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**WHITE PAPER**  
**ON**  
***'ESSENTIALLY DERIVED VARIETIES'***

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## CONTENTS

1. ABSTRACT .....	2
2. THE ‘BREEDER’S EXCEPTION’ & THE ADVENT OF GENETIC ENGINEERING: SHIFTING THE BALANCE IN FAVOR OF SUBSEQUENT PLANT BREEDERS .....	5
3. UPOV’S ‘EDV’ SCHEME AND ITS TRANSPOSITION PHASE.....	7
<i>a) Introduction.....</i>	7
<i>b) Application within the art. 13 of EU Council Regulation no. 2100/94 .....</i>	7
<i>c) Application within the Australian PBR Act (1994) .....</i>	9
<i>d) Enforcement of the EDV provisions in recent Case-law .....</i>	11
4. UPOV EFFORTS TO CLARIFY EDV: FROM 2009 TO 2017 EDV EXN .....	14
5. RELEVANCE OF THE ‘ESSENTIAL CHARACTERISTICS’ IN THE ASSESSMENT OF EDVs: THE PHENOTYPE PREFERENCE.....	15
6. A LEGAL PERSPECTIVE ON EDV ASSESSMENT.....	21
7. EDV AND COMPULSORY LICENSING .....	23
8. CONCLUSION.....	26

# WHITE PAPER

on

## *‘Essentially Derived Varieties’*

### 1. ABSTRACT

It is an established principle in the IP world that the effective reason for granting an exclusive right for a limited timeframe is that of incentivizing the enrichment of society, achieved by the creativity and investment of the person who created, (invented, observed, discovered) something new (Intellectual Property Rights) and/or useful (Industrial Property Rights).

Thus, the scope of an IP right is not only determined by the value of intervention but also by the extent of the finder’s contribution to foster the further development of society<sup>1</sup>.

Plant Breeders Rights undoubtedly constitute one of the most important life-science IPRs, as per UPOV Conventions principles and preambles. Through the *‘Farmer’s Privilege’* exception, UPOV has always satisfied the diverging scopes for (i) breeders: to introduce a full IPR securing their efforts aimed at introducing and developing always improved variety; and (ii) farmers’ ability in saving seed in order for the Nature to express its vital force (including by mutations).

EDV (legal) concept has been introduced by UPOV Convention (1991), on the basis of the *‘dependent patent’* within the patent law. Its primary objective was to limit the scope of

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<sup>1</sup> Legal perspectives on Essentially Derived Varieties- Gert Würtenberger, Revista Eletrônica do IBPI – p. 203, (2013) - <https://ibpieuropa.org/book/388>

the breeder's exception, by means of a dependency for '*Essentially Derived Varieties*' developed from a locally registered initial variety.

Therefore, the purported scope of EDV 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<sup>2</sup>.

Furthermore, it's always been matter of concern for many UPOV members and relevant stakeholders the fact that '*essential derivation*' should refer to the '*essential characteristics*' which are not necessarily those involved in the assessment of distinctness.<sup>3</sup>

As we know, the PVR system is subject to a considerable number of very time-consuming field trials, *de facto* giving the right holder a lead time advantage, as a third party's breeder would have to go through a similar time-consuming exercise before he could ever bring his new variety on the market<sup>4</sup>.

In order to acquire the interesting traits foreseen by successful breeding programs capable of speeding innovation, access to all possible biological materials is key element for plant breeders.

There's always been very little consensus within UPOV core members and relevant stakeholders over the genetic and morphological conformity threshold required for the identification of an EDV as opposed to the corresponding initial variety.

The intense debate surrounding the EDV concept and its legal provisions led UPOV to amend the first Explanatory Notes on EDV (2009) and to adopt the current version, dated April 6, 2017.<sup>5</sup>

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<sup>2</sup> Plant Breeder's Rights and Essentially Derived Varieties: Still Searching for Workable Solutions - Charles Lawson, Griffith Law School (2016), p. 1;

<sup>3</sup> Joel Guiard, The Development of the Provisions of Essentially Derived Varieties, UPOV Seminar on Essentially Derived Varieties (2013); [https://www.UPOV.int/edocs/mdocs/UPOV/en/UPOV\\_sem\\_ge\\_13/UPOV\\_sem\\_ge\\_13\\_ppt\\_1.pdf](https://www.UPOV.int/edocs/mdocs/UPOV/en/UPOV_sem_ge_13/UPOV_sem_ge_13_ppt_1.pdf)

