

Plant Breeder's Rights and Essentially Derived Varieties: Still Searching for Workable Solutions

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☞ Burden of proof; Derivative works; International law Plant varieties

The 1991 International Convention for the Protection of New Varieties of Plants (UPOV Convention) introduced the concept of “essentially derived varieties” (EDVs) expanding the scope of the plant breeder’s right. The purpose of EDVs was to limit “plagiarism”, “copycat breeding”, “mimic”, “imitation” or “cosmetic” varieties, and an unfair free-riding on the original plant breeder’s time and investment. This article addresses the meaning and threshold of EDVs in the context of the 1991 UPOV Convention and the technicality issues that have been considered in trying to identify and establish a suitable threshold. The article concludes that the threshold of EDVs is more than a mere quantitative technical question requiring a technical answer, such as a statistical index or a DNA sequence, and includes qualitative elements. Further work is required by the members of the 1991

UPOV Convention to articulate these quantitative and qualitative aspects of the EDV thresholds, and especially the likely standard of “essential characteristics”.

Introduction

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) was concluded in Paris in 1961, with revisions in 1972, 1978 and 1991 for the granting of a plant breeder’s right.¹ The 1961 and 1978 UPOV Conventions protected plant varieties with a new, distinct, uniform and stable character compared with other varieties,² and a protected plant variety could be used as a source of variation for breeding other varieties.³ Together these provisions allowed a protected plant variety to be used to develop a new variety that was itself eligible for protection with only a very, very minor difference from the initial variety.

By allowing only very minor differences between protected varieties a full plant breeder’s right, the concern was that this was allowing “plagiarism”, “copycat breeding”,⁴ “mimic”, “imitation” or “cosmetic” varieties,⁵ and an unfair free-riding on the original plant breeder’s time and investment.⁷ To address this the 1991 UPOV Convention introduced the concept of “essentially derived varieties” (EDVs),⁸ expanding the scope of a breeder’s right to a variety that was selected on the basis of a very minor difference, a mutation, a genetic modification, a backcross, a selection within a variety, and so on.⁹ The concern was that breeder’s rights should be strengthened so that “the exploitation — but not the breeding — of a variety that is essentially derived from a protected variety would be subject to the right granted to the breeder of the latter variety”.¹⁰ Thus, EDV is a “protection against fraudulent practices in which ‘new’ varieties are produced from current, protected ones without a genuine breeding effort”.¹¹

This article addresses the meaning and threshold of EDVs in the context of the 1991 UPOV Convention and the technicality issues that have been investigated in trying to identify and establish a suitable EDV threshold.

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¹ For an overview of the substantive developments in the 1991 Act see Barry Greengrass, “The 1991 Act of the UPOV Convention” [1991] E.I.P.R. 466.

² International Convention for the Protection of New Varieties of Plants 1978 art.6(1)(a); International Convention for the Protection of New Varieties of Plants 1961 art.6(1).

³ International Convention for the Protection of New Varieties of Plants 1978 art.5(3); International Convention for the Protection of New Varieties of Plants 1961 art.5(3).

⁴ Perhaps defined as “any act or use of material/technology in a breeding process that purposely makes a close imitation of an existing plant variety”: International Seed Federation, *ISF View on Intellectual Property* (ISF, 2012), p.19.

⁵ Enrico Noli, Maria Teriaca and Sergio Conti, “Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat” (2012) 29 *Molecular Breeding* 687, 688.

⁶ GHK Consulting, *Evaluation of the Community Plant Variety Right Acquis — Final Report* (GHK Consulting, 2011) p.14.

⁷ See Noel Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (Centre for Commercial Law Studies, 1992) pp.7–8; Greengrass, “The 1991 Act of the UPOV Convention” [1991] E.I.P.R. 466, 470–471. See also Danziger “Dan” *Flower Farm v Astée Flowers BV* 105.003.932/01, Court of Appeal, The Hague (2009) at [23]. Notably evolving breeding techniques are also increasing access to the germplasm of the parental lines: see, for example, J. Smith, T. Hussain et al., “Use of Doubled Haploids in Maize Breeding: Implications for Intellectual Property Protection and Genetic Diversity in Hybrid Crops” (2008) 22 *Molecular Breeding* 51.

⁸ See Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Publication No.346(E) (UPOV, 1992), pp.338–334.

⁹ International Union for the Protection of New Varieties of Plants, *Fourth Meeting with International Organizations: Revision of the Convention*, IOM/IV/2 (1989), p.12. See also World Intellectual Property Organization, *Introduction to Plant Variety Protection under the UPOV Convention* (2003), WIPO/IP/BIS/GE/03/11, paras 53–57.

¹⁰ See, for example, International Union for the Protection of New Varieties of Plants, *Revision of the Convention*, IOM/IV/2 (1989), pp.2 and 10–12. This has been a long-held concern: see, for example, International Union for the Protection of New Varieties of Plants, *Actes des Conférences Internationales pour la Protection des Obtentions Végétales 1957–1961, 1972*, UPOV Publication No.316 (UPOV, 1972), pp.92 and 109.

¹¹ F. van Eeuwijk and J. Law, “Statistical Aspects of Essential Derivation, With Illustrations Based on Lettuce and Barley” (2004) 137 *Euphytica* 129, 129. See also Stephen Smith, Elizabeth Jones and Barry Nelson, “The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties” in Roberto Tuberosa, Andreas Graner and Emile Frison (eds), *Genomics of Plant Genetic Resources: Managing, Sequencing and Mining Genetic Resources* (Springer, 2014), p.61.

The article is structured as follows: the next part outlines the 1991 UPOV Convention's EDV scheme; the following part addresses the meaning of the term "variety" and the way this term imports a taxonomic and phenotypic perspective to considering similarities and differences among plants eligible for breeder's rights; and the next part considers the various technical issues (including the burden of proof) that have been investigated in searching for a suitable EDV threshold. The article concludes that the threshold of EDVs is more than a mere technical question requiring a technical answer, and that further work is required by the members of the 1991 UPOV Convention to articulate the quantitative and qualitative aspects of the EDV thresholds.

The 1991 UPOV Convention scheme

The challenge in drafting a provision about EDVs in a revision of the 1978 UPOV Convention was to find language that conveyed the appropriate meaning—"the expression of the essential characteristics of the initial variety and the retention of that expression"¹²—as defining text. Despite a number of suggestions attempting to clarify this meaning,¹³ the outcome in the 1991 UPOV Convention was that the basic text at the start of negotiations that had been developed by the Administrative and Legal Committee by "general agreement"¹⁴ was very similar to the text finally adopted.¹⁵ The text finally adopted in the 1991 UPOV Convention provides for the plant breeder's exclusive rights¹⁶ and extends the scope of those rights to include EDVs, providing:

- "(a) The [exclusive rights over propagating material, harvested material and harvested material products, subject to the exceptions and exhaustion provisions] 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."¹⁷

The main elements of the EDV scheme as they were understood at the time were that¹⁸:

- **The protected variety is not itself an EDV (art.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. So, if variety C is an EDV of variety B that was itself an EDV of variety A, then "variety C does not fall within the scope of the protection of variety B".¹⁹ In other words, a plant breeder's right in a first plant variety only extends to a second plant breeder's right protected variety that is

¹² Diplomatic Conference, *Publication No.346(E)* (1992), p.456.

¹³ See Delegation of the United States of America, *Proposal for the Amendment of Article 14(1) Introduction and Article 14(2)(a) Introduction*, DC/91/9 (1991); Delegation of the United States of America, *Proposal for the Amendment of Article 14(2)(b)(i)*, DC/91/14 (1991); Delegation of Poland, *Proposal for the Amendment of Article 14(2)*, DC/91/63 (1991); Delegation of Japan, *Proposal for the Amendment of Article 14(2)*, DC/91/65 Rev (1991); Delegation of Japan, *Proposal for the Amendment of Article 14(2)(b)(iii)*, DC/91/66 (1991); Delegation of Germany, *Proposal for the Amendment of Article 14(2)*, DC/91/89 Rev (1991); Delegation of Germany, *Proposal for the Amendment of Article 15(1)*, DC/91/92 (1991); Delegation of Japan, *Proposal for the Amendment of Article 14(2)(b)(i)*, DC/91/111 (1991); Drafting Committee, *Draft Resolution on Article 14(5)*, DC/91/129 Rev (1991); Secretariat, *Resolution on Article 14(5)*, DC/91/140 (1991).

¹⁴ See Council of the International Union for the Protection of New Varieties of Plants, *Report*, CAJ/XXI (1987). See also Administrative and Legal Committee of the International Union for the Protection of New Varieties of Plants, *Report*, CAJ/XXIV (1989); Administrative and Legal Committee of the International Union for the Protection of New Varieties of Plants, *Report*, CAJ/XXIII (1988); Administrative and Legal Committee of the International Union for the Protection of New Varieties of Plants, *Report*, CAJ/XXII (1988).

¹⁵ See Diplomatic Conference, *Publication No.346(E)* (1992), p.29.

¹⁶ International Convention for the Protection of New Varieties of Plants 1991 art 14(1)(a). The exclusive rights are: "the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder: (i) production or reproduction (multiplication); (ii) conditioning for the purpose of propagation; (iii) offering for sale; (iv) selling or other marketing; (v) exporting; (vi) importing; (vii) stocking for any of the purposes mentioned in (i) to (vi), above".

¹⁷ International Convention for the Protection of New Varieties of Plants 1991 art.14(5).

¹⁸ See also Peter Button, "New Developments in the Union for the Protection of New Varieties of Plants (UPOV)" (2006) 714 *Acta Horticulturae* 195, 196–197 and 209.

¹⁹ See International Union for the Protection of New Varieties of Plants, *Sixth Meeting with International Organizations: Essentially Derived Varieties*, IOM/6/2 (1992), para.7.

“essentially derived” from the first protected variety.²⁰ Further, this does not place a burden of proof on the breeder’s rights” holder of varieties A or B to prove their protected variety is not itself an EDV against variety C.²¹

- **The EDV is predominantly derived from the initial variety (art.14(5)(b)(i)):**

this means that an EDV can only be predominantly derived from one variety, and only “when it retained virtually the whole genotype of the other variety” and “it is almost entirely derived from that variety”.²² This also means that the EDV must be a direct descendant of the initial variety.²³ Examples of how these EDV might be obtained include “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”.²⁴

- **The EDV retains the expression of the essential characteristics (art.14(5)(b)(i)):**

the essential characteristics are the heritable (genotype) characteristics from the initial variety “that are indispensable or fundamental to the [initial] variety” where the characteristics are “all features of a variety including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics”.²⁵ The “characteristics” might also include a biochemical test like a DNA screening probe.²⁶ The content of the terms “characteristics” and “expression” are set out in more detail below.

- **The EDV must result from the genotype or combination of genotypes (arts 14(5)(b)(i) and (iii)):**

the relevant characteristics are heritable characteristics only and do not include characteristics that are a response to the environment.²⁷

- **The EDV is itself clearly distinguishable (art.14(5)(b)(ii)):**

the EDV needs to be clearly distinguishable by whatever means (genotypic or environmental) from the initial variety.²⁸

- **The act of derivation are the only differences (art.14(5)(b)(iii)):**

this reaffirms that the differences that result from the act of derivation should only “be one or very few”.²⁹ Presumably an act of derivation that did not incorporate all the essential characters could not be an EDV because of the earlier requirement for an EDV “retaining the expression of the essential characteristics”. This may not, however, be so clear because during negotiations the finally adopted text suggest the varieties 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”.³⁰ Arguably then, an essential characteristic that is not expressed in the alleged EDV may not be enough to exclude a finding of an EDV with the differences resulting from the act of derivation being left out of the EDV considerations.³¹ The relationship between essential characteristics and the act of derivation remain under discussion.³²

In a practical sense a contracting party’s granting authority applying the EDV provision has a two-step process³³: the first requires the putative EDV to already

²⁰ See also Button, “New Developments in the Union for the Protection of New Varieties of Plants (UPOV)” (2006) 714 *Acta Horticulturae* 195, 196–197 and 209.

²¹ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.7.

²² International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.8. See also International Union for the Protection of New Varieties of Plants, *Sixth Meeting with International Organizations: Record of Meeting*, IOM/6/5 (1992), paras 19–21.

²³ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.15.

²⁴ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(1)(c). Notably “the examples, such as the selection of a natural or induced mutant, were not definitive but were just examples”: Diplomatic Conference, *Publication No.346(E)* (1992), p.456.

²⁵ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.9. See also International Union for the Protection of New Varieties of Plants, *Record of Meeting*, IOM/6/5 (1992), paras 22 to 23.2.

²⁶ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.9.

²⁷ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.10.

²⁸ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.11. See also Administrative and Legal Committee, *Report*, Sixty-Seventh Session, CAJ/47/8 (2003), Annex III.

²⁹ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.12. See also International Union for the Protection of New Varieties of Plants, *Record of Meeting*, IOM/6/5 (1992), paras 33–37. For a contrasting view see *Danziger “Dan” Flower Farm v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [18].

³⁰ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.19. See also Diplomatic Conference, *Publication No.346(E)* (1992), pp.344–346.

³¹ See *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [11].

³² For recent discussions see, for examples, Administrative and Legal Committee, *Report*, Sixty-Seventh Session, CAJ/67/15 (2013), para.19; Administrative and Legal Committee Advisory Group, *Report*, Seventh Session, CAJ-AG/12/7/7 (2012), paras 21–46; and so on.

