

Essentially Derived Varieties: A Workable Compromise Against Free Riding Breeders?

Charles Lawson

Australian Centre for Intellectual Property in Agriculture

Griffith Law School

Griffith University

Gold Coast Queensland 4222

AUSTRALIA

T – +61 (07) 5552 7249

E – c.lawson@griffith.edu.au

Essentially Derived Varieties: A Workable Compromise Against Free Riding Breeders?

1. Introduction

The *International Convention for the Protection of New Varieties of Plants* (UPOV Convention) was concluded in Paris in 1961 and followed with revisions in 1972, 1978 and 1991. These agreements establish an intellectual property scheme for granting plant breeder's rights. The 1961, 1978 and 1991 UPOV Conventions protected plant varieties that are new, distinct, uniform and stable compared to other varieties (1961 UPOV, Art 6(1)(a); 1978 UPOV, Art 6(1); 1991 UPOV, Art 5(1)), and a protected plant variety can be used for breeding other varieties (1961 UPOV, Art 5(3); 1978 UPOV, Art 5(3); 1991 UPOV, Art 15(1)(iii)). This means that a protected plant variety could be used to develop a new variety that is itself eligible for protection with only a very, very minor difference from the initial variety, including a cosmetic difference. The problem here was that with these minor advances gaining a breeder's right the breeder unfairly gets the commercial benefits from all the previous breeding efforts. To address this, the 1991 UPOV introduced the concept of Essentially Derived Varieties ("EDVs") expanding the scope of a breeder's right to include a variety that was selected on the basis of a very minor difference from an existing protected variety. The relevant 1991 UPOV text provides, in part:

- (5) [Essentially derived and certain other varieties]
 - (a) The provisions of paragraph (1) to paragraph (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 ...
 - (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 (Art 14(5)).

The effect of finding that a variety is an EDV is to extend the scope of the initial protected variety's breeder's right to the EDV (1991 UPOV, Art 14(5)(a)), subject to the initial protected variety not itself being an EDV (1991 UPOV, Art 14(5)(a)(i)). Where the initial variety is protected by a breeder's right this means: (i) the acts with the EDV (and its harvested materials and certain products) of production, reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, and stocking for any of these purposes, and so on, requires the authorization of the initial protected variety's breeder (for the term of the initial breeder's right) (1991 UPOV, Art 14(1)(a)); and, (ii) where the EDV is also protected then these acts of production, reproduction, and so on, require the authorization of both the initial protected variety's breeder and the EDV breeder during the term of protection (1991 UPOV, Art 14(1)(a)).

This chapter examines the likely interpretation of the 1991 UPOV EDV provisions highlighting the thresholds of "predominantly derived", "essential characteristics", "clearly distinguishable" and "conforms to the initial variety", and then an analyses of some of the cases addressing EDVs. The chapter concludes that while many of the legal issues about EDV remain unresolved, the practical effect of the EDV provisions has been successful in limiting minor advances gaining the full benefits of a breeder's right free riding on the previous breeding efforts.

2. PLACE OF EVDs IN UPOV 1991

A breeder's right is a right of exclusivity for certain acts following an assessment granting a breeder's right according to domestic laws consistent with the UPOV Convention. The breeder's right balances short term exclusivity (an exemption from certain kinds of competition in the market) against free and open access to new plant varieties. This term of exclusivity works as an incentive to promote more breeding. Within the scheme this balance between open access and exclusivity with various limits on exclusivity, exemption, exclusions, and exhaustion (1991 UPOV, Art 16)).

Within the 1991 UPOV scheme for a breeder's right the EDV provisions are included within the grouping of provisions dealing with the rights of the breeder (1991 UPOV, chapter V, Arts 14-19). Article 14 sets out the scope of the breeder's right, Article 15 provides for some exceptions, Article 16 deals with exhaustion, and Articles 17, 18 and 19 deal with restrictions, co-application of breeder's rights with other laws and the duration of the breeder's right respectively. Notably Article 14 sets out the exclusive rights that are conferred by a breeder's right, subject to exceptions (Article 15) and exhaustion (Article 16). A key feature of the breeder's right, and a key difference from other similar schemes like patenting, is that the breeder's right does not limit acts done for the purpose of breeding other varieties (Article 15(1)(iii)). This breeder's exemption is intended to promote the development of new varieties using existing varieties, and reflects a long practice among plant breeders of improving existing varieties – "by standing on the shoulders of giants" (Turnbull, p. 416).

These breeder's exclusive rights are then extended to three categories of varieties: EDVs (Article 14(5)(a)(i)), varieties that are not clearly distinguishable on the basis of "distinctness" (Article 14(5)(a)(ii)), and varieties whose production requires the repeated use of the protected variety (Article 14(5)(a)(iii)). While this listing uses the conjunctive "and" rather than the disjunctive "or", the preferable interpretation is probably that the exclusive rights that are conferred by a breeder's right (Articles 14(1)-(4)) extend to varieties in each grouping. In other words, a variety satisfying only the EDV threshold (Article 14(5)(a)(i)) does not also need to satisfy the other thresholds (Articles 14(5)(a)(ii) and (iii)) to gain the extended breeder's right through EDVs. The remaining parts of this chapter are premised on the thresholds of EDV (Article 14(5)(a)(i)) alone being sufficient to gain the extended breeder's right through EDVs.

3. SCOPE OF ARTICLE 14(5)(a)(i)

In interpreting Article 14(5)(a)(i) the following elements of the EDV scheme are apparent:

- (i) The protected variety is not itself an EDV (Article 14(5)(a)(i)) – This is the threshold requirement that the variety that is alleged to be an EDV is not itself derived from an EDV. The extended scope of the breeder's right for an EDV is only protected against the initial variety that is protected.