<sup>4</sup> Plant variety rights and patent: which way to go? – Maastricht University (2018); [www.maastrichtuniversity.nl/blog/2018/05/plant-variety-rights-and-patent-which-way-go](http://www.maastrichtuniversity.nl/blog/2018/05/plant-variety-rights-and-patent-which-way-go)

<sup>5</sup> [https://www.UPOV.int/edocs/expdocs/en/UPOV\\_exn\\_edv.pdf](https://www.UPOV.int/edocs/expdocs/en/UPOV_exn_edv.pdf)

The objective pursued by the Explanatory Notes consisted in reducing the degree of both legal uncertainty and judicial unpredictability affecting key-issues on EDV.

The above-mentioned document represents a sensitive step forward, especially in light of diverging perspectives over the relevance of phenotypical traits within the assessment of essential derivation, a tremendously difficult task especially for the local Courts, called to offer a judicial interpretation of the EDV norms.

However, some criticisms opposing the vision enshrined within the latest version of UPOV 2017 EXN on EDVs<sup>6</sup> have already been brought up, aiming to widen the scope of the first breeder's right by extending EDV to (potentially) all incrementally bred varieties (and not just *cosmetic* copies), so that phenotypical (as well as commercially and marketing relevant traits) might not play any role in the EDV assessment.

Given the profound implications of such an approach for the community of breeders, consumers and for national interests, also from a legal perspective (both interpretative and judicial), WebLegal has been offered the chance to provide its own contribution to the ongoing debate.

The present White Paper reflects WebLegal's independent assessment on the topics concerned, aimed at addressing the most controversial nodes relating to the concept of derivation as well as '*essential characteristics*', following the recent Explanatory Notes on Essentially Derived Variety released by UPOV ("2017 UPOV EXN EDV"), to further stimulate the global discussion among relevant stakeholders.

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<sup>6</sup> Comments to the Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention – CIOFORA (2016); [https://www.UPOV.int/edocs/mdocs/UPOV/en/caj\\_73/caj\\_73\\_comments\\_ciopora.pdf](https://www.UPOV.int/edocs/mdocs/UPOV/en/caj_73/caj_73_comments_ciopora.pdf)

## 2. THE 'BREEDER'S EXCEPTION' & THE ADVENT OF GENETIC ENGINEERING: SHIFTING THE BALANCE IN FAVOR OF SUBSEQUENT PLANT BREEDERS

A PBR regime ordinarily allows breeders to rely on existing plant varieties in incremental breeding programs, without any obligation to the party holding the PBR title of the initial variety: the '*breeder's exception*' constitutes a pillar within the entire UPOV system<sup>7</sup>.

For sake of knowledge, definition of what '*incremental breeding*' stands for might be useful in relation to EDVs. In particular, incremental breeding implies the development of an unlimited series of new varieties with each subsequent variety being bred from, and relying heavily on, the characteristics of the previous varieties<sup>8</sup>.

Further to the introduction of the breeder's exception within the international PBR system, as per the provisions enclosed within the UPOV Convention (1978), the breeders have always relied on this exception for further production of new varieties that may be improved or modified *e.g.* to cope with climate change, by enhancing their resistance to environmental stresses such as heat, cold, salinity and drought.

In the fruit industry, many other features are intensively targeted by breeders to the consumer's satisfaction, such as cold storage resistance, coloration, maturation and so on.

As a consequence, any commitment to implement a PBR regime that significantly restrict the application of the breeders' exception would risk to diluting the rationale of this fundamental rule, certainly inspired on grounds of public interest, as securing biodiversity and encouraging innovation.

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<sup>7</sup> [https://www.upov.int/edocs/mdocs/upov/en/caj\\_58/upov\\_exn\\_exc\\_draft\\_3.pdf](https://www.upov.int/edocs/mdocs/upov/en/caj_58/upov_exn_exc_draft_3.pdf);

<sup>8</sup> Clarification of plant breeding issues under the plant breeder's rights act 1994, p. 20, Australia (2002) <https://www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf>;

However, the breeder's exception has, in combination with other provisions of the UPOV Convention, caused concerns for UPOV Members and breeders' organizations.