³³ See also Smith, Jones and Nelson, “The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties” in *Genomics of Plant Genetic Resources* (2014), p.54.

satisfy the requirements for a breeder's right (with a new distinct, uniform and stable character compared to other common varieties)³⁴; and the second requires an assessment of the three cumulative criteria for determining EDV of: (i) being predominantly derived from the initial variety while retaining the expression of the essential characteristics; (ii) being clearly distinguishable; and (iii) conforming to the expressed essential characteristics of the initial variety (noting the apparent conflict between (i) and (iii)).³⁵ The first step was already well articulated with the assessment of newness, distinctness, uniformity and stability as part of the 1961 and 1978 UPOV Conventions.³⁶ It is the second step that poses the problems. In assessing the putative EDV there must be a comparison between the initial variety against the putative EDV and a determination whether the putative EDV satisfies the 1991 UPOV Convention EDV thresholds.³⁷

On the adoption of the EDV provision the uncertainty about the EDV thresholds was apparent,³⁸ and the Diplomatic Conference resolved to "request" the Secretary-General of UPOV to start work "on the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties".³⁹ The UPOV Administrative and Legal Committee (CAJ) and Administrative and Legal

Committee Advisory Group (CAJ-AG) have undertaken work on the scope of EDVs.⁴⁰ Despite ongoing discussions the participants have been unable to settle on common understandings about key elements of the EDV standard.⁴¹ This state of affairs continues, with UPOV contracting parties continuing to settle the meaning to the 1991 UPOV Convention text to apply EDV schemes within their jurisdictions.⁴² There are, however, some inherent preferences built into the 1991 UPOV Convention that shape the EDV scheme and affect the way the EDV thresholds are conceived.

The "variety" as the basic concept

The 1991 UPOV Convention requires contracting parties to "grant and protect breeder's rights"⁴³ to "all plant genera and species".⁴⁴ The "breeder's right" is then directed to a "variety" that is a "plant grouping"⁴⁵ that is "new", "distinct", "uniform" and "stable".⁴⁶ And it is the "breeder" that lodges the application⁴⁷ and then exercises the exclusive rights (or the breeder's licensee or assignee)⁴⁸ over the "variety".⁴⁹ This means that the content of the term "variety" is the object of the 1991 UPOV Convention's "breeder's right",⁵⁰ both as a

³⁴ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(1)(a)(i). See also International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3 (2002).

³⁵ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(1)(b). The apparent conflict between (i) and (iii) probably resolved by applying (i) as a measure of *genetic origin* and (iii) as a measure of *genetic similarity*: International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), paras 13–14. See also *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [10]–[11].

³⁶ International Convention for the Protection of New Varieties of Plants 1978 art.6(1)(a); International Convention for the Protection of New Varieties of Plants 1961 art.6(1).

³⁷ See also Smith, Jones and Nelson, "The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties" in *Genomics of Plant Genetic Resources* (2014), pp.54–56.

³⁸ See, for example, Diplomatic Conference, *Publication No.346(E)* (1992), pp.346–347.

³⁹ Diplomatic Conference, *Publication No.346(E)* (1992), pp.63, 157 and 346–349; Secretariat, *Resolution on Article 14(5)*, DC/91/140 (1991). See also Administrative and Legal Committee Advisory Group, *Report*, Seventh Session, CAJ-AG/12/7/3 (2012), paras 10–21; Delegation of Japan, *Proposal for the Amendment of Article 14(2)*, DC/91/65 Rev (1991).

⁴⁰ See Administrative and Legal Committee, *Report on Conclusions*, Sixty-Seventh Session, CAJ/67/14 (2013), paras 15–20; Administrative and Legal Committee, *Report*, Sixty-Fifth Session, CAJ/65/13 (2012), para.21; Administrative and Legal Committee, *Report*, Sixty-Third Session, CAJ/63/10 (2011), para.50; Administrative and Legal Committee, *Report*, Sixty-Second Session, CAJ/62/9 (2011), para.11; Administrative and Legal Committee, *Report*, Sixty-First Session, CAJ/61/12 (2010), paras 39, 70 and 72–73; Administrative and Legal Committee, *Report*, Sixtieth Session, CAJ/60/11 (2009), para.17; Administrative and Legal Committee, *Report*, Fifty-Ninth Session, CAJ/59/8 (2009), paras 19, 36 and 39; Administrative and Legal Committee, *Report*, Fifty-Eighth Session, CAJ/58/7 (2009), paras 54–63; Administrative and Legal Committee, *Report*, Fifty-Seventh Session, CAJ/57/7 (2008), paras 36–50; Administrative and Legal Committee, *Report*, Sixty-Seventh Session, CAJ/47/8 (2003), paras 26–38; Administrative and Legal Committee, *Report*, Forty-Sixth Session, CAJ/46/8 Rev (2003), para.50; Administrative and Legal Committee, *The Notion of "Essentially Derived Variety" in the Breeding of Ornamental Varieties*, Forty-Sixth Session, CAJ/46/7 (2002). See also Administrative and Legal Committee Advisory Group, *Report*, Seventh Session, CAJ-AG/12/7/7 (2012), paras 21–46; Administrative and Legal Committee Advisory Group, *Report*, Sixth Session, CAJ-AG/11/6/7 (2011), paras 12–21; Administrative and Legal Committee Advisory Group, *Report*, Fifth Session, CAJ-AG/10/5/7 (2010), paras 13–18; Administrative and Legal Committee Advisory Group, *Report*, Fourth Session, CAJ-AG/09/4/4 (2009), paras 22–25; Administrative and Legal Committee Advisory Group, *Report*, Second Session, CAJ-AG/07/2/8 (2007), paras 17–19; Administrative and Legal Committee Advisory Group, *Report on the Conclusions*, First Session, CAJ-AG/06/1/3 (2006), para.16.

⁴¹ See Administrative and Legal Committee Advisory Group, *Report*, Seventh Session, CAJ-AG/12/7/3 (2012); Administrative and Legal Committee Advisory Group, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision)*, Sixth Session, 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)*, Fifth Session, CAJ-AG/10/5/3 (2010).

⁴² Administrative and Legal Committee, *Development of Information Materials Concerning the UPOV Convention*, Sixty-Eighth Session, CAJ/68/2 (2013), paras 13–20; Administrative and Legal Committee, *Development of Information Materials Concerning the UPOV Convention*, Sixty-Seventh Session, CAJ/67/2 (2012), paras 13–15; and so on.

⁴³ International Convention for the Protection of New Varieties of Plants 1991 art.2.

⁴⁴ International Convention for the Protection of New Varieties of Plants 1991 art.3. There are some transitional arrangements, with existing UPOV members getting five years to achieve coverage of "all plant genera and species" (art.3(1)); new UPOV members must protect "at least 15 plant genera or species" on accession and after 10 years they achieve coverage of "all plant genera and species" (art.3(2)).

⁴⁵ A "plant grouping" means that the "variety" does not include "a single plant; (however, an existing variety may be represented by a single plant or part(s) of a plant, provided that such a plant or part(s) of the plant could be used to propagate the variety); a trait (eg disease resistance, flower color); a chemical or other substance (eg oil, DNA); a plant breeding technology (eg tissue culture)": International Union for the Protection of New Varieties of Plants, *Explanatory Notes on the Definition of Variety Under the 1991 Act of the UPOV Convention*, UPOV/EXN/VAR/1 (2010), p.4. Notably, however, plant breeder's rights in some jurisdictions apply more broadly than plants and include fungi and algae: see, for example, Plant Breeder's Rights Act 1994 (Cth) s.3(1) ("plant").

⁴⁶ International Convention for the Protection of New Varieties of Plants 1991 art.5(1).

⁴⁷ International Convention for the Protection of New Varieties of Plants 1991 art.10.

⁴⁸ International Convention for the Protection of New Varieties of Plants 1991 art.14(1)(b).

⁴⁹ International Convention for the Protection of New Varieties of Plants 1991 art.14(1).

⁵⁰ International Convention for the Protection of New Varieties of Plants 1991 art.14(1).

threshold requirement for the breeder's right and determining the scope of the right.⁵¹ The term "variety" is defined to mean:

"[A] plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be:

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes;
- distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- considered as a unit with regard to its suitability for being propagated unchanged."⁵²

This definition of "variety" is constrained by the meaning of the terms "taxon" in the context of "a single botanical taxon of the lowest known rank" and "genotype" in the context of "expression of the characteristics resulting from a given genotype or combination of genotypes". This is significant because these are technical terms that convey a particular perspective about the ways similarities and differences are considered and measured, and importantly, distinguished from others.⁵³

The taxonomy preference

The identification of similarities and differences in plants, animals and other organisms has been a long-term project in taxonomy that traces its origins to concerns that biological organisms be distinctly identified by a name so that a de-contextualised identifier of a specific kind of organism would allow global exchange.⁵⁴ The 1991 UPOV Convention reinforces this taxonomy preference. Two illustrations confirm this observation. First, the 1991 UPOV Convention frames its scheme according to taxonomy: the convention applies "to all plant genera and species",⁵⁵ extends the novelty to "a plant genus or species" recently created for the purposes of the convention,⁵⁶ limits exhaustion where "the plant genus or species" is not protected in a destination export market,⁵⁷ limits the uses of denominations for "the same plant species or of a closely related species",⁵⁸ and requires contracting parties to notify "the list of plant genera and

species" to which their domestic plant breeder's legislation applies.⁵⁹ In short, the 1991 UPOV Convention conceives "variety" through the lens of taxonomy. Secondly, the 1991 UPOV Convention was negotiated in the frame of taxonomy. A negotiations working group specifically addressed its task "to reach a technically satisfactory and objective definition of the term 'variety'".⁶⁰ Their deliberations adopted the phrase "a plant grouping within a single botanical taxon of the lowest known rank" to deal with "botanical taxon" meaning "any botanical taxon" and "known" to capture interspecific and intergeneric hybrids.⁶¹ Back before the Plenary the uses of the phrase "botanical taxon of the lowest known rank" was justified in the language of taxonomy and confirms that the definition of "variety" is conceived in the context of taxonomy:

"In the case of triticale, for example, there was, initially, neither question of the species level nor of the genus level (since triticale belonged neither to the genus *Triticum* nor the genus *Secale*), but — speaking only of the major ranks — to the family of Gramineae or — to be more precise — the subtribe of Triticineae ... the aim of the Conference should of course be to ensure that it was covered by the system of protection for new plant varieties."⁶²

There are two predominant meta-classification taxonomy methodologies that have developed. One methodology is focused on grouping organisms according to all anatomical and bio-molecular similarities (the "traditional" or pre-Darwin Linnaean system of taxonomy now accommodating the principle of common descent). The other methodology focuses on grouping organisms according to *some* anatomical and bio-molecular similarities of relatedness (also called phylogenetics—the post-Darwin system based on the principle of common descent). The key differences in these meta-classification methodologies is that the "traditional" (pre-Darwin Linnaean) system considers all similarities as meaningful while phylogenetics (post-Darwin) only takes account of some similarities associated with relatedness (shared-derived characters or synapomorphies) and expressly excludes retained primitive characteristics (or plesiomorphy). The difference in these meta-methodologies is essentially about the weight given to the anatomical and bio-molecular characters, the latter

⁵¹ This is an important distinction between plant breeder's rights and patents for inventions; in the latter case, the disclosures in the patent application (the claims, description, and so on) determine the scope of the patent: see Agreement on Trade-Related Aspects of Intellectual Property Rights art.29(1).

⁵² International Convention for the Protection of New Varieties of Plants 1991 art.1(vi). See also Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (1992), pp.20–22; Greengrass, "The 1991 Act of the UPOV Convention" [1991] E.I.P.R. 466, 467.

⁵³ See Michael Foucault, *The Order of Things* (Routledge Classic, 2002), pp.150–158.

⁵⁴ See, for example, Staffan Müller-Wille, "Nature as Marketplace: The Political Economy of Linnaean Botany" (2003) 35 *History of Political Economy* 154, 162–166 and the references therein; José María Elena Rosselló, "The UPOV Convention — The Concept of Variety and the Technical Criteria of Distinctness, Uniformity and Stability" in International Union for the Protection of New Varieties of Plants, *1991 Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention*, Publication No.727(E) (UPOV, 1994), pp.57–58.

⁵⁵ International Convention for the Protection of New Varieties of Plants 1991 art.3(1)(i) and (ii). and 3(2)(i) and (ii).

⁵⁶ International Convention for the Protection of New Varieties of Plants 1991 art.6(2).

⁵⁷ International Convention for the Protection of New Varieties of Plants 1991 art.16(1)(ii).

⁵⁸ International Convention for the Protection of New Varieties of Plants 1991 art.20(2).

⁵⁹ International Convention for the Protection of New Varieties of Plants 1991 art.36(1)(ii). See also Diplomatic Conference, *Publication No.346(E)* (1992), pp.138, 194, 202, 328; and so on.

⁶⁰ Diplomatic Conference, *Publication No.346(E)* (1992), p.137.

⁶¹ Diplomatic Conference, *Publication No.346(E)* (1992), p.138.

