For further repeated use of the variety as a parental line, breeder's permission is required.

Important points the breeders need to remember

1. The use of protected germplasm for generating new, improved varieties, without authorization from the breeder who developed the initial variety is permitted under convention act of the International Union for the Protection of New Varieties of Plants (UPOV, 1978)
2. The breeder's exemption is to encourage the continuous breeding progress and to prevent genetic erosion in elite breeding germplasm.
3. A protected variety is freely available to all the breeders as a germplasm resource including the protected varieties as the initial source for the purpose of producing new varieties.
4. As a researcher's Right, any protected variety may be freely used as a source of initial source of variation in breeding programs to develop new varieties.
5. For any further repeated use of the variety as a parental line, original breeder's permission is required
6. The new varieties developed by using the original variety may also be protected and exploited without any obligation on the part of its breeder.
7. But this provision can provoke any breeder to misuse the "breeder's exemption" and deny the credit and benefit sharing opportunity to the original breeder
8. The breeder's exemption may also promote 'copycat breeding' or 'cosmetic breeding'.
9. To eliminate the 'copycat breeding' or 'cosmetic breeding', the concept of 'essential derivation' was included in the revised UPOV convention Act (UPOV, 1991).

What is Essential derivation of varieties and hybrids?

According to the article 14(5) (b) UPOV "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;

(Meaning: An EDV can only have a juridical relevant dependency from one variety, "the initial variety", which is protected. It need not be directly derived from the initial variety. The EDV may also be bred by using one or more other variety or varieties predominantly derived from the initial

variety. The phrase 'the expression of the characteristics that results from a particular genotype or combination of genotypes' means that the distinction must be able to be established on the basis of phenotypic characteristics.)

- ii. It is clearly distinguishable from the initial variety; and

(Meaning: The derived variety must be an independent variety, distinguishable from the initial variety. A distinction at this level may have a very limited genetic basis.)

- 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.”

(Meaning: The derived variety may only differ from the original variety in differences resulting from the act of derivation.)

Thus an Essentially Derived Variety (EDV) can be defined as “A variety, which is distinct and predominantly derived from an initial variety, while retaining all the essential characteristics of that initial variety except the trait that is act of derivation”.

Thus, an application for the protection of EDVs can be done in India under the provisions of Protection of Plant Varieties and Farmers’ Rights Act (2001). The provisions of the act indicate that:

- i. After submission of an application for EDV protection, the Authority will get the variety examined whether the submitted EDV is a variety derived from the initial variety.
- ii. It will be done by conducting appropriate tests by following approved procedures as the authority may approve.
- iii. The breeder of an EDV will also have the same rights as that of the breeder of the original or initial variety.
- iv. The breeder deriving an EDV through various breeding procedures and having made an application for its protection needs to take authorization by the breeder of the initial variety compulsorily.
- v. If the initial variety breeder opposes the application submitted for protection of EDV, as and when it is published in the plant varieties journal, the onus of proving the fact that this EDV is derived from his initial variety is solely of the initial variety breeder.

- vi. The EDV breeder needs to take the consent of the initial variety breeder to commercially exploit the variety.

- vii. In case the EDV breeder denies that his variety is not an EDV and says that is a new variety, then the initial variety breeder can request the PPV&FR Authority or even high court and then the Supreme Court for settling the issue of identification of the varieties concerned as initial or as essentially derived. The onus of proving the fact that this EDV is derived from his initial variety is solely of the initial variety breeder.

- viii. According to the general rule of burden of proof, it is to the owner of the initial variety to prove essential derivation and then claim dependency. However, if the owner of the Initial Variety (IV) can give reasonable evidence of essential derivation (*prima facie* proof), International Seed Federation (ISF) is in favour of the reversal of the burden of proof. For *prima facie* proof, the following elements should be sufficient: strong phenotypic similarity; only small differences in some simply inherited characteristics; strong genetic similarity. If the owner of the IV has fulfilled one of the above requirements, then the second breeder would have to prove that there is no predominant derivation, or that he had not used the IV, or a variety essentially derived from that IV. As per the PPV & FR Act of India, the burden of proof lies with the developer of the IV. Also, the Act states that the breeder of the IV and the breeder of an EDV will have the same rights, which is a debatable statement.

- ix. The PPV&FR Act 2001 in India has empowered the Registrar of PPPV&FR Authority, New Delhi to legally decide about the EDV disputes.