- (ii) The EDV is predominantly derived from the initial variety (Article 14(5)(b)(i)) – This means that an EDV must be “predominantly derived” from one variety, and be a direct descendant of the initial variety.
- (iii) The EDV retains the expression of the essential characteristics (Article 14(5)(b)(i)) – The “essential characteristics” that the EDV must express are the heritable (genotype) characteristics from the initial variety, albeit these characteristics are assessed as expressed characteristics (phenotype).
- (iv) The EDV must result from the genotype or combination of genotypes (Articles 14(5)(b)(i) and (iii)) – The relevant characteristics are heritable characteristics (ie. genotype) that are expressed (ie phenotype) only and do not include characteristics that are only a response to the environment even though these characteristics might be assessed according to their expression (ie. phenotype).
- (v) The EDV is itself clearly distinguishable (Article 14(5)(b)(ii)) – The EDV needs to be “clearly distinguishable” by whatever means (genotypic or environmental) from the initial variety.
- (vi) The act of derivation are the only differences (Article 14(5)(b)(iii)) – This reaffirms that the differences that result from the act of derivation should only be minor – perhaps “one or very few” (see IOM/6/2 1992, [12]).

The practical effect of this scheme is that the process of establishing an EDV requires the following inquiries:

- (i) That the “initial variety” from which the putative EDV was derived must already satisfy the requirements for a breeder’s right (with a new, distinct, uniform and stable character compared to other common varieties). Without a protected “initial variety” there are no breeder’s rights to protect by a finding of EDV.
- (ii) That the putative EDV must already satisfy the requirements for a breeder’s right (with a new, distinct, uniform and stable character compared to other common varieties). As essential derivation is concerned only with varieties that are clearly distinguishable by whatever means from an initial variety, then the putative EDV will almost certainly be protectable with a breeder’s right independently from the “initial variety”.

- (iii) That the three cumulative criteria for determining EDV are satisfied: being predominantly derived from the initial variety, or a variety that was predominantly derived from the initial variety, while retaining the expression of the essential characteristics; being clearly distinguishable; and, conforming to the expressed essential characteristics of the initial variety (noting the apparent conflict between (i) and (iii)).

In assessing the putative EDV there must be a comparison between the “initial variety” against the putative EDV and a determination of how the “initial variety” and the putative EDV differ. This involves a quantitative comparison of differences (e.g. morphological, genetic, biochemical, and so on, and including commercial, economic and industrial differences) and a qualitative assessment of whether the differences are enough to confound a finding of EDV (or not enough so finding essential derivation). Article 14(5)(c) provides examples of the ways an EDV might be obtained. Notably, however, the term “may” means that a variety obtained these ways are not necessarily EDVs, and that EDVs can be obtained in other ways.

There are key terms in Article 14(5)(b) that have not been defined that are central to understanding the relevant thresholds: “predominantly derived”; “essential characteristics”; “clearly distinguishable”; and “conforms to the initial variety”. These are considered in turn.

“Predominantly derived”

In Article 14(5)(b)(i) the threshold of “predominantly derived” is assessed against either the “initial variety” or a variety that is “predominantly derived” from the “initial variety”. What constitutes “predominantly derived” remains uncertain, although there are indicators for how these terms have been interpreted. The document prepared for the Fourth Meeting with International Organisations in 1989 setting out an explanation of the proposed EDV text stated: “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)” (CAJ-AG/13/8/2 2013, Annex, [3]).

The Basic Proposal presented to the 1991 Diplomatic Conference stated: “it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, particularly through methods which have the effect of conserving the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety, such as the selection of a natural or induced mutant of the somaclonal variant, the selection of a variant, backcrossings or transformation by genetic engineering” (CAJ-AG/13/8/2 2013, Annex, [5]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “that a variety should only be essentially derived from another variety when it retained virtually the whole genotype of the other variety” and a “derived variety could not in practice retain the expression of the essential characteristics of the variety from which it is derived unless it is almost entirely derived from that variety” (IOM/6/2 1992, [8]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “Article 14(5)(b) lays down those conditions that must be satisfied in order that a later variety shall be deemed to be essentially derived from another variety (‘the initial variety’) ... The first such condition (established in Article 14(5)(b)(i)) requires that the later variety be derived from the initial variety which in turn requires that genetic materials of the initial variety have been used in the creation of the later variety. The first condition is accordingly concerned with the genetic origin of the later variety. The third such condition (established in Article 14(5)(b)(iii)) requires that the later variety conforms to (‘is made similar to’) the initial variety in the expression of the inherited essential characteristics of the initial variety apart from the differences which result from the act of derivation. The third condition is accordingly concerned with the degree of similarity of the later variety to the initial variety. Whilst the first condition also makes reference to the degree of similarity, the primary function of the first condition is to establish a requirement relating to the genetic origin of the variety” (IOM/6/2 1992, [13]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “It [International Association of Plant Breeders (ASSINSEL)] also went along with the interpretation that the words ‘predominantly derived from the initial variety’ meant that