⁶² Diplomatic Conference, *Publication No.346(E)* (1992), p.328.

phylogenetics giving greater weight to shared-derived (synapomorphy) characters (and excluding primitive features or plesiomorphy), and based on the principle of common descent (evolution) as opposed to mere shared characters. This is an ongoing controversy, especially with determining primitive versus derived character states and the weight to be given to sequence information.⁶³ Thus, for example, a primitive character will be excluded from a phylogenetic (post-Darwin) analysis while being given equal weighting in a “traditional” (pre-Darwin Linnaean) analysis. The consequence for taxonomy is that groupings based on the “traditional” system of taxonomy mandates that organisms be assigned to the Kingdom, Division/Phylum, Order, Family, Genus taxa, implying relatedness that may not actually exist.⁶⁴ The result of then adopting refinements on the basis of phylogenetics within the traditional taxonomy has been an ongoing development of uncertain classifications (“taxon stability” and the quest for mono-phylogeny).⁶⁵ This uncertainty is a direct consequence of the recent developments in comparative and functional genomics that now challenge the neat (evolutionary) conception of organismal relationships according to common ancestry and the “Tree of Life”, and demonstrate that non-adaptive processes are significant.⁶⁶ Importantly, while these developments do not challenge the proposition that extant life evolved from a single common ancestor, it does make tracing the particular steps of evolution and differentiation

extraordinarily difficult,⁶⁷ and makes the likely taxonomy for the two predominant meta-classification methodologies, and the merging of information resulting from these methodologies, open to considerable differences and controversies.⁶⁸ The result has been in recent decades a proliferation of taxonomies: three Domains⁶⁹; five Kingdoms⁷⁰; six Kingdoms⁷¹; six Super-groups⁷²; and so on.⁷³ While the five Kingdoms classification appears to remain the consensus, it is being challenged by these other schemes so that taxonomy itself cannot be said to be stable. Rather, taxonomy continues to develop taking advantage of new technological developments and the plethora of available (genetic) information.

These taxonomic classifications are linked to co-evolving naming codes for organisms traditionally treated as animals (International Code of Zoological Nomenclature), plants (International Code of Botanical Nomenclature and supplementary codes), bacteria (International Code of Nomenclature of Bacteria) and viruses (International Code of Virus Classification and Nomenclature and various other contested proposals). These co-evolving naming codes each require a description or diagnosis of the organism in the context of a taxonomic classification to differentiate the named entity from other taxa,⁷⁴ and these differences (and similarities) are increasingly fine as the classifications move towards the lower rank taxa of subspecies, varieties,

⁶³ See, for example, Jeffrey Schwartz and Bruno Maresca, “Do Molecular Clocks Run at All? A Critique of Molecular Systematics” (2006) 1 *Biological Theory* 357.

⁶⁴ See, for examples, E. Wiley, “An Annotated Linnaean hierarchy, with Comments on Natural Taxa and Competing Systems” (1979) 28 *Systematic Zoology* 308; G. Griffiths, “The Future of Linnaean Nomenclature” (1976) 25 *Systematic Zoology* 168.

⁶⁵ See, for example, Kevin de Queiroz and Jacques Gauthier, “Phylogenetic Taxonomy” (1992) 23 *Annual Review of Ecology and Systematics* 449, 454–457 and the references therein.

⁶⁶ See, for example, James Brown, “Ancient Horizontal Gene Transfer” (2003) 4 *Nature Reviews Genetics* 121. Notably, comparative analysis of genomes suggests that there may even be horizontal gene transfer between Domains: see, for example, Karen Nelson, Rebecca Clayton et al., “Evidence for Lateral Gene Transfer between Archaea and Bacteria from Genome Sequence of *Thermotoga maritima*” (1999) 399 *Nature* 323. See also Michael Lynch, “The Frailty of Adaptive Hypotheses for the Origins of Organismal Complexity” (2007) 104 *Proceedings of the National Academy of Sciences of the United States of America* 8597.

⁶⁷ See, for example, W. Mat, H. Xue and J. Wong, “The Genomics of LUCA” (2008) 13 *Frontiers in Bioscience* 5605; A. Mushegian, “Gene Content of LUCA, the Last Universal Common Ancestor” (2008) 13 *Frontiers in Bioscience* 4657. See also Arturo Becerra, Luis Delaye et al., “The Very Early Stages of Biological Evolution and the Nature of the Last Common Ancestor of the Three Major Cell Domains” (2007) 38 *Annual Review of Ecology, Evolution, and Systematics* 361.

⁶⁸ See, for example, Martin Embley and William Martin, “Eukaryotic Evolution, Changes and Challenges” (2006) 440 *Nature* 623 (an in particular compare references 57–61 and 62–64 about the origins of mitochondria). For an overview of the contested values in recent taxonomy contrast, for examples, Mark Blaxter, “The Promise of a DNA Taxonomy” (2004) 359 *Philosophical Transactions of the Royal Society of London B: Biological Science* 669; Quentin Wheeler, “Taxonomic Triage and the Poverty of Phylogeny” (2004) 359 *Philosophical Transactions of the Royal Society of London B: Biological Science* 571, 576–578.

⁶⁹ See Carl Woese, “Interpreting the Universal Phylogenetic Tree” (2000) 97 *Proceedings of the National Academy of Sciences USA* 8392; Carl Woese, Otto Kandler and Mark Wheelis, “Towards a Natural System of Organisms: Proposal for the Domains Archaea, Bacteria, and Eucarya” (1990) 87 *Proceedings of the National Academy of Sciences USA* 4576.

⁷⁰ See R. Whittaker, “New Concepts of Kingdoms of Organisms” (1969) 163 *Science* 150.

⁷¹ See Thomas Cavalier-Smith, “Only Six Kingdoms of Life” (2004) 271 *Philosophical Transactions of the Royal Society of London B: Biological Science* 1251. See also William Balch, Linda Magrum et al., “An Ancient Divergence Among the Bacteria” (1977) 9 *Journal of Molecular Evolution* 305.

⁷² See, for example, Laura Wegener Parfrey, Erika Barbero et al., “Evaluating Support for the Current Classification of Eukaryotic Diversity” (2006) 2(12) *PLoS Genetics* 2062 (e220). Notably, this “super group” classification system has not gained consensus support albeit some of the details about relationships are being considered and addressed: see, for example, Fabien Burki, Kamran Shalchian-Tabrizi et al., “Phylogenomics Reshuffles the Eukaryotic Supergroups” (2007) 2(8) *PLoS One* 1 (e790); Jeremiah Hackett, Hwan Su Yoon et al., “Phylogenomic Analysis Supports the Monophyly of Cryptophytes and Haptophytes and the Association of Rhizaria with Chromalveolates” (2007) 24 *Molecular Biology and Evolution* 1702. See also Patrick Keeling, Gertraud Burger et al., “The Tree of Eukaryotes” (2005) 20 *Trends Ecology and Evolution* 670; Sina Adl, Alastair Simpson et al., “The New Higher Level Classification of Eukaryotes with Emphasis on the Taxonomy of Protists” (2005) 52 *Journal of Eukaryotic Microbiology* 399.

⁷³ See generally David Walsh and Ford Doolittle, “The Real ‘Domains’ of Life” (2005) 15 *Current Biology* R237; Thorsten Allers and Moshe Mevarech, “Archaeal Genetics — The Third Way” (2005) 6 *Nature Reviews Genetics* 58.

⁷⁴ See, for examples, International Code of Zoological Nomenclature art.13.1; International Code of Botanical Nomenclature art.32.1; International Code of Nomenclature of Bacteria r.27(2); International Code of Virus Classification and Nomenclature r.5.

forms, cultivars, and so on.⁷⁵ The current naming codes⁷⁶ are presently weighed in favour of grouping organisms according to the “traditional” (or pre-Darwin Linnaean) system of taxonomy and any anatomical and bio-molecular *similarities* (and specifically to Genera and Species).⁷⁷ Alternatives that address phylogenetics (and cover all organisms) are currently proposed with some effects for naming.⁷⁸ Despite these alternative schemes, resolving differences using taxonomy and the related names at high-level taxa of Kingdoms and Divisions (Phyla) is likely to remain useful, while such distinctions at lower level taxa might not be so useful.⁷⁹ To address these lower level taxa distinctions other naming codes have been adopted to address the specifically different requirements of the organisms being distinguished. This is particularly necessary for plants in cultivation⁸⁰ because they rapidly diverge from their wild relatives on domestication (domestication syndrome)⁸¹ often losing undesirable morphological and physiological traits.⁸² For plants the International Code of Nomenclature for Cultivated Plants (Cultivated Plant Code) essentially⁸³ adds to the International Code of Botanical Nomenclature by adding extra elements to names to differentiate lower level variations (below Species taxon).⁸⁴

The Cultivated Plant Code is based around the “cultivar”, the “group” and the “grex”. A grex is the category for assemblages of plant based on parentage and applies only to orchids.⁸⁵ The “cultivar” (with the term “variety” being a common equivalent)⁸⁶ and the “group” are both assemblages of plants.⁸⁷ The “group” is “[a] taxon at or below the rank of species that is no longer

recognized as having taxonomic value in botany yet which continues to have utility in agriculture, horticulture or silvicultural classification”.⁸⁸ The “cultivar” is “an assemblage of plants that: (a) has been selected for a particular character or combination of characters; (b) is distinct, uniform and stable in these characters; and (c) when propagated by appropriate means, retains those characters”.⁸⁹ In effect, a “cultivar” is the most basic taxonomic unit of a cultivated plant and a “group” is an assemblage of similarly named cultivars.⁹⁰ The consequence of the Cultivated Plant Code is to bring some consistency to nomenclature by setting out the basic rules for naming.⁹¹ While not perfect, the stability of names is assisted by international listings of prominent names, including various checklists and registers of known names published by the various International Cultivar Registration Authorities,⁹² the *List of Stabilized Names* by the International Seed Testing Association,⁹³ the *Explanatory Notes on Variety Denominations under the UPOV Convention* by the UPOV secretariat,⁹⁴ and so on.

The intention of the 1991 UPOV Convention was to confine the scope of the “breeder’s right” to a “variety” according to its taxonomic identification at “the lowest known [taxon] rank”. The significance for our purposes is that both taxonomy and the naming codes are the mechanism for addressing the meaning of “taxon” in the definition of “variety”. Each variety is thus diagnosed according to the agreed principles of taxonomy and the naming codes, and then assigned a denomination (a unique naming identifier)⁹⁵ consistent with that taxonomy

⁷⁵ Notably the naming codes expressly exclude directly linking naming to taxonomy, so as to separate the name of the organism from the characters of the organism: see International Code of Zoological Nomenclature, Preamble; International Code of Botanical Nomenclature, Preamble 1 and 9; International Code of Nomenclature of Bacteria, General Consideration 4. In contrast, the classification and naming of “viruses” coincide: International Code of Virus Classification and Nomenclature r.1. Further, International Code of Nomenclature for Cultivated Plants perhaps reflects the ambiguity in this strict separation between naming and taxonomy: “The *International Code of Botanical Nomenclature* provides for names in Latin form for taxa of all organisms traditionally treated as plants whose naming is not governed by this *Code*” (footnote omitted); International Code of Nomenclature for Cultivated Plants, Preamble 8. See generally David Gledhill, *The Names of Plants*, 4th edn (Cambridge University Press, 2008); Roger Spencer, Robert Cross and Peter Lumley, *Plant Names: A Guide to Botanical Nomenclature*, 3rd edn (CSIRO Publishing, 2007).

⁷⁶ See International Code of Zoological Nomenclature, International Code of Botanical Nomenclature and supplementary codes, International Code of Nomenclature of Bacteria, Code of Virus Classification and Nomenclature and various other contested proposals: see generally Sandra Knapp, Gerardo Lamas et al., “Stability or Stasis in the Names of Organisms: The Evolving Codes of Nomenclature” (2004) 359 *Philosophical Transactions of the Royal Society London B* 611 and the references therein.

⁷⁷ See, for example, Thomas Cavalier-Smith, “A Revised Six-kingdom System of Life” (1998) 73 *Biological Reviews* 203, 203 and 213–214. This also flows through to the uses of language in the naming schemes: see De Queiroz and Gauthier, “Phylogenetic Taxonomy” (1992) 23 *Annual Review of Ecology and Systematics* 449, 452–453.

⁷⁸ See, for examples, BioCode (Werner Greuter, George Garrity et al., “Draft BioCode (2011): Principles and Rules Regulating the Naming of Organisms” (2011) 60 *Taxon* 201; David Hawksworth, “Introducing the Draft BioCode” (2011) 60 *Taxon* 199) and PhyloCode (Michel Laurin and Philip Cantino, “Second Meeting of the International Society for Phylogenetic Nomenclature: A Report” (2007) 36 *Zoologica Scripta* 109; Matjaz Kuntner and Ingi Agnarsson, “Are the Linnean and Phylogenetic Nomenclatural Systems Combinable? Recommendations for Biological Nomenclature” (2006) 55 *Systematic Biology* 774).

⁷⁹ See, for examples, Eugene Koonin, “The Biological Big Bang Model for the Major Transitions in Evolution” (2007) 2 *Biology Direct* 21; Kevin Nixon, James Carpenter and Dennis Stevenson, “The PhyloCode Is Fatally Flawed, and the ‘Linnaean’ System Can Easily Be Fixed” (2003) 69 *Botanical Review* 111; Yuri Wolf, Igor Rogozin et al., “Genome Trees and the Tree of Life” (2002) 18 *Trends in Genetics* 472.

⁸⁰ Being “deliberately selected plants that may have arisen by intentional or accidental hybridization in cultivation, by selection from existing cultivated stocks, or from variants within wild populations that are maintained as recognizable entities solely by continued propagation ... sometimes referred to as cultigens”: International Code of Nomenclature for Cultivated Plants, Preamble 1 (footnote “cultivated plants”).

⁸¹ See Karl Hammer, “Das Domestikationssyndrom” (1984) 32 *Die Kulturpflanze* 11. See also Epimaki Koinange, Shree Singh and Paul Gept, “Genetic Control of the Domestication Syndrome in Common Bean” (1996) 36 *Crop Science* 1037.