Major criteria, tools and Protocols for determining EDVs

We should know that still there are debates going on the issue of determining the EDVs. According to the International Association of Plant Breeders (Assinsele, 1994), the distinctness and essential derivation are two different and distinct concepts (Assinsele, 1999). Hence we need to know and understand the issues being debated and standardized internationally to aid the process of EDV recognition. In India we still don't have the approved standards and procedures to determine the EDV status. Hence, in the absence of approved standards and procedures, any EDV can get registered as new variety, thus denying the credit to the original breeder. However, till the designated protocols and laboratories are in place, we need to understand the following intricacies involved in

arriving at an EDV to differentiate the same from original variety:

- i. At the outset, as per (Assinset, 1999), we should determine the genetic conformity between initial variety and the putative EDV
- ii. The first step therefore is to determine the Distinctness, Uniformity and Stability (DUS) of the EDV.
- iii. The phrase 'expression of characteristics that result from the genotypes or combination of genotypes' makes it clear that in this respect only expressed, genetically heritable, characteristics, should be taken into account as per article 14(5) (b) of UPOV.
- iv. The most important information required is genotypic information and genetic distance (GD) to distinguish between essentially derived and independent variety.
- v. The genetic distance (GD) is nothing but difference between two entities (i.e., plant varieties) that can be described by allelic variation (Nei, 1973). This should be done accurately and should be reproducible
- vi. To achieve the same, all the breeders should maintain the detailed pedigree information across years and seasons, which can be produced in case of litigations. The courts or the PPV&FR authority may call for verification of pedigree to determine the extent of predominant derivation. If detailed and accurate pedigree records not submitted for verification, then the breeder's claim for his variety and its protection can be disqualified.
- vii. The distinctness is assessed based on difference in the expression of at least one characteristic
- viii. The essential derivation is determined based on conformity to almost all the genome and on most of the essential characteristics resulting from that genome
- ix. The word distinctness determines the gambit of protection and the word essential derivation determines the scope of protection.
- x. Various standardized tools and protocols need to be used to determine distinctness and essential derivation, through morphological and physiological characteristics, including DNA analysis.
- xi. All the breeding efforts of the breeders also need to maintain Heterosis data obtained from crossing inbred lines. This can also serve as reliable information for estimating genetic conformity, since yield and heterosis are governed by genes spread across the genome. For better validity cross-, self-, and sib-pollinations should be tested for at least two years in replicated environments.
- xii. It is also essential to maintain the data on agronomic performance in hybrid, as it can also be used for identification of inbreds for distinctness or for dependency (Troyer et al., 2002).
- xiii. It is the need of the hour that we should standardize most suitable molecular tools to distinguish an EDV from an initial variety through use of standardized markers to trace chromosomal segments from the parent to their progeny and empirical evaluation of genetic relatedness. Molecular markers have proved to be important tools for identification of EDVs in crops like maize (Heckenberger *et al.*, 2002, 2003, Staub *et al.*, 1993, 1996).
- xiv. Molecular assessment of genetic similarity or distance is quantitative, and its interpretation is unaffected by environment when the observed polymorphisms have a genetic basis and experimental conditions are rigorously controlled. Nevertheless, quantification of genetic difference based on any molecular descriptor is subject to sampling or technical error. Sampling error can be minimized by scoring a large number of individuals and by replication.
- xv. The AFLPs, SSRs and RFLPs (Powell et al., 1996) and more recently, SNPs (Single Nucleotide Polymorphisms) have been successfully used for identification of EDVs in various crops.
- xvi. In crop species where the genetically codominant SSR or SNP markers have not been determined in sufficient numbers, it would be preferable to use AFLP markers; such an application of AFLP markers in roses led to clear determination of EDVs (Vosman et al., 2004).
- xvii. Protocols for determination of EDV could vary significantly from crop to crop and from generation to generation (Wang and Berman do 2000). How many markers and which markers should be used for the determination of an EDV are important questions that have to be answered on a crop-by-crop basis. In a project initiated recently under the PPV&FRA (Govt. of India), the Division of Genetics at the Indian Agricultural Research Institute (IARI), New Delhi, is presently developing procedures and protocols for determining the EDVs in rice, wheat, maize and pearl millet.
- xviii. There are various statistical parameters required to be taken into consideration for the estimation of genetic distance (Heckenberger et al., 2005). An important statistical parameter in determining an EDV is the probability of making Type I (varieties

are the same when in fact they are not) or Type II (varieties are different when in fact they are the same) errors. Moreover, statistical estimates of error must satisfy the type of precision that the judicial system may demand (i.e., beyond a reasonable doubt). Of particular importance among the statistical tools in relation to genetic diversity analysis are the confidence probability tests. Resampling techniques such as 'bootstrap' and 'jackknife' are important, particularly in relation to application of molecular marker data for analysis of genetic distance, and for finding the smallest set of markers that can provide an accurate assessment of genetic relationships among a set of genotypes (Mohammadi and Prasanna, 2003).