derivation could only exist from one variety. However, it had discussed a case ... in which a variety A was crossed with a variety B and the progeny was selected in such a way that the new variety came very close to the genome of variety B. It was ASSINSEL's view that such a case was to be dealt with rather like the case of a backcross and could indeed be covered by the phrase in question. ASSINSEL felt, however, that such cases should be examined with great prudence and that the question of the threshold value had to play a decisive part" (IOM/6/5 1992, [19] extracted in CAJ-AG/11/6/3 2011, Annex II).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: "[Association of Plant Breeders of the European Economic Community (COMASSO)]'s view [is] that the interpretation of the [terms 'predominantly derived from the initial variety'] was correct and that indeed only one variety could be the initial variety" (IOM/6/5 1992, [19] extracted in CAJ-AG/11/6/3 2011, Annex II).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: "The decisive fact was whether the new variety essentially contained the genome of one of the parent varieties. The method of breeding was not laid down at any point" (IOM/6/5 1992, [19] extracted in CAJ-AG/11/6/3 2011, Annex II).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 and in the UPOV Council *Explanatory Notes* in 2017 states: "The requirement of predominant derivation from an initial variety means that a variety can only be essentially derived from one variety. The intention is that a variety should only be essentially derived from another variety when it retains virtually the whole genotype of the other variety. A derived variety could not, in practice, retain the expression of the essential characteristics of the variety from which it is derived unless it is almost entirely derived from that initial variety" (UPOV/EXN/EDV/2 Draft 5 2014, [4]; UPOV/EXN/EDV/2 2017, [4]).

The salient point of interpretation is that "predominantly derived" refers to the origin of the putative EDV and only that it must be derived from the "initial variety". In contrast, a variety expressing the "essential characteristics" and bred from a variety other than the "initial variety" cannot be an EDV. This interpretation is also preferable as it makes sense of the

apparent conflict between Article 14(5)(b)(i) and Article 14(5)(b)(iii) (addressed further below).

“Essential characteristics”

In Articles 14(5)(b)(i) and (iii) the threshold of “essential characteristics” is assessed against the “initial variety”. What constitutes “essential characteristics” remains uncertain, although there are indications for how these terms might be interpreted. The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “The essential characteristics are those which are indispensable or fundamental to the variety. ‘Characteristic’ would seem to embrace all features of a variety including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics. It is suggested that the result of a biochemical test conducted on a variety, for instance, a screening test using a genetic probe, is a characteristic of the variety. [The terms in Article 14(5)(b)(i)] ‘while retaining’ requires that the expression of the essential characteristics be derived from the initial variety” (IOM/6/2 1992, [9]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “A judgement on the question of the degree of similarity must be reached on the basis of the essential characteristics which result from the genotype. ‘Essential’ has the meanings ‘fundamental’ or ‘indispensable’. The language finally adopted in Article 14(5)(iii) replaced Article 14(2)(b)(iii) of the Basic Proposal considered by the Diplomatic Conference. Article 14(2)(b)(iii) of the Basic Proposal provided that the essentially derived variety must ‘conform to the genotype or combination of genotypes of the initial variety ...’ This language was initially replaced by the adoption by the Conference of the proposal of Japan contained in document DC/91/66 which proposed that Article 12(2)(iii) of the Basic Proposal be reworded to read: ‘(iii) the characteristics that are the expression of its genotype or its combination of genotypes conform to those of the initial variety apart from the differences which result from the method of derivation.’ It is suggested that Article 14(2)(b)(iii) of the Basic Proposal and the Japanese proposal which replaced it called for the degree of similarity between varieties to be assessed on the basis of the characteristics of the variety taken as a whole and not on the basis of individual characteristics taken in isolation. The language of the Japanese proposal was subsequently amended by the Drafting Committee but it is suggested that no

change in substance was intended. It is suggested that it should not be possible to conclude that a derived variety does not attain the necessary degree of similarity simple because it does not express one single characteristics (perhaps very simply inherited) taken in isolation” (IOM/6/2 1992, [19]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “Theoretically, if variety A is crossed with variety B and variety X is selected from the resulting progeny, if variety X derives less than half of its essential heritable characteristics (ie. of its genotype) from A and more than half from B, it will be essentially derived from B since apart from the characteristics derived from A, it conforms to the expression of the essential characteristics of B. This is clearly not the intended interpretation. A later variety cannot fulfil the conditions of Article 14(5)(b)(i) unless it is predominantly derived from the initial variety while retaining, without qualification in Article 14(5)(b)(i), the expression of the essential heritable characteristics of the initial variety” (IOM/6/2 1992, [21]).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 states: “The following might be considered in relation to the notion of “essential characteristics”: (i) characteristics that are indispensable or fundamental; (ii) 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; (iii) characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user; (iv) characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics, (v) essential characteristics may or may not be characteristics used for the examination of distinctness, uniformity and stability (DUS); (vi) 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); (vii) essential characteristics may be different in different crops/species” (UPOV/EXN/EDV/2 Draft 5 2014, [6]).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 states: “The following might provide an illustration of non-essential characteristics: Colour of anthers in a wheat variety; Colour of flower in an apple variety” (UPOV/EXN/EDV/2 Draft 5 2014, [7]).

The UPOV Council *Explanatory Notes* in 2017 states: “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/EXN/EDV/2 2017, [6]; see also UPOV/EXN/EDV/2 Draft 5 2014, [4]).

The salient point of interpretation is that “essential characteristics”, in the context of Articles 14(5)(b)(i) and (iii), refers to any feature of a variety that is “indispensable” or “fundamental” to the “initial variety”. Notably, the “essential characteristics” in the context of Articles 14(5)(b)(i) and (iii) are morphological, physiological, biochemical, genetic, and so on, characters, the term has a broader meaning, *and* commercial, economic and industrial characteristics.