⁸² See David Spooner and Ronald van den Berg, “Plant Nomenclature and Taxonomy” (2003) 28 *Horticultural Reviews* 1, 10 and the references therein. See also Junhua Peng, Dongfa Sun and Eviatar Nevo, “Domestication Evolution, Genetics and Genomes in Wheat” (2011) 28 *Molecular Breeding* 281, 285–287 and the references therein.

⁸³ The exceptions concern some cultigen hybrids and some ancient cultigens: see Spencer, Cross and Lumley, *Plant Names* (2007), pp.49–50 and 139–140.

⁸⁴ International Code of Nomenclature for Cultivated Plants, Preamble 1 and Principle 2. See also Spooner and Van den Berg, “Plant Nomenclature and Taxonomy” (2003) 28 *Horticultural Reviews* 1, 33–45.

⁸⁵ International Code of Nomenclature for Cultivated Plants art.4.1.

⁸⁶ International Code of Nomenclature for Cultivated Plants art.2 (n.2).

⁸⁷ International Code of Nomenclature for Cultivated Plants arts 2.3 and 3.1.

⁸⁸ International Code of Nomenclature for Cultivated Plants art.3.3.

⁸⁹ International Code of Nomenclature for Cultivated Plants art.2.3.

⁹⁰ See Spooner and Van den Berg, “Plant Nomenclature and Taxonomy” (2003) 28 *Horticultural Reviews* 1, 10.

⁹¹ International Code of Nomenclature for Cultivated Plants arts 8, 18 and 20–24.

⁹² See International Society for Horticultural Science, “International Cultivar Registration Authorities”, <http://www.ishs.org/sci/icra.htm> [Accessed May 27, 2014].

⁹³ International Seed Testing Association, *List of Stabilized Names*, 6th edn (International Seed Testing Association, 2013).

⁹⁴ International Union for the Protection of New Varieties of Plants, *Explanatory Notes on Variety Denominations under the UPOV Convention*, UPOV/INF/12/1 (2006).

⁹⁵ International Convention for the Protection of New Varieties of Plants 1991 arts 5(2) and 20.

and the relevant naming code.⁹⁶ As a construct the term “variety” is, and always will be, open to criticism for being imprecise.⁹⁷ The important point, though, is that the term “variety” in the context of EDV is conceived as an object defined by its similarities and differences according to the conventions (the methods and principles) of taxonomy and the naming codes.⁹⁸

The phenotype preference

The definition of “variety” is also constrained by the meaning of the term “genotype” in the context of “the expression of the characteristics resulting from a given genotype or combination of genotypes”.⁹⁹ This use is consistent with a taxonomic assessment of a variety in that the genotype is the heritable features of the variety and includes the expressed characters of the plant as a result of its genetic heritage. Other elements of the definition of “variety” are that the variety is “defined by the expression of the characteristics resulting from a given genotype or combination of genotypes” and “distinguished from any other plant grouping by the expression of at least one of the said characteristic”.¹⁰⁰ The “characteristics” in this formulation are conceived according to the threshold requirements for newness (novelty), distinctness, uniformity and stability—the DUS testing.¹⁰¹ The threshold is satisfied for: “stability”, where the relevant characteristics are unchanged after repeated propagation¹⁰²; “uniformity”, where the characteristics are sufficiently uniform¹⁰³; and “distinctness”, where the variety “is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application”.¹⁰⁴ The “characteristics” of the variety are the features of the plant that define the variety.¹⁰⁵ Thus, the “characteristics” of a

variety are generally the phenotypic features (such as leaf shape, node length, growth rates, and so on),¹⁰⁶ and might also include a biochemical test like a DNA screening probe for a phenotype linked gene,¹⁰⁷ reaction to factors (such as herbicides),¹⁰⁸ and so on.¹⁰⁹ The basic requirement for a suitable “characteristic” is that it is “expressed”, and:

“[I]ts expression:

- (a) results from a given genotype or combination of genotypes ...;
- (b) is sufficiently consistent and repeatable in a particular environment;
- (c) exhibits sufficient variation between varieties to be able to establish distinctness;
- (d) is capable of precise definition and recognition ...;
- (e) allows uniformity requirements to be fulfilled;
- (f) allows stability requirements to be fulfilled, meaning that it produces consistent and repeatable results after repeated propagation or, where appropriate, at the end of each cycle of propagation.”¹¹⁰

The “expression” of these characteristics may then be broadly considered as the apparent phenotype linked to the genotype (such as the length of a stem being short, medium or long) variously framed as “qualitative”, “quantitative”, “pseudo-qualitative” and “special” phenotypes,¹¹¹ and the “new types of characteristics” being the array of biochemical and molecular markers linked to phenotypic characteristics.¹¹² The importance of these distinctions is that the “genotype” is confined in the 1991 UPOV Convention to being the “expression” of the genotype as “characteristics” that requires some kind of

⁹⁶ See International Union for the Protection of New Varieties of Plants, *Explanatory Notes on Variety Denominations under the UPOV Convention*, UPOV/INF/12/4 (2012). See also Brad Sherman, “Taxonomic Property” (2008) 67 *Cambridge Law Journal* 560, 566–573.

⁹⁷ For a critique see, for example, Mark Janis and Stephen Smith, “Technological Change and the Design of Plant Variety Protection Regimes” (2007) 82 *Chicago-Kent Law Review* 1557, 1570–1579. See also Barry Greengrass, *Report of the Committee of Experts on the Interface between Patent Protection and Plant Breeder’s Rights*, WIPO/UPOV/CE/1/4 (1990). For an elegant example of the confusion in language see Robert Clausen, “On the Use of the Terms ‘Subspecies’ and ‘Variety’” (1941) 43(509) *Rhodora* 157.

⁹⁸ See Foucault, *The Order of Things* (2002), pp.150–158.

⁹⁹ International Convention for the Protection of New Varieties of Plants 1991 art.1(vi).

¹⁰⁰ International Convention for the Protection of New Varieties of Plants 1991 art.1(vi).

¹⁰¹ International Convention for the Protection of New Varieties of Plants 1991 art.5(1). See also International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3 (2002), para.2.4.3.

¹⁰² International Convention for the Protection of New Varieties of Plants 1991 art.9.

¹⁰³ International Convention for the Protection of New Varieties of Plants 1991 art.8.

¹⁰⁴ International Convention for the Protection of New Varieties of Plants 1991 art.7.

¹⁰⁵ International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3 (2002), para.2.4.1.

¹⁰⁶ A range of test guidelines directed to specific plant varieties are provided by UPOV: see, for examples, International Union for the Protection of New Varieties of Plants, *Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability: Zea mays L.*, TG/2/7 (2009); International Union for the Protection of New Varieties of Plants, *Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability: Lolium spp.*, TG/4/8 (2006); and so on.

¹⁰⁷ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.9.

¹⁰⁸ International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3 (2002), para.2.5.3.

¹⁰⁹ See also M. Camlin, “Plant Cultivar Identification and Registration — The Role of Molecular Techniques” (2003) 625 *Acta Horticulturae* 37.

¹¹⁰ International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3 (2002), para.4.2.1.

¹¹¹ International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants* (TG/1/3), paras 4.4 and 4.6.

¹¹² International Union for the Protection of New Varieties of Plants, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants* (TG/1/3), para.4.7. See also International Union for the Protection of New Varieties of Plants, *Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)*, TG/15/1 (2013).

linkage between a genotypic feature (such as a gene) and a measurable “characteristic” phenotype (such as a leaf shape).¹¹³ Thus, biochemical and molecular techniques have some application either where a genotypic character (such as a DNA sequence) is directly linked to the phenotypic character (such as leaf shape),¹¹⁴ or where the genotypic characters is identified using molecular markers is a proxy for a phenotypic character (often using statistical models to measure sufficient thresholds of difference),¹¹⁵ but not a genotypic characteristic unlinked to a phenotypic characteristic (such as unlinked single nucleotide polymorphisms, sequence repeats, and so on).¹¹⁶ In effect the 1991 UPOV Convention is directed to *only* measurable phenotypes, and genotypic features are relevant *only* when they are linked to phenotypic characteristics because the phenotype (generally morphological or physiological) is the expression of the characteristics from the genotype.¹¹⁷ This apparent rejection of genotypic characters, predominantly in the form of molecular markers, remains probably because of a concern that accepting these unlinked genotypic characters will erode the worth of breeder's rights because the degree of distinctness between varieties will decrease with the increasingly fine molecular differences that are presently not apparent in distinctness assessments.¹¹⁸ Significantly, however, the focus on phenotype does not exclude the operation of genotypic techniques:

“[I]t should not be forgotten that the work of plant breeders at the molecular level is aimed at improvements in the phenotype, whether that is at the level of plant morphology, development or biochemical or physiological properties. What is relevant is the resulting characteristics of the variety. Regardless of the processes involved, a farmer or grower will ultimately require the work of the plant

breeder to be encapsulated in a new plant variety—which is the subject matter of protection in the UPOV system.”¹¹⁹

While genotype may not be the significant focus in assessing newness, distinctness, uniformity and stability, it is notably that the EDV provision also refers to “genotype” although with a slightly different context.¹²⁰ The similar phrases appear in both the definition of “variety” and the thresholds for EDV with the addition of the term “essential” for EDV—so, “the expression of the *essential* characteristics resulting from a given genotype or combination of genotypes” (emphasis added).¹²¹ In the context of the EDV thresholds the phrase appears as a base line for comparison of the initial variety against the putative EDV with the thresholds for the EDV being “predominantly derived”, “clearly distinguishable”, retains the “essential characteristics” and any “differences” result from the acts of derivation.¹²² Put differently, the initial variety and the putative EDV must both have (almost) the same phenotypic characteristics, but the EDV only needs to be “clearly distinguishable”. There are no limits on these “distinguishable” characteristics being merely the expressed characteristics from genotypes or combinations of genotypes, and so the “distinguishable” characteristics might include *any* measures of differences (within the conventions of taxonomy and the naming codes), including molecular and biochemical differences that are apparent *only* in the genetic information of the variety.

The analysis so far asserts that the inherent preferences in the 1991 UPOV Convention are for similarities and differences between an initial variety and a putative EDV to be assessed according to the conventions of taxonomy and the naming codes, and that the distinctions between the initial variety and the putative EDV are not confined to mere phenotypic differences. This means that genotypic

¹¹³ See, for example, International Union for the Protection of New Varieties of Plants, *Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)*, UPOV/INF/18/1 (2011), paras 3.1.1 to 3.2.3. See also International Union for the Protection of New Varieties of Plants, *Ad hoc Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (BMT Review Group)*, CAJ/45/5 (2002). Notably, the Enlarged Board of Appeal of the European Patent Office in *NOVARTIS/Transgenic Plant G01/98* (2000) OJ EPO 111, 126 stated about the term in the EC Regulation on Community Plant Variety Rights that “[t]he reference to the expression of the characteristics that result from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information”. For an alternative view see Michael Camlin, “Plant Cultivar Identification and Registration — The Role for Molecular Techniques” (2003) 625 *Acta Horticulturae* 37, 39; Stephen Smith, Elizabeth Jones et al., “Genomic Approaches and Intellectual Property Protection for Variety Release: A Perspective from the Private Sector” in *Genomics of Plant Genetic Resources* (2014), pp.35–37.

¹¹⁴ International Union for the Protection of New Varieties of Plants, *Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)*, UPOV/INF/18/1, para.2.1. See also International Union for the Protection of New Varieties of Plants, *BMT Review Group*, CAJ/45/5 (2002), para.10, option 1, and Annex (Proposal 1).

¹¹⁵ International Union for the Protection of New Varieties of Plants, *Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)*, UPOV/INF/18/1 (2011), paras 2.1 and 2.4. See also International Union for the Protection of New Varieties of Plants, *BMT Review Group*, CAJ/45/5 (2002), para.10, option 2, and Annex (Proposals 2–4); International Union for the Protection of New Varieties of Plants, *Ad Hoc Subgroup of Technical and Legal Experts of Biochemical and Molecular Techniques* (BMT Review Group), BMT-RG/Apr09/2 (2009).

¹¹⁶ International Union for the Protection of New Varieties of Plants, *Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)*, UPOV/INF/18/1 (2011), para.2.1. See also Button, “New Developments in the Union for the Protection of New Varieties of Plants (UPOV)” (2006) 714 *Acta Horticulturae* 195, 197–203; International Union for the Protection of New Varieties of Plants, *BMT Review Group*, CAJ/45/5 (2002), para.10, option 3, and Annex (Proposals 5 and 6).

¹¹⁷ For some criticism of this feature of the 1991 UPOV Convention see John Laws, Stephen Anderson et al., “Characterisation of Maize Germplasm: Comparison of Morphological Datasets Compiled Using Different Approaches to Data Recording” (2012) 56 *Maydica* 1. See also International Union for the Protection of New Varieties of Plants, *The Estimation of Molecular Genetic Distances in Maize or DUS and ED Protocols: Optimization of the Information and New Approaches of Kinship*, BMT/3/6 (1995).

¹¹⁸ See F. van Eeuwijk and C. Baril, “Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation” (2000) 541 *Acta Horticulturae* 35, 36.

¹¹⁹ Jay Sanderson, “Why UPOV is Relevant, Transparent and Looking to the Future: A Conversation with Peter Button” (2013) 8 *Journal of Intellectual Property Law and Practice* 615, 618.