- xix. Various methods through which EDVs can be derived are (i) mutation (either natural or induced) (Debener et al., 2000, Vosman et al., 2004). (ii) somacolonial variation; (iii) conventional backcross breeding; (iv) molecular marker-assisted selection (MAS) during backcrossing; and (v) genetic transformation (transgenic technology)

International seed Federation's initiatives to differentiate Identification of EDVs

The International seed federation (ISF) has taken initiatives since 2001 with the use of molecular markers to assess genetic distances and for determination of genetic distance thresholds for EDVs. At present, both SSRs and SNPs are the most commonly used marker systems for EDV determination in maize (Heckenberger et al., 2002, 2005).

The inference drawn from the studies on Maize was that, based on Roger's distance (82% or higher) one can differentiate putative EDV from initial variety by using SSR markers. The ISF Maize and Sorghum Section recommends considering a second threshold of 90% using all the markers as a strong indication of predominant derivation. A code of conduct has been adopted by the French maize seed industry members as follows: "Above the threshold of 90% the variety should be considered as an EDV without further discussion; between 82 and 90% there is possible essential derivation and the parties have to negotiate; below 82% there is no essential derivation.

For lettuce, the inter-varietal genetic diversity is based on the use of AFLP (Amplified Fragment Length Polymorphism) markers. Based on the results of the study, the ISF working group decided to propose a threshold of 0.96 Jaccard. If the Jaccard

coefficient is higher than 0.96, the breeders will try to reach an amicable settlement. If this settlement cannot be reached, the breeder of the Initial variety may ask for the arbitration, according to the ISF rules for disputes settlement and the mediators/conciliators or arbitrators may ask for the reversal of the burden of proof. The breeders of the putative EDV will have to provide the information that is relevant to determining the status of his variety. They may be asked to open their breeding records to an independent neutral expert.

More recently, based on the general opinion of its members, ISF (2005) has moved to the definition of only one threshold that would divide the scale of conformity into two parts: below the threshold there would be no presumption of essential derivation, above the threshold there would be presumption of essential derivation and the burden of proof of non predominant derivation would fall on the breeder of the putative essentially derived variety. The threshold will certainly vary from species to species, depending on the existing genetic variability within the species and the established breeding procedures.

Some Contentious Issues related to EDVs: Cascade of derivation and Principle of dependence

We need to remember the fact that to get the protection for essentially derived variety, the initial variety must be protected first because the dependence can only exist in relation to protected variety.

While determining whether a variety is EDV or not, it is to be noted that, an EDV can be directly derived from the initial variety or from any variety that itself is predominantly derived from the initial variety. Hence there can be "cascade" of derivations. In determining the cascade of derivation, it should be noted that each EDV shall only be dependent on one, the protected initial variety; a cascade of dependence shall not exist. This principle of dependence has been introduced to better protect the breeder of the initial variety and not those having made just derivations.

Conclusions

a. Points of reference for breeders

- Breeders should ascertain their legal access and freedom to use all parent materials employed in their breeding programs, before starting the program.
- Breeders should pay more attention to the consequences of their breeding work when working

with protected varieties within the "breeder's exemption".

- Breeders will need to employ the tools necessary for assessing such profiles in their research programs. Such tools would not only be useful for protection of intellectual property, but also in improving breeding efficiency.

b. Conformity threshold for EDVs

- The conformity thresholds for essential derivation will come to exist in future. To know their freedom to operate in relation to such conformity thresholds, breeders will need a good knowledge of phenotypic, molecular and physiological profiles of their genetic material and their experimental varieties. It is obvious they need to document breeding histories and legally access the germplasm they are dealing with right from the beginning.

c. Registration of plant varieties as EDVs

- Regarding the registration of a plant variety, the applicant should properly draft his / her claims in such a manner that no loopholes are left. Authority has provided a list of essential characteristics and also there is a provision for adding any special characters. Therefore, it is for the applicant to ensure accurate filing of the application.
- Denomination has to be carefully chosen for both new varieties and transgenics. Applicant should ensure that denomination of transgenic variety is the same as the one used for seeking approval of GEAC.
- A PVP application can be strengthened when molecular markers are used in conjunction with stable, well-documented phenotypic descriptors that describe the distinctiveness of a variety.

d. Molecular tools to aid EDVs

- In cases of alleged infringement, DNA fingerprinting can provide estimates of genetic distance for determining varietal distinctness or essential derivation. However, the protocols, especially the number of markers to be used and interpretation have to be perfected to the satisfaction of all stake holders.

e. Licensing, commercialization and public-private partnership

- Speedup the process of licensing and commercialization to stop the leakage of genetic material, especially for the public institutions it should be a priority.
- The public-private partnership in research, evaluation and commercialization will aid better understanding to evolve custom-made genetic stocks

and finished trait specific products. This will enhance understanding and minimize litigations, and increase overall efficiency of breeding (Vilas *et al.*, 2009 a & b).