“Clearly distinguishable”

In Article 14(5)(b)(ii) the threshold of “clearly distinguishable” is assessed against the “initial variety”. What constitutes “clearly distinguishable” remains uncertain, although there are indicators for how these terms might be interpreted. The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “These words [‘it is clearly

distinguishable for the initial variety’] establish that essential derivation is concerned only with varieties that are clearly distinguishable from an initial variety and which are accordingly protectable independently from the initial variety” (IOM/6/2 1992, [11]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “Article 14(5)(b) lays down those conditions that must be satisfied in order that a later variety shall be deemed to be essentially derived from another variety (‘the initial variety’). The second of those conditions (established in Article 14(5)(b)(ii)) requires only that the later variety be clearly distinguishable from the initial variety and requires no further comment” (IOM/6/2 1992, [13]).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 and the UPOV Council *Explanatory Notes* in 2017 states: “The phrase ‘it is clearly distinguishable from the initial variety’ establishes that essential derivation is concerned only with varieties that are clearly distinguishable, in accordance with Article 7, from the initial [protected] variety and which are accordingly protectable independently from the initial [protected] variety. Article 14(5)(a)(ii) would apply if the variety is ‘not clearly distinguishable in accordance with Article 7 from the protected variety’” (UPOV/EXN/EDV/2 2017, [7]; UPOV/EXN/EDV/2 Draft 5 2014, [8]).

The salient point of interpretation is that “clearly distinguishable”, in the context of Article 14(5)(b)(ii), requires that the putative EDV be independently protectable.

“Conforms to the initial variety”

In Article 14(5)(b)(iii) the threshold of “conforms to the initial variety” is assessed against the “initial variety”. What constitutes “conforms to the initial variety” remains uncertain, although there are indicators for how these terms might be interpreted. The document prepared for the Fourth Meeting with International Organisations in 1989 setting out an explanation of the proposed EDV text stated: “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)” (extracted in CAJ-AG/13/8/2 2013, Annex, [3]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “The words [in Article 14(5)(b)(iii)] ‘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 the words of [Article 14(5)(b)(i)]. 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.’ A comparison between subparagraphs (i) and (iii) of Article 14(5)(b) is somehow problematic in that (i) would seem to require the whole of the expression of the essential characteristics that result from the genotype of the initial variety while (iii) requires only that the derived variety conforms to the initial variety except for differences resulting from the act of derivation ... The examples of essential derivation given in Article 14(5) (c) make clear that the differences which result from the act of derivation should be one or very few” (IOM/6/2 1992, [12]).

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “Article 14(5)(b) lays down those conditions that must be satisfied in order that a later variety shall be deemed to be essentially derived from another variety (‘the initial variety’) ... The third such condition (established in Article 14(5)(b)(iii)) requires that the later variety conforms to (‘is made similar to’) the initial variety in the expression of the inherited essential characteristics of the initial variety apart from the differences which result from the act of derivation. The third condition is accordingly concerned with the degree of similarity of the later variety to the initial variety” (IOM/6/2 1992, [13]).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 and the UPOV Council *Explanatory Notes* in 2017 states: “A judgment on the question on the degree of conformity must be reached on the basis of the essential characteristics which result from the genotype of the initial variety” (UPOV/EXN/EDV/2 2017, [8]; UPOV/EXN/EDV/2 Draft 5 2014, [9]).

The document prepared (for ongoing negotiation) for the Administrative and Legal Committee Advisory Group in 2014 and the UPOV Council *Explanatory Notes* in 2017 states:

“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 [Articles 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’ ... 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 necessary mean that a variety is essentially derived. The variety would also be required to fulfil the definition stated in Article 14(5)(b)” (UPOV/EXN/EDV/2 2017, [9]-[10]; UPOV/EXN/EDV/2 Draft 5 2014, [10]).

The UPOV Council *Explanatory Notes* in 2017 states: “The derived variety must retain almost the totality of the genotype of the initial variety and be different from that variety by a very limited number of characteristics” (UPOV/EXN/EDV/2 2017, [11]).

The salient point of interpretation is that “conforms to the initial variety”, in the context of Article 14(5)(b)(iii), refers to a comparison between the “initial variety” and the putative EDV, and that there is a high degree of similarity, with the differences that result from the act of derivation being only “one or very few”. Put differently, more than “one or very few” differences between the “initial variety” and the putative EDV suggest there is no essential derivation.

3. Resolving the Apparent Conflict between Article 14(5)(b)(i) and (iii)

Article 14(5)(b)(i) provides that the putative EDV must be predominately derived “while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety” and Article 14(5)(b)(iii) provides “except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics”.

The document prepared for the Sixth Meeting with International Organisations in 1992 stated: “Article 14(5)(b) lays down those conditions that must be satisfied in order that a later variety shall be deemed to be essentially derived from another variety (‘the initial variety’) ...

The first such condition (established in Article 14(5)(b)(i)) requires that the later variety be derived from the initial variety which in turn requires that genetic materials of the initial variety have been used in the creation of the later variety. The first condition is accordingly concerned with the genetic origin of the later variety. The third such condition (established in Article 14(5)(b)(iii)) requires that the later variety conforms to ('is made similar to') the initial variety in the expression of the inherited essential characteristics of the initial variety apart from the differences which result from the act of derivation. The third condition is accordingly concerned with the degree of similarity of the later variety to the initial variety. Whilst the first condition also makes reference to the degree of similarity, the primary function of the first condition is to establish a requirement relating to the genetic origin of the variety" (IOM/6/2 1992, [13]).

The preferable resolution to this apparent conflict is to read Article 14(5)(b)(i) as requiring only that the putative EDV be genetically related to the "initial variety" so that there is a genetic lineage between the putative EDV and the "initial variety", and that Article 14(5)(b)(iii) imposes a quantitative and qualitative comparison of phenotypic (being the expression results of the genotype) "essential characteristics" except for the acts of derivation differences.