¹²⁰ The basic text for EDV of the 1991 UPOV Convention's reference to “genotype” was of concern to some negotiators in that they considered that conformity to a genotype could not be assessed while the “expression of the genotype” could be assessed: see Diplomatic Conference, *Publication No.346(E)* (1992), pp.344–346. See also International Union for the Protection of New Varieties of Plants, *BMT Review Group*, CAJ/45/5 (2002).

¹²¹ International Convention for the Protection of New Varieties of Plants 1991 arts.1(vi) and 14(5)(b)(i) and (iii).

¹²² International Convention for the Protection of New Varieties of Plants 1991 art.14(5).

measures are potentially available in assessing EDV. The next question is about the technical limits that have been investigated in addressing the EDV thresholds.

The technicality issues

Plant breeding essentially involves discovering or creating genetic variation in a plant and then selecting from the available variation desirable traits using skill and judgment aided by an array of technologies. For an EDV there is a threshold of difference that expands the scope of the breeder's right in the initial variety because the putative EDV is not different enough to justify its own full breeder's right. The question is where and how to set that threshold of difference so that a particular plant can be said to be, or not to be, an EDV? The 1991 UPOV Convention is unhelpful here, as it provides neither a method for determining similarity (genetic conformity) nor a technical standard (breeding method) for benchmarking the initial variety or putative EDV, albeit some methods are mentioned as examples that might lead to a finding of essential derivation.¹²³ The challenge for objectifying law here, therefore, is to find a suitable measure of difference and a common understanding of where the threshold of sufficient difference lies (albeit within the conceptions of difference according to the taxonomy and the naming codes). This appears to be a simple technical problem of assessing and measuring genetic relatedness. The issue is how to measure genetic relatedness and who has the burden of proof?

Measuring difference

Genetic relatedness can be measured in many ways—pedigree analysis, morphological markers, physiological markers, cytological markers, biometric analysis of qualitative and quantitative markers, heterosis, segregation variances, isozymes, and more recently, the plethora of molecular markers using techniques such as restriction fragment length polymorphisms (RFLPs), random amplified polymorphic DNAs (RAPDs), sequence characterised amplified regions (SCARs), amplified fragment length polymorphisms (AFLPs), simple sequence repeats (SSRs or microsatellites), inter-simple sequence repeats (ISSRs), single nucleotide polymorphisms (SNPs), and so on.¹²⁴ The advent of whole genome sequencing (and particularly Next Generation Sequencing)¹²⁵ now makes direct comparisons of whole genomes possible that should allow a precise description of genetic relatedness including the sequences directly contributed by the parentals.¹²⁶

At the time of the 1961 UPOV Convention, however, relatedness was essentially only measurable according to morphological, physiological and cytological markers. By the 1991 UPOV Convention there were an additional array of biochemical and molecular markers. Since the 1991 UPOV Convention there have been significant developments and advances in molecular technology and the means of interpreting the various molecular (and biochemical) markers. This has been particularly evident in the considerable body of evidence that has now accumulated demonstrating that a variety of molecular techniques directed to plant DNA, including non-expressed molecular markers, and analyses using statistical models can provide useful measures of

¹²³ Notably the United States Supreme Court in *JEM AG Supply Inc v Pioneer Hi-Bred International Inc* 534 U.S. 124, 140 (2001) stated “[p]ractically, this means that hybrids created from protected varieties are also protected”.

¹²⁴ See Roberto Tuberosa, Andreas Graner and Rajeev Varshney, “Genomics of Plant Genetic Resources: An Introduction” (2011) 9 *Plant Genetic Resources* 151 and the references therein; J. Glaszmann, B. Kilian et al., “Accessing Genetic Diversity for Crop Improvement” (2010) 13 *Current Opinion in Plant Biology* 167 and the references therein.

¹²⁵ See, for example, Paul Visendi, Jacqueline Batley and David Edwards, “Next Generation Sequencing and Germplasm Resources” in *Genomics of Plant Genetic Resources* (2014), pp.369–390; Rajeev Varshney, Spurthi Nayak et al., “Next Generation Sequencing Technologies and their Implications for Crop Genetics and Breeding” (2009) 27 *Trends in Biotechnology* 522.

¹²⁶ See, for example, Glaszmann et al., “Accessing Genetic Diversity for Crop Improvement” (2010) 13 *Current Opinion in Plant Biology* 167.

similarity and difference.¹²⁷ The question is whether the 1991 UPOV Convention is amenable to measuring EDVs taking advantage of all the available techniques and how these measures should be deployed?

The EDV standard essentially requires that the putative EDV is not itself an EDV,¹²⁸ be “predominantly derived” from the initial variety,¹²⁹ and be “clearly distinguishable from the initial variety”,¹³⁰ while the putative EDV still “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”.¹³¹ The construction of these threshold requirements for an EDV are significant because they essentially impose two distinct measuring standards¹³²: (1) that the putative EDV be linked to an initial variety from which it can be said to be “predominantly derived”—a question of genetic

origin¹³³; and (2) the EDV to conform to the essential characteristics and yet be clearly distinguishable—a question of the degree of similarity.¹³⁴ While these are effectively two different technical standards that need to be satisfied, in most instances, however, genetic origin and genetic similarity are both addressed by an assessment of “genetic distance”—a numerical measure of how recently a common ancestor was shared based on a technical assessment of the genomes.

The question of genetic origin is simply an issue of determining the pedigree of the putative EDV and that its genealogy can be traced to the alleged initial variety. This is now a relatively simple technical challenge using molecular markers,¹³⁵ there being a range of techniques with varying degrees of effectiveness in assessing

¹²⁷ See, for examples dealing specifically with essential derivation, Noli, Teriaca and Conti, “Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat” (2012) 29 *Molecular Breeding* 687; A. Kahler, J. Kahler et al., “North American Study on Essential Derivation in Maize: II. Selection and Evaluation of a Panel of Simple Sequence Repeat Loci” (2010) 50 *Crop Science* 486; E. Jones, W. Chu et al., “Development of Single Nucleotide Polymorphism (SNP) Markers for Use in Commercial Maize (*Zea mays* L.) Germplasm” (2009) 24 *Molecular Breeding* 165; L. Crespel, A. Pernet et al., “Application of ISSRs for Cultivar Identification and Assessment of Genetic Relationships in Rose” (2009) 128 *Plant Breeding* 501; Thomas Borchert, Joerg Krueger and Annette Hohe, “Implementation of a Model for Identifying Essentially Derived Varieties in Vegetatively Propagated Calluna vulgaris Varieties” (2008) 9 *BMC Genetics* 56; J. Gustafson, M. Maccaferri et al., “Relationships among Durum Wheat Accessions. II. A Comparison of Molecular and Pedigree Information” (2007) 50 *Genome* 385; M. Heckenberger, M. Bohn et al., “Identification of Essentially Derived Varieties with Molecular Markers: An Approach Based on Statistical Test Theory and Computer Simulations” (2005) 111 *Theoretical and Applied Genetics* 598; M. Heckenberger, M. Bohn et al., “Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Hymozygous Lines: II. Morphological Distances and Heterosis in Comparison with Simple Sequence Repeat and Amplified Fragment Length Polymorphism Data in Maize” (2005) 45 *Crop Science* 1132; Heckenberger, M. Bohn and A. Melchinger, “Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Hymozygous Lines: I. Simple Sequence Repeat Data from Maize Inbreds” (2005) 45 *Crop Science* 1120; J. Staub, S. Chung and G. Fazio, “Conformity and Genetic Relatedness Estimation in Crop Species Having a Narrow Genetic Base: The Case of Cucumber (*Cucumis sativus* L.)” (2005) 124 *Plant Breeding* 44; Van Eeuwijk and Law, “Statistical Aspects of Essential Derivation, With Illustrations Based on Lettuce and Barley” (2004) 137 *Euphytica* 129, above n 11; Ben Vosman, Dirk Visser et al., “The Establishment of ‘Essential Derivation’ Among Rose Varieties Using AFLP” (2004) 109 *Theoretical and Applied Genetics* 1718; J. Smith and M. Senior, “The Utility of Simple Sequence Repeat (SSR) Data to Preferentially Identify Progeny Lines of Maize (*Zea mays* L.) that are Bred from Known Inbred Parents” (2000) 45 *Maydica* 205; T. Gilliland, R. Coll et al., “Estimating Genetic Conformity Between Related Ryegrass (*Lolium*) Varieties. 1. Morphology and Biochemical Characterisation” (2000) 6 *Molecular Breeding* 569; and so on. See also Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, EDV — The ISF Approach, BMT/12/22 (2010); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Standards for Helping to Determine EDV Status in Maize (Zea Mays L.) using SSRs and Future Prospects Using SNPs*, BMT/12/14 (2010); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *The Use of Molecular Techniques when Infringement of PBR or Essentially Derived Varieties is Suspected*, BMT/11/28 (2008); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Concepts of Dependence and Essential Derivation. The Possible Use of DNA Markers*, BMT/11/24 (2008); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Essentially Derived Varieties (EDV) in the Area of Asexually Reproduced Ornamental and Fruit Varieties*, BMT/11/22 (2008); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Putting the EDV Concept into Practice for Maize: SSRs Today and SNPs Tomorrow? (Revised)*, BMT/11/18 REV (2008); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *The Assessment of Essential Derivation in Grapevine*, BMT/11/16 (2008); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Study on Essential Derivation in Corn in North America — Abbreviated Report on Phase 3*, BMT-TWA/MAIZE/2/7-D (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Identifying Essentially Derived Varieties with Molecular Markers*, BMT-TWA/MAIZE/2/7-C (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: The SEPROMA Approach — Technical Issues*, BMT-TWA/MAIZE/2/7-B (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Concepts of Essential Derivation and Dependence; Possible Use of DNA Markers: The Maize Case*, BMT-TWA/MAIZE/2/7-A (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Essential Derivation and Diversity Issues in Winter Wheat*, BMT/9/10 (2005); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *International Seed Federation (ISF) Oilseed Rape Essentially Derived Varieties (EDV) Study*, BMT/9/7 (2005); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Essential Derivation in Lettuce*, BMT/8/18 (2003); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Statistical Aspects of Essential Derivation*, BMT/8/17 (2003); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *The Use of Microsatellites for Identifying Putative EDV's in Rose*, BMT/8/16 (2003); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Molecular and other Markers for Establishing Essential Derivation in Crop Plants (MMEDV) — An Overview*, BMT/8/15 (2003); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *A Description and Update of MMEDV (Molecular and Other Markers for Establishing Essential Derivation in Crop Plants) — An EU FP5 Project*, BMT/7/14 (2001); Jan de Riek, “Are Molecular Markers Strengthening Plant Variety Registration and Protection?” (2001) 552 *Acta Horticulturae* 215; Van Eeuwijk and Baril, “Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation” (2000) 541 *Acta Horticulturae* 35; Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Assessment of Essential Derivation (by ASSINSEL)*, BMT/5/15 (1998); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Assessment of Essential Derivation Using Molecular Markers: A Tomato Pilot Study (by ASSINSEL)*, BMT/5/13 (1998); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Conclusions of a Model Study on Essential Derivation Using Tomato as a Crop*, BMT/4/17 (1997).

¹²⁸ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(a)(i).

¹²⁹ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(i).

¹³⁰ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(ii).

¹³¹ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(iii).

¹³² See also Smith, Jones and Nelson, “The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties” in *Genomics of Plant Genetic Resources* (2014), pp.54–56.

¹³³ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(a)(i) and (b)(i). See also International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992) para.13.

¹³⁴ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(ii) and (iii). See also International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.13.

¹³⁵ David Rodrigues, Francisco de Alcántara Neto and Ivan Schuster, “Identification of Essentially Derived Soybean Cultivars Using Microsatellite Markers” (2008) 8 *Crop Breeding and Applied Biotechnology* 74, 77; Heckenberger, Bohn et al., “Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Hymozygous Lines” (2005) 45 *Crop Science* 1120, 1138 and 1139. See also Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, *Molecular and other Markers for Establishing Essential Derivation in Crop Plants (MMEDV) — An Overview*, BMT/8/15 (2003).

relationships,¹³⁶ including proteins,¹³⁷ RFLPs,¹³⁸ AFLPs,¹³⁹ SSRs,¹⁴⁰ ISSRs,¹⁴¹ SNPs,¹⁴² and so on. The advent of whole genome sequencing will make the description of genetic origin much more accurate with the ability to identify the parental origins of particular sequences, although a combination of techniques (multiplexed genotyping technology) will provide the finest detailed genetic associations.¹⁴³ The increasing sophistication of genetic analysis also means that genetic origin is easily determined with the analysis able to clearly identify the various genetic contributions of the parental varieties through the generations.¹⁴⁴ It can be anticipated that affordable whole genome sequencing will make measuring genetic origin a very precise assessment.¹⁴⁵

The question of genetic similarity and where to draw the thresholds for EDV is more problematic. The generalised theoretical underpinning measuring genetic similarity rests on expected parental contributions of

inbreds with Mendelian inheritance of 50 per cent from each parent of an F₂-derived inbred, 75 per cent for a backcrossed-derived (BC₁-derived) inbred, and 25 per cent for a donor parent of a BC₁-derived inbred.¹⁴⁶ Based on these models, estimates of contributions using a range of possible genetic and mathematical properties can be calculated using various assumptions measuring markers of similarity and difference, whether they are morphological, physiological or genetic.¹⁴⁷ Essentially, allelic variation at marker loci provides a measure of conformity and disconformity.¹⁴⁸ In recent times various studies using the array of molecular techniques including RFLPs, AFLPs, SSRs (microsatellites), SNPs, and so on, demonstrate that molecular markers can be used to determine genetic similarity.¹⁴⁹ There remain, however, some technical challenges with the likely need to establish standardised procedures,¹⁵⁰ and with the extent of genetic diversity within each crop species differing measures of genetic similarity (also termed conformity) using

¹³⁶ See, for examples, Javier Ibáñez, Dolores Vélez et al., "Molecular Markers for Establishing Distinctness in Vegetatively Propagated Crops: A Case Study in Grapevine" (2009) 119 *Theoretical and Applied Genetics* 1213; Borchert, Krueger and Hohe, "Implementation of a Model for Identifying Essentially Derived Varieties in Vegetatively Propagated Calluna vulgaris Varieties" (2008) 9 *BMC Genetics* 56; M. Maccaferri, M. Sanguineti et al., "Relationships Among Durum Wheat Accessions. II. A Comparison of Molecular and Pedigree Information" (2007) 50 *Genome* 385; A. Garcia, L. Benchimol et al., "Comparison of RADP, RFLP, AFLP and SSR Markers for Diversity Analysis in Tropical Maize Inbred Lines" (2004) 27 *Genetics and Molecular Biology* 579; Wayne Powell, Michele Morgante et al., "The Comparison of RFLP, RAPD, AFLP and SSR (Microsatellite) Markers for Germplasm Analysis" (1996) 2 *Molecular Breeding* 225.