- We need to strive to establish mechanisms to exchange ideas by providing appropriate platforms to help set goals for both research organizations and the seed industry. Seed associations and public sector organizations need to facilitate this process.

f. Preparedness to protect EDVs

- The trainings on frontier areas of plant variety protection help to clarify the confusions both in scientific and legal terms.
- Seed Associations in India in collaboration with ICAR and SAUs should lead the way to establish the standards for differentiating EDVs through molecular marker assisted tools as in Europe, USA and Australia.
- An interface between public and private sector should be established to have special purpose referral labs to establish standards for EDVs and also to refer the litigation oriented testing in these independent labs to aid the legal process.
- A separate and independent body to conduct DUS testing other than SAUs and ICAR can also be thought of, which may be run on fee-based models.
- Special interest groups to work on areas like EDVs, researchable issues, licensing and public-private partnership be formed. Regular meetings to aid the process may be held to interface with seed industry and the public agencies.
- There is a need for advanced laboratories for screening of varieties developed through biotechnological research to establish their distinctiveness and also establish the synergy between IP protection and bio-safety regulations.

g. Capacity building

- Public research organizations should set higher standards in plant breeding research, research outcomes and also commercialization. Funding and empowerment to speed such issues efficiently and quickly should not be a constraint.
- Capacity building in the frontier areas should be pursued by ICAR institutions, SAUs and the Indian Plant Breeder's association to strengthen private and public sector cooperation and collaboration through such learning workshops and trainings.



Suggested Readings

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Cascade of derivation and Principle of dependence				
Situation	Detail	Condition	Application of dependency	Permission
I	$A \rightarrow A^+ \rightarrow A^{++} \rightarrow A^{+++}$	<ul style="list-style-type: none"> • A protected • $A^+A^{++}A^{+++}$, EDVs of A with additional features 	$A^+A^{++}A^{+++}$ dependent on A with conformity of predominance	Development of $A^+A^{++}A^{+++}$ would need
II	$B \rightarrow B^+ \rightarrow B^{++} \rightarrow B^{+++}$	<ul style="list-style-type: none"> • B is not protected • $B^+B^{++}B^{+++}$, EDVs of B with additional features 	$B^+B^{++}B^{+++}$ dependent on B with conformity of predominance	Since B is not protected EDV developer need no permission
III	$C \rightarrow C^+ \rightarrow C^{++} \rightarrow C^{+++}$	<ul style="list-style-type: none"> • C protected since 2000 • $C^+C^{++}C^{+++}$, EDVs of C with additional features 	$C^+C^{++}C^{+++}$ dependent on C with conformity of predominance	Since C is protected from 2000, developer of EDV need permission and share benefit for a period of protection of C
IV	$D \rightarrow D^+ \rightarrow D^{++} \rightarrow D^{+++}$	<ul style="list-style-type: none"> • D protected • D^+ is EDV • $D^{++}D^{+++}$ are EDV, do not have predominance trait of D 	<ul style="list-style-type: none"> • D^+ is dependent on D with conformity of predominance • D^{++} and D^{+++} do not have conformity of predominance to D • D^{++} and D^{+++} have conformity of predominance to D^{++} or D^{+++} but cannot be dependent on D^{++} or D^{+++} since both are EDV 	<ul style="list-style-type: none"> • D^+ developer need permission for use of IV D • D^{++} and D^{+++} developer need permission from either D^+ or D^{++} as they are EDV's
V	$E \rightarrow E^+ \rightarrow F \rightarrow F^+$	<ul style="list-style-type: none"> • E protected • E^+ is EDV of E • F through EDV of E^+ but new • F^+ is EDV of F 	<ul style="list-style-type: none"> • E^+ is dependent on E with conformity of predominance • F now goes beyond EDV, because new • F^+ EDV of F with conformity of predominance 	<ul style="list-style-type: none"> • Development of E^+ is need permission from E developer • Developer of F do not need permission from E developer as it is new variety • Developer of F^+ need permission from developer of F
VI	$G = H$ (similar to G)	<ul style="list-style-type: none"> • G is protected • H is similar to G, but do not appear in parentage 	<ul style="list-style-type: none"> • H is not dependent on G 	H's owner do not need permission from G

IV= Initial variety, EDV=essentially derived variety, +, ++, +++ different levels of EDV
 Adopted from: Hunter RB (1999). Essentially derived and dependency, some examples, Intellectual Property Committee, CSTA, Vancouver BC