As a relevant example of how Article 14(5)(b)(i) might be applied when considering selecting varieties from within existing variation and induced mutations, the document prepared for the Sixth Meeting with International Organisations in 1992 provides:

Example 6: Natural and induced mutations

A mutation is discovered in variety A and used to create a new variety B.

Question: Is variety B essentially derived from variety A? Does the position differ if the mutation from a simple genetic change or if the change is more complex, or if the mutation is artificially induced?

Answer:

- (i) Variety B is predominantly derived from variety A and is clearly distinguishable from variety A.
- (ii) Whether the mutation is naturally or artificially induced is irrelevant.
- (iii) The only remaining questions are whether variety B is derived from variety A while retaining the expression of the essential characteristics that result from the genotype of variety A and whether

variety B conforms with variety A so as to satisfy Article 14(5)(b)(iii). In most cases this will be so and variety B will be essentially derived from variety A.

- (iv) The complexity of the genetic change may, however, result in a mutation that no longer retains the expression of the essential characteristics that result from the genotype of variety A. In this case variety B would not be essentially derived from variety A.
- (v) Where variety A is a mutation of an unprotected variety X, variety B may be essentially derived from variety A but will not fall within the scope of protection of variety A since variety A is itself an essentially derived variety. This fact will be of importance for species where mutation breeding is a frequently used technique” (IOM/6/2 1992, Annex, Question 6).

Where selections are made within existing variation and induced mutations it is likely the main issue will be: (i) determining the differences between the “initial variety” and the putative EDV; (ii) identifying the “essential characteristics” of the “initial variety” and the putative EDV; and (iii) identifying the differences that result from the act of derivation; and then judging: (iv) whether the “initial variety” and the putative EDV are “clearly distinguishable” (Article 14(5)(b)(ii)); and (v) whether the “essential characteristics” of the “initial variety” and the putative EDV are sufficiently similar to be an EDV, or different enough for there to be no essential derivation?

Notably, the document prepared for the Sixth Meeting with International Organisations in 1992 stated: “The question of the genetic origin of the later variety posed by Article 14(5)(b)(i) is primarily a question of fact to be established using all available evidence including the personal testimony of individual witnesses, laboratory and field record books, knowledge concerning the inheritance of particular characteristics, the results of biochemical tests and so on. The question of degree of similarity of the later variety to the initial variety [posed by Article 14(5)(b)(iii)] primarily calls for a value judgement whether the later variety does or does not conform to the initial variety in the expression of its essential, heritable characteristics” (IOM/6/2 1992, [13]).

The salient point about evidence here is that the question of the genetic origin (Article 14(5)(b)(i)) is a question of fact and requires any evidence that establishes facts about the origins and biological similarities/differences between the “initial variety” and the EDV. Meanwhile, the question of degree of similarity when assessing the “essential characteristics”

of the “initial variety” and the putative EDV (Article 14(5)(b)(iii)) calls for any evidence about similarities/differences between the “initial variety” and EDV (including commercial, economic and industrial evidence).

4. What the cases say?

Unfortunately, the litigation about EDVs has been uncertain. The basic provisions in the 1991 UPOV agreement have been implemented with variations to address some of the drafting compromises and oversights apparent in the 1991 UPOV EDV provisions. The litigated schemes in Europe (Holland, Germany and Italy), Israel and Australia do, however, provide interesting insights into the kinds of evidence that might establish an EDV, and the significant effect of which party bears the onus of proof in establishing or rebutting a finding of EDV.

The early case in Holland in *Van Zanten Plants B.V. v Hofland B.V.* (2008) 310918/KG ZA 08-594, District Court of The Hague (6 August 2008) was a clear example of an EDV. The freesia variety “Ricastor” was subject to a Dutch breeder’s right. Another variety marketed as “Mercurius” was alleged to be an EDV. The evidence showed there were no genetic differences (100 per cent genetic relationship) and the morphological differences were minor as they were almost identical. The outcome was to find an EDV. Perhaps importantly, there was no evidence to counter the AFLP data (using a Jaccard-index) showing the 100 per cent genetic relationship, and the argument that “Mercurius” was cultivated from seedlings was not a credible explanation for the high degree of genetic relationship. In short, both plants were 100 per cent homologous, and there could certainly be no other conclusion (there was a presumption of infringement) than that “Mercurius” was essentially derived from “Ricastor”.

The litigation over the *Gypsophila* varieties in *Astée Flowers B.V. v Danziger “Dan” Flower Farm* (2005) 198763, Court of The Hague (13 July 2005), *Danziger “Dan” Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01, Court of Appeal, The Hague (29 December 2009) and *Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V.* (2009) 1228/03, District Court, Tel-Aviv-Jaffa were less clear and have a legacy of uncertainty. The litigation was about whether variety “Blancanieves” was an EDV of “Million Stars” and “Summer Snow”. In Holland *Astée Flowers B.V. v Danziger “Dan” Flower Farm* (2005) 198763 the agreed evidence was

that the “Blancanieves” and “Summer Snow” were created through the application of chemicals (colchicines) to achieve polyploidisation. The court decided the varieties were not essentially derived because 17 of the 21 observable phenotypic characters were different. Significantly the court bypassed the technical genetic evidence because it was considered biased and unreliable. On appeal in *Danziger “Dan” Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01 the plaintiff’s evidence was that the AFLP technique applied by its expert had a Jaccard index showing genetic similarity of 0.944 and 0.937, while the defendant’s expert had a Jaccard index of genetic similarity of 0.82 and 0.87. Again, the court rejected this evidence concluding that the AFLP technique was “open to objection” and that “although similarity, measured by the Jaccard index, and affinity are correlated, an individual index value will not provide the degree of certainty about an affinity, which is required in order to conclude (on a preliminary basis) that evidence of derivation has been produced” ([16]). The court then considered the phenotypic similarity looking at the morphological data. Here the court again considered that the Community Plant Variety Office’s finding of 17 morphological differences enabling registration was enough to be more than the threshold for EDV of “one or a few inheritable characteristics” ([22]). As there were substantial numbers of morphological differences then “proof that Blancanieves is an EDV ... has therefore not been furnished”, and no other attempt to furnish evidence was allowed ([22]).