¹³⁷ See, for example, Gilliland, Coll et al., "Estimating Genetic Conformity Between Related Ryegrass (*Lolium*) Varieties" (2000) 6 *Molecular Breeding* 569.

¹³⁸ See, for examples, R. Bernardo, J. Romero-Severson et al., "Parental Contribution and Coefficient of Coancestry Among Maize Inbreds: Pedigree, RFLP, and SSR Data" (2000) 100 *Theoretical and Applied Genetics* 552; J. Smith, E. Chin et al., "An Evaluation of the Utility of SSR Loci as Molecular Markers in Maize (*Zea mays* L.): Comparisons with Data from RFLPs and Pedigree" (2007) 95 *Theoretical and Applied Genetics* 163; J. Smith and O. Smith, "Restriction Fragment Length Polymorphisms can Differentiate among US Maize Hybrids" (1991) 31 *Crop Science* 893.

¹³⁹ See, for examples, X. Qi and P. Lindhout, "Development of AFLP Markers in Barley" (2007) 254 *Molecular and General Genetics* 330; M. Maccaferri, S. Stefanelli et al., "Relationships Among Durum Wheat Accessions. I. Comparative Analysis of SSR, AFLP and Phenotypic Data" (2007) 50 *Genome* 373; I. Roldán-Ruiz, E. Calsyn et al., "Estimating Genetic Conformity Between Related Ryegrass (*Lolium*) Varieties. 2. AFLP Characterization" (2000) 6 *Molecular Breeding* 593.

¹⁴⁰ See, for examples, Maccaferri, Stefanelli et al., "Relationships Among Durum Wheat Accessions. I. Comparative Analysis of SSR, AFLP and Phenotypic Data" (2007) 50 *Genome* 373; Martin Heckenberger, Martin Bohn et al., "Variation of DNA Fingerprints Among Accessions within Maize Inbred Lines and Implications for Identification of Essentially Derived Varieties. I. Genetic and Technical Sources of Variation in SSR Data" (2002) 10 *Molecular Breeding* 181; Bernardo, Romero-Severson et al., "Parental Contribution and Coefficient of Coancestry Among Maize Inbreds" (2000) 100 *Theoretical and Applied Genetics* 552; Smith, Chin et al., "An Evaluation of the Utility of SSR Loci as Molecular Markers in Maize (*Zea mays* L.)" (2007) 95 *Theoretical and Applied Genetics* 163; Smith and Smith, "Restriction Fragment Length Polymorphisms can Differentiate among US Maize Hybrids" (1991) 31 *Crop Science* 893.

¹⁴¹ See, for example, Crespel, Pernet et al., "Application of ISSRs for Cultivar Identification and Assessment of Genetic Relationships in Rose" (2009) 128 *Plant Breeding* 501.

¹⁴² See, for example, Delphine van Inghelandt, Albrecht Melchinger et al., "Population Structure and Genetic Diversity in a Commercial Maize Breeding Program Assessed with SSR and SNP Markers" (2010) 120 *Theoretical and Applied Genetics* 1289; E. Jones, H. Sullivan et al., "A Comparison of Simple Sequence Repeat and Single Nucleotide Polymorphism Marker Technologies for the Genotypic Analysis of Maize (*Zea mays* L.)" (2007) 115 *Theoretical and Applied Genetics* 361.

¹⁴³ See Kyujung Van, Dong Hyun Kim et al., "Genomics of Plant Genetic Resources: Past, Present and Future" (2011) 9 *Plant Genetic Resources: Characterization and Utilization* 155.

¹⁴⁴ For an elegant example of this sophistication, see P. Gupta, S. Rustgi and R. Mir, "Array-based High-throughput DNA Markers for Crop Improvement" (2008) 101 *Heredity* 5. More generally see Tuberosa, Graner and Frison (eds), *Genomics of Plant Genetic Resources* (2014) and the chapters therein; Robert Cooke and James Reeves, "Plant Genetic Resources and Molecular Markers: Variety Registration in a New Era" (2003) 1 *Plant Genetic Resources* 81; and so on.

¹⁴⁵ See, for example, Emma Mace, Shuashuai Tai et al., "Whole-Genome Sequencing Reveals Untapped Genetic Potential in Africa's Indigenous Cereal Crop Sorghum" (2013) 4 *Nature Communications* 2320. See also Pauline Ng and Ewen Kirkness, "Whole Genome Sequencing" in Michael Barnes and Gerome Breen (eds), *Genetic Variation: Methods and Protocols* (Springer Science, 2010), pp.215–226; Amy Coombs, "The Sequencing Shakeup" (2008) 26 *Nature Biotechnology* 1109.

¹⁴⁶ Noting, of course, that the observed and expected parental contributions may also be different because of selection and genetic drift.

¹⁴⁷ See, for example, Noli, Teriaca and Conti, "Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat" (2012) 29 *Molecular Breeding* 687, and the references therein. See also J. Reif, A. Melchinger and M. Frisch, "Genetical and Mathematical Properties of Similarity and Dissimilarity Coefficients Applied in Plant Breeding and Seed Bank Management" (2005) 45 *Crop Science* 1; V. Lombard, P. Dubreuil, C. Dillmann and C. Baril, "Genetic Distance Estimators Based on Molecular Data for Plant Registration and Protection: A Review" (2001) 546 *Acta Horticulturae* 55; Jiankang Wang and Rex Bernardo, "Variance of Marker Estimates of Parental Contribution to F₂ and BC₁-Derived Inbreds" (2000) 40 *Crop Science* 659.

¹⁴⁸ See generally Van Eeuwijk and Law, "Statistical Aspects of Essential Derivation, With Illustrations Based on Lettuce and Barley" (2004) 137 *Euphytica* 129; Van Eeuwijk and Baril, "Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation" (2000) 541 *Acta Horticulturae* 35.

¹⁴⁹ See, for examples, Noli, Teriaca and Conti, "Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat" (2012) 29 *Molecular Breeding* 687; Barry Nelson, Alex Kahler et al., "Evaluation of the Numbers of Single Nucleotide Polymorphisms Required to Measure Genetic Gain Distance in Maize (*Zea mays* L.)" (2011) 51 *Crop Science* 1470; Stephen Smith, Eric Hoeft et al., "Genetic Diversity Among US Sunflower Inbreds and Hybrids: Assessing Probability of Ancestry and Potential for Use in Plant Variety Protection" (2009) 49 *Crop Science* 1295; Rodrigues, De Alcântara Neto and Schuster, "Identification of Essentially Derived Soybean Cultivars Using Microsatellite Markers" (2008) 8 *Crop Breeding and Applied Biotechnology* 74; Vosman, Visser et al., "The Establishment of 'Essential Derivation' Among Rose Varieties Using AFLP" (2004) 109 *Theoretical and Applied Genetics* 1718; R. Bernardo and A. Kahler, "North American Study of Essential Derivation in Maize: Inbreds Developed Without and With Selection from F₂ Populations" (2001) 102 *Theoretical and Applied Genetics* 986; Bernardo, Romero-Severson et al., "Parental Contribution and Coefficient of Coancestry Among Maize Inbreds" (2000) 100 *Theoretical and Applied Genetics* 552; C. Dillmann, A. Bar-Hen et al., "Comparison of RFLP and Morphological Distances between Maize (*Zea mays* L.) Inbred Lines — Consequences for Germplasm Protection Purposes" (1997) 95 *Theoretical and Applied Genetics* 92. See also International Union for the Protection of New Varieties of Plants, *The Estimation of Molecular Genetic Distances in Maize or DUS and ED Protocols: Optimization of the Information and New Approaches of Kinship*, BMT/3/6 (1995).

¹⁵⁰ See Smith, Jones et al., "Genomic Approaches and Intellectual Property Protection for Variety Release" in *Genomics of Plant Genetic Resources* (2014), pp.39–42; Noli, Teriaca and Conti, "Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat" (2012) 29 *Molecular Breeding* 687. See also, for examples, Nelson, Kahler et al., "Evaluation of the Numbers of Single Nucleotide Polymorphisms Required to Measure Genetic Gain Distance in Maize (*Zea mays* L.)" (2011) 51 *Crop Science* 1470; Kahler, Kahler et al., "North American Study on Essential Derivation in Maize" (2010) 50 *Crop Science* 486; Paul Nelson, Nathan Coles et al., "Molecular Characterisation of Maize Inbreds with Expired US Plant Variety Protection" (2008) 48 *Crop Science* 1673.

molecular markers will need to be determined for each crop.¹⁵¹ These problems aside, the main controversy is about the degree of conformity required between the initial variety and the putative EDV—"[d]isputes exist around empirical and statistical questions regarding the optimal traits and test statistic to be used".¹⁵² As a generalisation measures of conformity are expressed as "1" (or 100 per cent) meaning complete similarity, "0" meaning complete dissimilarity, and a decimal value between one and zero as the measure of the degree of similarity (with 0.95 generally meaning the varieties are 95 per cent similar).¹⁵³ There are various statistical methodologies for assessing degrees of similarity and dissimilarity, and as yet, no consensus about where the EDV thresholds might or should be set.¹⁵⁴

A major agitator for a workable EDV scheme has been the International Seed Federation (ISF) as a means of resolving disputes and elucidating the EDV concept so that there is "greater clarity" and "reduced infringements".¹⁵⁵ The ISF has proposed various position papers,¹⁵⁶ technical rules,¹⁵⁷ EDV guidelines for disputes about various crops¹⁵⁸ and a protocol for resolving disputes.¹⁵⁹ The ISF has also been a major funder and co-ordinator of research establishing the various technical

standards for a viable EDV scheme.¹⁶⁰ The outcome of this research has been to propose threshold measures of genetic relatedness for each crop that is "a trigger point to initiate a discussion between the breeders of the initial variety and the breeders of the putative [EDV]".¹⁶¹ Above the upper threshold, or "red" zone, the putative EDV is "regarded as an EDV without further procedures"; above a lower threshold, or "orange" zone, the putative EDV "triggers a dispute between parties" and the burden of proof shifts to the owner of the putative EDV to prove that it is not an EDV; and below the lower threshold, or "green" zone, the putative EDV is considered not to be an EDV.¹⁶² Where agreement cannot be reached then the matter is to be arbitrated according to the ISF rules.¹⁶³ The various EDV guidelines for disputes about various crops provide for the thresholds where the burden of proof shifts to the putative EDV owner or discussions might be initiated of a 0.6 Jaccard coefficient for perennial ryegrass,¹⁶⁴ a Roger's distance of 82 per cent for maize,¹⁶⁵ a Dice coefficient of 0.85 for spring and winter oilseed rape,¹⁶⁶ a coefficient of parentage of greater than 87.5 per cent for cotton,¹⁶⁷ and a 0.96 Jaccard coefficient for lettuce.¹⁶⁸ Perhaps notably these thresholds require very

¹⁵¹ See, for example, Wang and Bernardo, "Variance of Marker Estimates of Parental Contribution to F2 and BC1-Derived Inbreds" (2000) 40 *Crop Science* 659; M. Heckenberger, J. Muminovic et al., "Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Homozygous Lines: III. AFLP Data from Maize Inbreds and Comparison with SSR Data" (2006) 17 *Molecular Breeding* 111. See also Reif, Melchinger and Frisch, "Genetical and Mathematical Properties of Similarity and Dissimilarity Coefficients Applied in Plant Breeding and Seed Bank Management" (2005) 45 *Crop Science* 1; Van Eeuwijk and Law, "Statistical Aspects of Essential Derivation, With Illustrations Based on Lettuce and Barley" (2004) 137 *Euphytica* 129, above n 11.

¹⁵² Van Eeuwijk and Baril, "Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation" (2000) 541 *Acta Horticulturae* 35, 36.

¹⁵³ Reif, Melchinger and Frisch, "Genetical and Mathematical Properties of Similarity and Dissimilarity Coefficients Applied in Plant Breeding and Seed Bank Management" (2005) 45 *Crop Science* 1, 1; Van Eeuwijk and Baril, "Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation" (2000) 541 *Acta Horticulturae* 35, 36–37.