Most notably, the assumption that the breeder's exception would not have a detrimental impact on PBRs was challenged, further to the advent of molecular plant breeding techniques and the absence of a comparable provision under the patent law.

There were concerns that, when combined with the low threshold of distinctness and limited infringement provisions, the breeder's exception allowed, or even encouraged, *copying* and *plagiarism* in plant breeding<sup>9</sup>.

In light of this, UPOV Convention (1991) aimed at providing for a manner to compensate the breeder of the initial variety, because of the predominant use and exploitation of its variety made by another breeder.

In other words, the objective was to strengthen the breeder's rights 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'*<sup>10</sup>.

Nonetheless, the enforcement of the provisions relating to essential derivation has always been one of the main issues for UPOV, because of the poor legal certainty surrounding its legislative definitions.

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<sup>9</sup> Plants, People and Practices – Jay Sanderson, Cambridge (2017) p. 205;

<sup>10</sup> Noel Byrne, Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties (Centre for Commercial Law Studies, 1992, London), pp 7-8;

### 3. UPOV'S 'EDV' SCHEME AND ITS TRANSPOSITION PHASE

#### ***a) Introduction***

The main challenge in drafting a provision about EDVs was to find the most appropriate meaning for the wording '*the expression of the essential characteristics of the initial variety and the retention of that expression*' to be included into the relevant definition.

Despite a sensitive number of suggestions provided by both members and observers involved, the final provision enclosed within the UPOV Convention (1991) was very close to the basic draft at the beginning of negotiations that had been developed during the Administrative and Legal Committee.

Pursuant to article 14 (5) of the UPOV Convention (1991), a variety has to be deemed as '*essentially derived*' when it fulfils the following requirements in relation to the initial variety:

- Predominant derivation from the initial variety (article 14 (5)(b)(i));
- Clear distinctness in the sense of art. 7 (article 14 (5)(b)(ii));
- Conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety (article 14 (5)(b)(iii)).

If any of the above cumulative requirements is not fulfilled, there is no essential derivation.

#### ***b) Application within the art. 13 of EU Council Regulation no. 2100/94***

In light of the transposition of the wording enclosed within UPOV Convention (1991), it can be noted that the EU community legislator has drawn the content of Article 13 (1) and (2) of Council Regulation 2100/94 (the Basic Regulation) by means of a non-literal approach.



Article 13 of the Basic Regulation specifies, to summarize, that the holder of a Community plant variety right is entitled to reproduce and exploit material from the protected variety and that third parties require his authorization to carry out such acts.

Paragraph 5 of that Article rules that the scope of protection of the breeder of a registered variety further extends to *'varieties that are essentially derived from the variety for which a Community plant variety right has been granted, if that variety is not itself an essentially derived variety'*.

The first difference between the definition of EDV enclosed within the UPOV Convention (1991) and the transposition of the Basic regulation 2100/94 is that the terms *'while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety'* is not included in the latter.

Regulation text furthermore talks of *'conforms essentially ... in the expression of the characteristics'* while the UPOV Convention talks of *'conforms to ... in the expression of the essential characteristics'*.

Opposite to those addressing the above-mentioned differences as sort of alternative interpretation of the expression *'essential characteristics'*<sup>11</sup>, such legislative amendments have been qualified by former CPVO President Bart Kiewiet as an *'editorial intervention to clarify the definition'*. The Community legislator did assumedly not intend to introduce a notion of EDV that deviated from the one laid-down in the UPOV Convention<sup>12</sup>.

The definition set out in the Basic Regulation suggests that the words *'in the expression of the essential characteristics'* should be intended as implying that art. 13 (6) will only be applicable if the breeder's work has not resulted in one or more new morphological or physiological characteristics capable of precise recognition and description.