Another unresolved question in the appeal in *Danziger “Dan” Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01 under the *Regulation (EC) 2100/94 of the Council Concerning Community Plant Variety Rights of 27 July 1994*, L 277/1 was the burden of proof remaining with the plaintiff to establish essential derivation. In this case this meant that the plaintiff (Danziger) needed to prove EDV, noting the shifting onus and the consequence of formally shifting the onus of proof:

The Court is of the opinion that according to Dutch procedural law, as the occasion arises, (virtually) the same result can be achieved as with reversal of the burden of proof, by taking the ground, based on evidence furnished by the breeder of the initial variety, that evidence of an EDV has been furnished for the time being and allowing the other party to prove the contrary. The difference with a reversal of the burden of proof is that the risk of evidence continues to lie with the breeder of the initial variety, which is only important in the event that any uncertainty about the derivation continues to exist ([12]).

Applying this standard, any evidence that revealed a genealogical link between the putative EDV and the initial variety will be relevant. And once a plaintiff provides evidence of the genealogical link that is credible then the other party will be obliged to refute that evidence, in effect shifting the onus of proof to the defendant ([12]). The result is, in practice, the same as formally transferring the onus to the defendant once the plaintiff has established a reasonable allegation. Significantly, however, the court here rejected the AFLP technique evidence showing a close genetic similarity in favour of many phenotypic differences in effect favouring phenotype over genotype. The result was that the plaintiff retained the burden of proof and was unable to rely on the evidence of Jaccard indexes showing genetic similarity of 0.944 and 0.937 that might have been expected to shift the burden and seek a credible explanation from the defendant. And this is what happened in the Israeli litigation on almost identical evidence.

In Israel in *Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V.* (2009) 1228/03, the litigation was pursued under the *Plant Breeder's Right Law 5733-1973* where the burden of proving EDV was on the defendant to establish that the variety was not an EDV if "genetic conformity" was shown:

Where an action is brought by the holder of an original protected variety (hereafter: plaintiff) against the holder of a variety, in respect of which it is argued that it is an essentially derived variety (hereafter: defendant), the defendant shall bear the burden of proof that the variety is not essentially derived, if the plaintiff has proven one of the following:

- (1) genetic conformity between the original variety protected and the variety, in respect of which it is claimed to be essentially derived variety;
- (2) the variety, claimed to be essentially derived variety maintains, except for minor differences, the expression of the essential characteristics that arise out of the genotype or out of a combination of genotypes of the original protected variety (*Plant Breeder's Right Law, 5733-1973, s 62A*).

The Israeli District Court rejected the defendant's argument that only morphological characters might be considered – as had happened in the litigation in Holland – and accepted the genetic AFLP evidence of the plaintiff that showed that of 214 markers using six primers the contested varieties differed by only five markers ([14]). The court also rejected the defendant expert's assertion that AFLP was not an appropriate measure of EDV because the

randomly selected primers targeted genetic differences that were not necessarily linked to markers of significant traits for EDV – the assertion accepted by the court in Holland ([14]). The court reasoned that what the legislated standard required was “genetic conformity” and the AFLP analysis addressed that issue. With this shifted burden of proof, the defendant was both unable to credibly prove how “Blancanieves” was created (see [21]), and unable to provide any credible morphological evidence of the differences between the varieties because the defendant’s expert witness died before the hearing and their subsequent expert did not conduct a thorough morphological examination merely conducting an “initial examination” (see [14] and [19]). Surprisingly the court interpreted the EDV threshold of conforming to the initial variety as not being limited to “one trait or a small number of morphological traits” ([18]). This meant that evidence of multiple morphological differences (and variety registration accepted the varieties were distinct) were not proof against a finding of EDV like they had been in the litigation in Holland. Meanwhile the plaintiff conducted comprehensive morphological examinations:

[The plaintiff’s expert witness] personally supervised the planting of the plants in a standard greenhouse, in two different areas, where in every plot the two varieties were planted in several repetitions. Approximately half a year after their planting, and after they firstly blossomed, the plants were trimmed and a new wave of florescence was observed. The comparison between the morphological characteristics of the varieties has been conducted by Prof Weiss continuously during the whole length of the growing period – while paying attention to a great number of parameters; and its findings were, that the essential characteristics of the Registered Variety are retained in Blancanieves. The only morphological differences which were found by [the plaintiff’s expert witness] were as follows: the Registered Variety had longer stems than those of Blancanieves, flowering date of Blancanieves was approximately two weeks later than the flowering date of the Registered variety, and the flowers of Blancanieves contained more petals than the flowers of the Registered Variety. Based on these findings, [the plaintiff’s expert witness] established that the morphological difference which was found, results from the act of derivation of the genotype ([20]).

The outcome of the decision is significant because this demonstrates that on almost identical evidence courts in Holland and Israel reached different conclusions, interpreting the EDV thresholds very differently.