¹⁵⁴ See Noli, Teriaca and Conti, "Identification of a Threshold Level to Assess Essential Derivation in Durum Wheat" (2012) 29 *Molecular Breeding* 687; Reif, Melchinger and Frisch, "Genetical and Mathematical Properties of Similarity and Dissimilarity Coefficients Applied in Plant Breeding and Seed Bank Management" (2005) 45 *Crop Science* 1; Van Eeuwijk and Law, "Statistical Aspects of Essential Derivation, With Illustrations Based on Lettuce and Barley" (2004) 137 *Euphytica* 129. See also Stephen Smith, "Intellectual Property Protection for Plant Varieties in the 21st Century" (2008) 48 *Crop Science* 1277, 1285–1286; W. Lesser and M. Mutschler, "Balancing Investment Incentives and Social Benefits when Protecting Plant Varieties" (2004) 44 *Crop Science* 1113, 1116; Forrest Troyer and Torbet Rocheford, "Germplasm Ownership: Related Corn Inbreds" (2002) 42 *Crop Science* 3, 9–10. For an illustration of the complexity in determining crop specific thresholds, see Borchert, Krueger and Hohe, "Implementation of a Model for Identifying Essentially Derived Varieties in Vegetatively Propagated Calluna vulgaris Varieties" (2008) 9 *BMC Genetics* 56.

¹⁵⁵ International Seed Federation, *ISF View on Intellectual Property* (2012), p.19.

¹⁵⁶ See, for examples, International Seed Federation, *ISF View on Intellectual Property* (ISF, 2012); International Seed Federation, *Use of DNA Markers for DUS Testing, Essential Derivation and Identification* (ISF, 2006); International Seed Federation, *Essential Derivation from a Not-yet Protected Variety and Dependency* (ISF, 2005); and so on.

¹⁵⁷ See International Seed Federation, *Issues to be Addressed by Technical Experts to Define Molecular Marker Sets for Establishing Thresholds for ISF EDV Arbitration* (ISF, 2010).

¹⁵⁸ International Seed Federation, *Guidelines for Handling a Dispute on Essential Derivation in Ryegrass* (ISF, 2009); International Seed Federation, *ISF Guidelines for the Handling of a Dispute on Essential Derivation of Maize Lines* (ISF, 2008); International Seed Federation, *Guidelines for the Handling of a Dispute on Essential Derivation in Oilseed Rape* (ISF, 2007); International Seed Federation, *Guidelines for the Handling of a Dispute on Essential Derivation in Cotton* (ISF, 2007); International Seed Federation, *Guidelines for the Handling of a Dispute on Essential Derivation in Lettuce* (ISF, 2004).

¹⁵⁹ International Seed Federation, *Regulation for the Arbitration of Disputes concerning Essential Derivation (RED)* (ISF, 2010); International Seed Federation, *Explanatory Notes: Regulation for the Arbitration of Disputes concerning Essential Derivation (RED)* (ISF, 2010); International Seed Federation, *List of International Arbitrators for Essential Derivation* (ISF, 2010).

¹⁶⁰ See, for example, Heckenberger, Bohn et al., "Identification of Essentially Derived Varieties with Molecular Markers" (2005) 111 *Theoretical and Applied Genetics* 598; Heckenberger, Bohn et al., "Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Homozygous Lines" (2005) 45 *Crop Science* 1132; Roldán-Ruiz, Calsyn et al., "Estimating Genetic Conformity Between Related Ryegrass (*Lolium*) Varieties" (2000) 6 *Molecular Breeding* 593; Gilliland, Coll et al., "Estimating Genetic Conformity Between Related Ryegrass (*Lolium*) Varieties" (2000) 6 *Molecular Breeding* 569; and so on. See also Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Concepts of Essential Derivation and Dependence; Possible Use of DNA Markers*, BMT-TWA/MAIZE/2/7-A (2007); International Union for the Protection of New Varieties of Plants, *Addendum to Document BMT-TWA/Maize/2/7-a*, BMT-TWA/MAIZE/2/7-A ADD (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: The SEPROMA Approach — Technical Issues*, BMT-TWA/MAIZE/2/7-B (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Identifying Essentially Derived Molecular Markers*, BMT-TWA/MAIZE/2/7-C (2007); Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular — Crop Subgroups, *EDV in Corn: Study on Essential Derivation in Corn in North America — Abbreviated Report on Phase 3*, BMT-TWA/MAIZE/2/7-D (2007).

¹⁶¹ International Seed Federation, *Dispute in Cotton* (2007), para.5; International Seed Federation, *Dispute in Oilseed Rape* (2007), para.5.

¹⁶² International Seed Federation, *Explanatory Notes* (2010), p.2 (footnote). See also Smith, Jones and Nelson, "The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties" in *Genomics of Plant Genetic Resources* (2014), pp.59–60.

¹⁶³ See International Seed Federation, *Regulation for the Arbitration* (2010); International Seed Federation, *List of International Arbitrators* (2010).

¹⁶⁴ International Seed Federation, *Dispute in Ryegrass* (2007), p.1.

¹⁶⁵ International Seed Federation, *Dispute in Maize Lines* (2008), p.2.

¹⁶⁶ International Seed Federation, *Dispute in Oilseed Rape* (2007), p.1.

¹⁶⁷ International Seed Federation, *Dispute in Cotton* (2007), p.1.

¹⁶⁸ International Seed Federation, *Dispute in Lettuce* (2004), p.1.

specific protocols¹⁶⁹ and, reflecting the uncertainty, “shall be reviewed in the light of the experience gained and the technical and scientific [evolution]/[advancements]”.¹⁷⁰

The problems with these approaches, however, is that statistical analysis is based on models that are a simplification of the natural world¹⁷¹ and different models can (and do) give different results.¹⁷² The molecular tests are also open to technical criticism (about procedures, conditions, marker numbers and locations, source populations, repeats, standard errors, and so on). The main criticism, however, is that the markers are mere correlations of similarity rather than evidence of actual similarity.¹⁷³ The court in *Danziger v Astée Flowers* critiquing the use of an AFLP analysis as evidence of genetic conformity for EDV stated:

“In the opinion of the Court, for the (reliable) determination of genetic conformity by means of DNA markers, the use of multi-allelic markers and a reliable sampling of the entire genome are the most important conditions. Because of their nature, AFLP markers cannot be regarded as multi-allelic markers. Moreover, it is unknown to what extent the markers used ... represent the *Gypsophila* genome. Taking account of the fact that AFLP markers occur in strong clusters in the genomes of many plant varieties, a number of 230 to 260 markers provides insufficient certainty in the opinion of the Court about the desired representative sampling of the *Gypsophila* genome. Furthermore, dominant markers such as AFLP markers overestimate the real degree of identity between genotypes, since they do not reveal the possible underlying heterozygosity (in AFLP terms: the single presence of a DNA fragment) ... Compared to multi-allelic markers, as used in forensic DNA research, AFLP markers have a moderate distinguishing capacity. The degree to which this is compensated by scoring a large number of AFLP markers is limited, however, as becomes evident from the inaccuracy of the Jaccard indices established hereafter ... The Jaccard index is calculated between two varieties by dividing the number of times that a marker occurs in both varieties by the number of times that a marker occurs in either one of the two varieties. At a given degree of affinity (eg full brother/sister, parent/descendant), the Jaccard index is able to assume divergent values for similarity. This is primarily caused by the fact that, when comparing two closely related individuals, identical and non-identical genome

segments alternate with each other in accordance with an (unpredictable) process of coincidence. This ‘fragment-wise’ occurrence of identical and non-identical parts of the genome is a source of variation, even if extremely large numbers of markers are used, in the similarity index between close relatives. The ultimate spread that occurs in Jaccard indices is determined by: (a) the number of chromosomes in the relevant species; (b) the number of markers used; and (c) the degree to which these ‘cover up’ the genome. The stronger the clustering of markers on the genome, the larger the variation in observed similarity will be between couples of individuals with the same degree of affinity. The consequence of all this is 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.”¹⁷⁴

This suggests that a statistical analysis combined with the various molecular marker techniques may not be sufficient, and that establishing EDV according to thresholds of genetic relatedness will likely remain contested. As an alternative, however, whole genome sequencing might provide a better measure of similarity because there can be a direct comparison between the whole sequence of the initial variety and the putative EDV. With the increasing sophistication of bioinformatics this means that the identification of the precise sequences that are the same and different across the whole genome can be made. This will be direct evidence and not a correlation, albeit the comparisons will rely on statistical models that have inherent assumptions that might be challengeable.

Burden of proof

Critical to establishing EDV is proving that the elements of the 1991 UPOV Convention right as it has been implemented in domestic laws.¹⁷⁵ The base against which a variety is assessed as a putative EDV for the purposes of the 1991 UPOV Convention standard is the initial protected variety from which the alleged putative EDV is predominantly derived.¹⁷⁶ Proving EDV is likely to be a difficult matter of evidence where the defendant does

¹⁶⁹ For example, maize requires at least 150 highly polymorphic (average polymorphic information content between 0.6 and 0.7 with a minimum of 0.3) and evenly distributed SSR markers and using Roger’s distances: International Seed Federation, *Dispute in Maize Lines* (2008), pp.1–2.

¹⁷⁰ International Seed Federation, *Dispute in Oilseed Rape* (2007), p.1; International Seed Federation, *Dispute in Cotton* (2007), p.1; International Seed Federation, *Dispute in Lettuce* (2004), p.1. See also International Seed Federation, *Dispute in Ryegrass* (2007), p.1; International Seed Federation, *Dispute in Maize Lines* (2008), p.2.

¹⁷¹ For an insightful analysis of the mathematical and genetic properties of coefficients see, for example, Reif, Melchinger and Frisch, “Genetical and Mathematical Properties of Similarity and Dissimilarity Coefficients Applied in Plant Breeding and Seed Bank Management” (2005) 45 *Crop Science* 1; V. Lombard, C. Baril et al., “Genetic Relationships and Fingerprinting of Rapeseed Cultivars by AFLP: Consequences for Varietal Registration” (2000) 40 *Crop Science* 1417.

¹⁷² In *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [15] three independent AFLP procedures delivered three different Jaccard genotypic similarities for the *Gypsophila* varieties “Dangypmini” and “Blancanieves”.

¹⁷³ For an example of detailed critique see *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [16]–[17].

¹⁷⁴ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [16].

¹⁷⁵ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), paras 13–14.

¹⁷⁶ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b).

not readily admit the derivation.¹⁷⁷ The 1991 UPOV Convention is silent on the burden of proof making it possible for contracting parties to reverse the onus of proof requiring the defendant to refute essential derivation.¹⁷⁸ The question remains, however, how to establish the base standard against which a variety can be assessed as a putative EDV and then when the burden should move from the plaintiff to the defendant? The litigation over *Gypsophila* varieties between Danziger "Dan" Flower Farm (Danziger) and Astée Flowers BV (Astée) illustrates the issues.¹⁷⁹

Danziger obtained a plant breeder's right in a variety named "Dangypmini" (trade marked as "Million Stars") and Astée obtained a plant breeder's right in another variety named "Blancanieves". Morphologically "Dangypmini" and "Blancanieves" were clearly distinct in the height of plants, branching, flower-stem length and flower diameter¹⁸⁰ with the Community Plant Variety Office finding 17 morphological differences.¹⁸¹ Suspicious of the genealogy of "Blancanieves", Danziger conducted genetic tests and established that there was a high degree of genetic relatedness between "Dangypmini" and "Blancanieves", and that "Dangypmini" was a diploid while "Blancanieves" was a tetraploid presumably achieved through multiplication of the "Dangypmini" genome.¹⁸² Danziger demanded Astée cease any uses of "Blancanieves" because it infringed Danziger's breeder's right and then wrote to its customers advising that the Astée "Blancanieves" was an EDV and infringed its plant breeder's rights.¹⁸³ Danziger commenced action in Holland and Israel asserting infringement on the basis that "Blancanieves" was an EDV of "Dangypmini".¹⁸⁴

In Holland the first instance court rejected Danziger's assertion that "Blancanieves" was an EDV of "Dangypmini".¹⁸⁵ In Israel, however, the first instance court accepted Danziger's assertions.¹⁸⁶ The treatment of the burden of proof by the different courts and the quality of the evidence submitted is insightful.

In Israel, under the Plant Breeder's Right Law 5733-1973, the burden of proving EDV shifts to the defendant to prove that the variety is not an EDV, the court noting that "[t]he provision concerning the reversal of the burden of proof concerning [EDV] ... is unique to the Israeli Law and there is no similar in the [1991 UPOV] Convention or in the Dutch law".¹⁸⁷ The relevant provision was:

"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."¹⁸⁸

The District Court rejected the defendant Astée's (the first named co-defendant was Hananya Azolay) argument that only morphological characters might be considered¹⁸⁹ and accepted the genetic AFLP evidence of the defendants that showed that of 214 markers using six primers the "Blancanieves" and "Dangypmini" varieties differed by only five markers.¹⁹⁰ The court also rejected the defendant's 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.¹⁹¹ The court reasoned that what the legislated

¹⁷⁷ For some of the likely problems see Smith, Jones and Nelson, "The Use of Molecular Markers to Assist in the Determination of Essentially Derived Varieties" in *Genomics of Plant Genetic Resources* (2014), pp.55–56. This may not always be the case as *Van Zanten BV v Hofland BV* 310918/KG ZA 08-594, District Court, The Hague (2008) demonstrated with evidence founding an EDV based on identical AFLP profiles and 38 out of 39 morphological characters being the same.

¹⁷⁸ International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), paras 17–18.

¹⁷⁹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009); *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009).

¹⁸⁰ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [5].

¹⁸¹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [21].

¹⁸² *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [4].

¹⁸³ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [4] and [5].

¹⁸⁴ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [5]; *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [5].

¹⁸⁵ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [5].

¹⁸⁶ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [23].

¹⁸⁷ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [16].

¹⁸⁸ Plant Breeder's Right Law 5733-1973 s.62A.

¹⁸⁹ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [14].

¹⁹⁰ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [14].

¹⁹¹ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [14].

standard required was “genetic conformity” and the AFLP analysis addressed that issue.¹⁹² With this burden of proof the defendant was both unable to credibly¹⁹³ prove how “Blancanieves” was created,¹⁹⁴ and unable to provide any credible¹⁹⁵ morphological evidence¹⁹⁶ of the differences between “Blancanieves” and “Dangypmini”.¹⁹⁷ Surprisingly the court interpreted the EDV threshold of conforming to the initial variety¹⁹⁸ as not being limited to “one trait or a small number of morphological traits”.¹⁹⁹ This meant that evidence of multiple morphological differences (and variety registration accepted the varieties were distinct) were not proof against a finding of EDV.²⁰⁰ Meanwhile the plaintiff conducted comprehensive morphological examinations:

“[Danziger’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 [Danziger’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, [Danziger’s expert witness] established that the morphological difference which was found, results from the act of derivation of the genotype.”²⁰¹

The conclusion of the decision is significant in pointing out that Astée’s evidence was poor and its witnesses less that credible compared to Danziger’s evidence and witnesses.²⁰²

In Holland under the European Community Plant Variety Rights Regulation the burden of proof remains with the plaintiff to establish essential derivation.²⁰³ This meant that 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.”²⁰⁴

Relying on similar molecular evidence to the Israeli case, Danziger presented genetic evidence of AFLP analysis showing a Jaccard similarity based on two independent tests between “Blancanieves” and “Dangypmini” of 0.944 and 0.937.²⁰⁵ Astée’s evidence was a similar AFLP analysis was a Jaccard similarity of 0.82 and 0.87.²⁰⁶ Astée, however, criticised the use of AFLP analysis challenging the identity of the “Blancanieves” materials, the use of a sufficient representative sample, the primer combinations and the merits of AFLP itself.²⁰⁷ The court agreed that AFLP 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”.²⁰⁸

¹⁹² *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [14].

¹⁹³ Noting that the defendant’s breeder provided poor breeding documentation that was not clear and his oral evidence raised doubt about the breeding processes: *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [21].

¹⁹⁴ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [21].

¹⁹⁵ Noting that 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”: *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [19].

¹⁹⁶ Noting that the defendants had asserted that only morphological characters were relevant in assessing EDV: *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [14].

¹⁹⁷ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [19].

¹⁹⁸ Here the Israeli Plant Breeder’s Right Law 5733-1973 s.36(e)(i)(a) restates the 1991 UPOV Convention art.14(5)(b)(i).

¹⁹⁹ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [18].

²⁰⁰ See International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.12, which provides only “one or very few” differences should be apparent from the act of derivation.

²⁰¹ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [20].

²⁰² *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [21].

²⁰³ Regulation 2100/94 Concerning Community Plant Variety Rights [1994] OJ L277/1.

²⁰⁴ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [12].

²⁰⁵ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [14].

²⁰⁶ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [15].

²⁰⁷ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [15].

²⁰⁸ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [16].

The court then considered the phenotypic similarity looking at the morphological data. Here the court considered that the Community Plant Variety Office's finding of 17 morphological differences between "Blancanieves" and "Dangypmini" enabling registration was enough to be more than the threshold for EDV of "one or a few inheritable characteristics".²⁰⁹ As there were substantial numbers of morphological differences then "proof that Blancanieves is an EDV of [Dangypmini] has therefore not been furnished", and no other attempt to furnish evidence was allowed.²¹⁰ The case in Holland essentially shows that any evidence that reveals 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.²¹¹ The result is in practice the same as formally transferring the onus to the defendant once the plaintiff has established a reasonable allegation.

Discussion

As originally intended, the UPOV Conventions relaxed the novelty, inventive step (non-obviousness) and written description requirements of patents in favour of protecting incremental plant developments.²¹² The original driving perspective was that patents for inventions required a specification that a person skilled in the art might follow to reproduce the invention, while plant breeding was more concerned with propagating existing plants for their particular characteristics (traits).²¹³ At that stage any new, distinct, uniform and stable differences using varieties from any source was sufficient to found a new breeder's right.²¹⁴ The 1991 UPOV Convention then introduced EDV specifically to address the concern that a breeder's right could be gained for very minimal breeding essentially free-riding on the original breeder's time and investment.²¹⁵ The EDV standard attempts to set the threshold for whether a plant variety is different enough to justify an entirely separate breeder's right.

The analysis in this article shows that EDV under the 1991 UPOV Convention is essentially an assessment of an initial variety against a putative EDV to assess the phenotypic *and* genotypic differences. The preferred means of measuring these differences for EDV have so far relied on an array of techniques and statistical models to quantify similarity and difference as an index (such as a Jaccard index). These technical means, as the decision of the Dutch Court of Appeals in *Danziger v Astée* demonstrated, are not necessarily sufficient to certainly conclude EDV with the main problem being that existing molecular techniques do not sample the genome at a sufficient level of detail to definitively identify similarity and difference.²¹⁶ The developments of whole genome sequencing, however, has the potential to resolve these exiting technical problems by providing a very precise description of the genetic differences between the initial variety and the putative EDV at the level of sequence code. The challenge will still remain, however, to determine how much similarity and difference is enough to pass the EDV threshold. The limited number of court decisions show that courts can make this decision, although the evidence and outcomes in the litigation over *Gypsophila* varieties show the courts weight this evidence differently.²¹⁷

The 1991 UPOV Convention threshold technical questions relate to genetic origin and genetic similarity.²¹⁸ This evidence alone, however, does not then address the critical issue of whether the putative EDV "conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combinations of genotypes".²¹⁹ The term "essential characteristics" is not defined and their assessment will always be a matter of degree. The litigation over *Gypsophila* varieties between *Danziger* and *Astée*²²⁰ demonstrates that making these judgments about EDV is generally going to be very difficult.²²¹ The putative EDV in that litigation had 17 morphological differences from the initial variety, of which nine related to plant architecture and flower morphology.²²² The putative EDV was also generated by polyploidisation (doubling the ploidy using the chemical colchicine).²²³ The Dutch court

²⁰⁹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [22]. See also International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.12, which provides only "one or very few" differences should be apparent from the act of derivation.

²¹⁰ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [22].

²¹¹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [12].

²¹² See Graham Dutfield, "Turning Plant Varieties into Intellectual Property: The UPOV Convention" in Geoff Tansey and Tasmin Rajotte (eds), *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (Earthscan, 2008), p.33 and the references therein.

²¹³ See Dutfield, "Turning Plant Varieties into Intellectual Property" in *The Future Control of Food* (2008), p.33 and the references therein.

²¹⁴ See International Convention for the Protection of New Varieties of Plants 1978 arts 5(3) and 6(1)(a).

²¹⁵ See Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (1992), pp.7–8; Greengrass, "The 1991 Act of the UPOV Convention" [1991] E.I.P.R. 466, 470–471.

²¹⁶ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [16].

²¹⁷ Comparing the Dutch and Israeli court decisions in *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009); *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009).

²¹⁸ See International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(ii) and (iii).

²¹⁹ International Convention for the Protection of New Varieties of Plants 1991 art.14(5)(b)(iii).

²²⁰ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009); *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009).

²²¹ This may not always be the case: see, for example, *Van Zanten BV v Hofland BV* 310918/KG ZA 08-594, District Court, The Hague (2008) where the AFLP profiles were identical and 38 out of 39 morphological characters were the same.

²²² *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [21].

²²³ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [17].

found there was no EDV²²⁴ while on almost identical evidence the Israeli court found there was EDV.²²⁵ The Dutch court rejected the molecular AFLP evidence as being unsatisfactory because it was “not suitable”,²²⁶ while the Israeli court did not need to determine this matter as the AFLP evidence established sufficient similarity for the burden of proof to shift to the defendant and they were unable under the Israeli legal standard to refute EDV.²²⁷ Most importantly for our purposes, however, the Dutch court, applying the 1991 UPOV Convention-consistent Dutch law, framed the “essential characteristics” as the characters that determine the “cultural and practical values” and that are unique to the initial variety compared with other varieties:

“[T]he Court notes that which characteristics are essential to a variety is closely related to the cultural and practical values of that variety. Essential to a variety are (is) those (that) unique (combination of) characteristics which determine the cultural and practical values and from which the variety derives its variability. The characteristics on which the distinguishability from other varieties is based may be morphological characteristics which are not relevant to the cultural and practical values. This is often the case with arable crops. However, with ornamental crops, entirely in line with the purpose for which they are grown, it is mostly the morphological characteristics which largely determine the cultural and practical values. In the case of *Blancanieves*, the Community Plant Variety Office ... found 17 morphological differences with [*Dangypmini*], based on which *Blancanieves* is distinguishable from any other variety ... This covers nine characteristics which are related to plant architecture and flower morphology; these are specifically characteristics which, apart from characteristics such as resistance against diseases and plagues, vase life and such like, are important for the cultural and practical values of a cut flower such as *Gypsophila*. The aforementioned morphological differences between *Blancanieves* and [*Dangypmini*] must therefore most certainly be regarded as relevant.”²²⁸

The significance for our purposes was that the Dutch court was able to identify the essential characters as phenotypes linked to genotypes (stable characters identified in determining the variety was distinct, uniform and stable)²²⁹ and the morphological characters that determined the plant’s purpose as an ornamental crop.²³⁰ The Dutch court also found that the EDV was confined to only “one or very few” inheritable “essential characteristics”.²³¹ What made these characteristics essential from the court’s perspective was their “cultural and practical values”.

The Israeli decision on this point was unhelpful. The court interpreted the Israeli law, as a consequence of the amendment to reverse the onus of proof, as not being limited to a small number of traits.²³² The evidence of the plaintiff identified three differing morphological characters (stem length, flowering date and petal numbers) and the other measured characters were retained, presumably including the essential characteristics even though they were not expressly identified.²³³ The evidence relied on by the defendant, once the burden was shifted, was then disregarded because it was inadequate.²³⁴ The result was that the court never actually identified the essential characteristics at issue²³⁵ because the shift in onus and the paucity of the defendant’s evidence (after key parts of it were rejected) meant there was no need to specifically determine the “essential characteristics”.

Beyond the court decisions, some national laws implementing the 1991 UPOV Convention have tried to address the meaning of “essential characteristics”. For example, the Australian Plant Breeder’s Rights Act 1994 (Cth), which is consistent with the 1991 UPOV Convention,²³⁶ defined “essential characteristics” as “heritable traits ... that contribute to the principal features, performance or value of the variety”.²³⁷ The point here is that the 1991 UPOV Convention does not define these terms and this is likely to be a significant node of uncertainty in applying the EDV thresholds. This is because both the concept of “essential” is inherently qualitative and members of the 1991 UPOV Convention have framed the concept differently and involving matters of degree unrelated to the conventions of taxonomy and the naming codes (“cultural and practical values”, “performance or value”, and so on).

²²⁴ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [22] and [30].

²²⁵ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [23].

²²⁶ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [35].

²²⁷ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [16]–[18].

²²⁸ *Danziger v Astée*, 105.003.932/01, Court of Appeal, The Hague (2009) at [21].

²²⁹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [22].

²³⁰ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [21].

²³¹ *Danziger v Astée* 105.003.932/01, Court of Appeal, The Hague (2009) at [20]. See also International Union for the Protection of New Varieties of Plants, *Essentially Derived Varieties*, IOM/6/2 (1992), para.12.

²³² See *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [18].

²³³ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [20].

²³⁴ *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [19].

²³⁵ Notably references to experts listing essential characteristics did not actually identify those characters: see *Danziger v Azolay* 1228/03, District Court, Tel-Aviv-Jaffa (2009) at [10], [11], [19] and [20].

²³⁶ Commonwealth, *Hansard*, Senate, March 24, 1994, p.2306 (John Faulkner, Manager of Government Business in the Senate); Commonwealth, *Hansard*, House of Representatives, August 24, 1994, p.157 (Francis Walker, Minister for Administrative Services).

²³⁷ Plant Breeder’s Rights Act 1994 (Cth) s.3(1).

While this present EDV question is situated in the context of plant breeder's rights under the 1991 UPOV Convention, similar challenges face other intellectual property schemes and their operative threshold standards: non-obviousness and description in patent law; substantial copying in copyright; appearance in design law; distinguishing marks in trade mark law; and so on. In each instance the issue is how to adequately describe and define (adequately bound) the legal object. The particular challenge of EDVs is to usefully conceptualise biological organisms as objects of law within the particular frame of (sexually and asexually) inherited variability. The EDVs and plant breeder's right also provides a particularly interesting dimension as molecular and biochemical techniques together with complex statistical models can increasingly define differences and similarities to a very, very fine level of detail among plants. The

prospect of whole genome sequencing potentially enables *every* genetic difference to be defined and described. Clearly EDV is about finding a balance that addresses the menace that EDV was intended to address—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 differences between protected varieties.²³⁸

It is certain, however, that EDV is not merely a technical question that can be resolved with a technical answer such as a statistical index or a DNA sequence. There are also qualitative aspects of the EDV thresholds, likely the standard of "essential characteristics". The ongoing challenge for the members of the 1991 UPOV Convention will be to establish suitable technical standards for measuring genetic origin and genetic conformity, and providing guidance about the meaning of the qualitative aspects of the EDV thresholds.

²³⁸ See Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (1992), pp.7–8; Greengrass, "The 1991 Act of the UPOV Convention" [1991] E.I.P.R. 466, 470–471.