The more recent German decision in *Probstdoder Saatzucht GmbH & Co. KG v Pflanzzucht Oberlimpurg* (101) 7 0 442t04, Court of First Instance of Mannheim, Civil Chamber (10

December 2010) did not really progress our understanding. The owner of the initial plant breeder protected variety became aware of a similar plant breeder protected variety and conducted tests revealing no genetic or other differences suggesting a very close genetic relationship between the varieties. After attempting to negotiate and unhappy with resolving the matter, the owner of the initial variety started litigation. The court appointed an expert to conduct a marker analysis using SSR markers, and this showed a genetic similarity of 99 per cent. The court accepted that the later variety was an EDV. On appeal challenging the genetic analysis and failure to consider phenotypic analysis the parties settled and the matter was discontinued. Perhaps like the litigation in Holland in *Van Zanten Plants B.V. v Hofland B.V.* (2008) 310918/KG ZA 08-594 where there is no or very few genetic differences there needs to be a credible explanation for the high degree of genetic relationship. Without that explanation there is an uncontested EDV.

And the later Italian decision in *Almo s.p.a. v Sardo Piemontese Sementi Soc. Coop. Società Agricola* (2015) 3519/2015, Turin Trial Court (14 May 2015) concerning Almo s.p.a.'s GLADIO rice seed and Sa.Pi.Se.'s SIRIO CL seed both covered by breeder's rights. Almo s.p.a. asserted that SIRIO CL was simply derived by crossing the GLADIO plant with another plant that was resistant to imidazolinone herbicides and then probably a backcross with a GLADIO plant, so SIRIO CL was nothing more than a variety essentially derived from GLADIO – in other words GLADIO with resistance to the imidazolinone herbicides. Almo s.p.a.'s evidence showed that three out of 38 characters were different between the varieties in addition to resistance to the imidazolinone herbicides while Sa.Pi.Se.'s evidence was that four characters were different in addition to the resistance to the imidazolinone herbicides. The court appointed expert's DNA analysis showed that out of the 25 genetic markers, 21 were inherited from GLADIO and just 4 from the other parent ([12]). The court appointed expert found:

after having indicated the essential characteristics of a rice variety and the specific characteristics of GLADIO that are reproduced in SIRIO CL, ruled out the possibility of the latter variety being derived from the former, owing to the fact that some of the characteristics were not "unique and specific" to GLADIO but were instead already present, in combination, in other, earlier rice varieties, while other characteristics (productive capacity, rice quality obtained or yield after industrial processing, tillering capacity and plant vigour) could not be regarded as essential characteristics for the purposes of this case, since those were strongly influenced by the environment, and in the case of some, were not specific to GLADIO but were

instead present in earlier varieties, together with other characteristics relating to the grain type and the duration of the vegetative cycle. [The expert] then went on to note that SIRIO CL derived the characteristic of “resistance to herbicides” not from GLADIO but rather from the other parent ([9]).

In applying the EDV standard under the *Regulation (EC) 2100/94 of the Council Concerning Community Plant Variety Rights of 27 July 1994*, L 277/1 the court considered that the essential characteristics of a rice variety are grain type, duration of the vegetative cycle, productive capacity, quality of the rice obtained or yield after industrial processing, plant vigour, tillering capacity, and resistance to herbicides ([11]). Of these characteristics plant vigour and tillering capacity were not considered relevant for EDV assessment, while grain type, duration of the vegetative cycle, productive capacity, quality of the rice obtained or yield after industrial processing were relevant, and found to be the shared by both GLADIO and SIRIO CL ([11]). On this basis the court concluded that SIRIO CL was an EDV derived from GLADIO ([12]). The significant evidence appears to have been that SIRIO reproduced the four genotype characteristics of grain type, duration of the vegetative cycle, productive capacity, and quality of the rice obtained or yield after industrial processing from GLADIO and that of the 25 genetic markers considered 21 were inherited from GLADIO ([12]). Put simply, the court found that taking a commercially successful variety and introducing a single resistance gene (and backcrossing) satisfied the EDV thresholds.

The Australian approach to EDV in the *Plant Breeder’s Rights Act 1994* (Cth) (PBR Act) provides an interesting contrast to the *Almo s.p.a. v Sardo Piemontese Sementi Soc. Coop. Società Agricola* (2015) 3519/2015 decision. The PBR Act developed two important elaborations on the UPOV 1991 requirements: (1) defining the “essential characteristics” as “heritable traits ... that contribute to the principal features, performance and value of the variety” (s 3); and (2) shifting the onus requiring the “important (as distinct from cosmetic) features” to be demonstrated if the second variety is not to be declared an EDV (s 4). The effect of these elaborations has been to introduce commercial imperatives into the EDV assessment. For example, the decision *Sir Walter v B12* (2005) considered the protected lawn grass variety “Sir Walter” and the second variety “B12” bred from that initial variety (UPOV 2013, pp. 54-55). The differences between the varieties were colour and internode length (the stalk between leaves) differences and that these were *not* important features as required by s 4(c).

The evidence, however, was that the shorted internode length was important as it increased the “thatch” of the grass with resulting wear tolerance and that this was an important feature for using the grass, on golf courses and the like. There was also evidence from two separate growing trials that demonstrated there was a statistically significant node length difference to a high degree of confidence. Based on this evidence the assertion of EDV was rejected. Other similar cases include *Sir Walter v Kings Pride* (2007) (UPOV 2013, pp. 56-57).

These cases reveal the complex interplay between genotypic and phenotypic evidence and some of the nuances in how courts might deal with this evidence. Perhaps most importantly, however, the cases reveal that a careful tracing of the sources of germplasm and detailed records of the breeding go a long way to overcoming questions about EDV. The cases also show that where varieties are very closely related with little advance on the initial variety then an EDV is very likely the outcome.

5. Discussion

The menace that EDV was intended to address was an unfair free riding on the original plant breeder’s time and investment by allowing a full plant breeder’s right for only very minor development of a protected variety. The model of dependent patents probably appealed to plant breeders so that they could get an adequate remuneration for their breeding when later breeder’s exploited their work relying only on minor breeding advances. The ubiquitous scenario was the genetically modification of a commercially successful variety with a single unimportant gene. The 1991 UPOV EDV provisions attempt to capture for the original breeder their fair returns while still allowing and promoting new breeding initiatives. Importantly, the finding of an EDV does not upset the breeder’s rights in either the initial variety or the EDV. The finding of an EDV confers on the owner of the initial variety from which it is essentially derived the breeder’s rights in that variety irrespective of whether the EDV is protected or not. This means that the owner of an EDV must engage with the owner of the initial variety and negotiate their exploitation of the EDV.

That there remains uncertainty about EDVs is reflected in the ongoing work of UPOV to find a clear explanation of their operations. The most recent *Explanatory Notes on Essentially Derived Varieties under The 1991 Act of the UPOV Convention* provide for a workable scheme

(UPOV/EXN/EDV/2 2017). As the litigation in Holland and Israel in *Danziger "Dan" Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01 and *Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V.* (2009) 1228/03 respectively illustrates, however, national laws implementing these 1991 UPOV standards vary with additional requirements, and some procedural hurdles that have a decisive effect on the outcomes. These include the kinds of evidence – recalling that *Danziger "Dan" Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01 in Holland rejected the genetic evidence from applying the AFLP technique – and the burden of proof – recalling that *Danziger "Dan" Flower Farm v Astée Flowers B.V.* (2009) 105.003.932/01 in Holland didn't find the threshold had been met for shifting the burden while in Israel in *Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V.* (2009) 1228/03 did, and the outcomes in each case based on essentially the same evidence were completely the opposite.

The issue remains of whether this all actually matters. Perhaps the introduction of the EDV standard has effectively achieved its purpose of preventing the unfair free riding on the original plant breeder's time and investment by establishing a process, albeit flawed, signalling to would-be breeders of new varieties to carefully document their source materials, and then carefully trace their breeding activity. As the decisions in *Van Zanten Plants B.V. v Hofland B.V.* (2008) 310918/KG ZA 08-594 and *Probstdoder Saatzucht GmbH & Co. KG v Pflanzzucht Oberlimpurg* illustrate, a credible explanation for the high degree of genetic relationship between varieties is necessary to at least counter the EDV finding. Further, the Australian cases of *Sir Walter v B12* and *Sir Walter v Kings Pride* (UPOV 2013, pp. 54-57) demonstrate that even where there are small differences, where these have an important commercial effects that are (arguably) more than free riding earlier breeding – as was the case in the Italian decision in *Almo s.p.a. v Sardo Piemontese Sementi Soc. Coop. Società Agricola* (2015) 3519/2015 that merely incorporated an imidazolinone herbicides gene into a valuable commercial variety – then subsequent breeders can be accommodated. The lack of cases in recent times suggests that breeders may have heeded these decisions and, in effect, addressed the menace that EDV was intended to resolve without finally resolving the technical legal questions.

References

Cases

Almo s.p.a. v Sardo Piemontese Sementi Soc. Coop. Società Agricola 3519/2015, Turin Trial Court (14 May 2015).

Astée Flowers B.V. v Danziger “Dan” Flower Farm (2005) 198763, Court of The Hague (13 July 2005).

Danziger “Dan” Flower Farm v Astée Flowers B.V. (2009) 105.003.932/01, Court of Appeal, The Hague (29 December 2009).

Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V. (2009) 1228/03, District Court, Tel-Aviv-Jaffa.

Probstdoder Saatzucht GmbH & Co. KG v Pflanzzucht Oberlimpurg (7 0 442t04), Court of First Instance of Mannheim, Civil Chamber (10 December 2010).

Sir Walter v B12 (2005) Plant Breeder’s Rights Office, Australia (cited in UPOV 2013, pp. 54-55).

Sir Walter v Kings Pride (2007) Plant Breeder’s Rights Office, Australia (cited in UPOV 2013, pp. 56-57).

Van Zanten Plants B.V. v Hofland B.V. (2008) 310918/KG ZA 08-594, District Court of The Hague (6 August 2008).

Reports and other documents

CAJ-AG/11/6/3. 2011. Administrative and Legal Committee Advisory Group, Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision). UPOV: Geneva.

CAJ-AG/13/8/2. 2013. Administrative and Legal Committee Advisory Group, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision)*. UPOV: Geneva.

IOM/6/2. 1992. International Union for the Protection of New Varieties of Plants, *Sixth Meeting with International Organizations: Essentially Derived Varieties*. UPOV: Geneva.

IOM/6/5. 1992. International Union for the Protection of New Varieties of Plants, *Sixth Meeting with International Organizations: Record of Meeting*. UPOV: Geneva.

Turnbull H (Editor). 1959. *The Correspondence of Isaac Newton*, Volume 1. Cambridge University Press: Cambridge.

UPOV. 2013. International Union for the Protection of New Varieties of Plants, *Seminar on Essentially Derived Varieties*. UPOV: Geneva.

UPOV/EXN/EDV/2. 2017. Council of International Union for the Protection of New Varieties of Plants, *Explanatory Notes on Essentially Derived Varieties under The 1991 Act of the UPOV Convention*. UPOV: Geneva.

UPOV/EXN/EDV/2 Draft 5. 2014. Administrative and Legal Committee Advisory Group, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention*. UPOV: Geneva.