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<sup>11</sup> Comments to the Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention – CIOFORA (2016) [https://www.upov.int/edocs/mdocs/upov/en/caj\\_73/caj\\_73\\_comments\\_ciopora.pdf](https://www.upov.int/edocs/mdocs/upov/en/caj_73/caj_73_comments_ciopora.pdf);

<sup>12</sup> Essentially Derived Varieties— Bart Kiewiet, CPVO (2006), p. 2 [https://cpvo.europa.eu/sites/default/files/documents/articles/EDV\\_presentation\\_PlantumNL\\_March\\_2006\\_BK.pdf](https://cpvo.europa.eu/sites/default/files/documents/articles/EDV_presentation_PlantumNL_March_2006_BK.pdf);

### ***c) Application within the Australian PBR Act (1994)***

As core member of UPOV, the Australian Government has always encouraged the adoption within the international PBR system of a rather qualitative, fact-based approach to assessing essential derivation.

The wording enclosed within the Australian PBR act follows the UPOV Convention but has three important clarifications in regard to essentially derived varieties<sup>13</sup>:

- It defines ‘*essential characteristics*’;
- It specifies what is not an EDV and how the ‘*EDV chain*’ is broken;
- It states that the national authority administers EDV.

The Australian ‘bright line’ approach has been showcased by Mr. Doug Waterhouse (Chief PBR – IP Australia) during the UPOV Seminar on essentially Derived Varieties, held in 2013, explaining that ‘*these elaborations were designed to provide certainty/clarity for users and consistent administration – i.e. they provide a ‘bright line’ so that all stakeholders can confidently anticipate the regulatory outcome of an EDV claim – and therefore avoid the immediate need for recourse to the courts*’<sup>14</sup>.

Further to the innovations as per UPOV Convention (1991), the Australian legislation introduced a detailed definition of ‘*essential characters*’ within the EDV concept, by adding to the Plant Breeder’s Rights Act (1994) a qualitative layer to the test of essential derivation, in so far as it uses the expression ‘*important (as distinct from cosmetic) features.*’

According to the Oxford Dictionary (dictionaries always help!), ‘*important*’ means that differences between the initial variety and the putative EDV need to be ‘*of great significance or value*’.

The definition above shall lead to the conclusion that ‘*important*’ will be construed in terms of functional considerations, such as *performance* and/or *market value*<sup>15</sup>, in close relation with the

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<sup>13</sup> Experience on Essentially Derived Varieties in Australia – Doug Waterhouse (2013), p. 2 [https://www.upov.int/edocs/mdocs/upov/en/upov\\_sem\\_ge\\_13/upov\\_sem\\_ge\\_13\\_ppt\\_9.pdf](https://www.upov.int/edocs/mdocs/upov/en/upov_sem_ge_13/upov_sem_ge_13_ppt_9.pdf);

<sup>14</sup> UPOV Seminar on Essentially Derived Varieties, Geneva (2013) p. 53 [https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

<sup>15</sup> Expert Panel on Breeding, Clarification on Plant Breeding Issues Under the Plant Breeders’ Rights Act 1994, p. 22;

definition of the ‘essential characteristics’ as enclosed within the PBR Act, referring to ‘*heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety*’<sup>16</sup>.

In light of this rationale, pursuant to the provisions of the Australian PBR Act, a variety cannot be declared an EDV whenever it contains an important characteristic which differentiates it from the initial variety and adds to the *performance* or *value* of the variety itself<sup>17</sup>.

Moreover, during the UPOV Administrative and Legal Committee Advisory Group (2014), the Australian Government suggested the adoption of an alternative approach, to cope with those issues arising from the unclear definition of EDV as set out within the text of UPOV Convention (1991)<sup>18</sup>.

In particular, a feasible solution was deemed to be based on the Vienna Convention on the Law of Treaties (1969), whose article 31 (1) rules as follows:

*‘A treaty should be interpreted in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose’.*

Bearing in mind that UPOV (1978) Mission Statement was ‘*to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society*’, the combination of the above provisions, together with the elaborations delivered by the Australian PBR act (1994), would certainly represent a very useful tool to provide the EDV concept with a coherent and uniform legal framework, to the benefit of both breeders and consumers<sup>19</sup>.

In summary, the Australian experience teaches that it is only when an exhaustive legislative definition of EDV has been reached, that protection for the first breeder in case of plagiarism

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<sup>16</sup> [http://classic.austlii.edu.au/au/legis/cth/consol\\_act/pbra1994222/s3.html](http://classic.austlii.edu.au/au/legis/cth/consol_act/pbra1994222/s3.html);

<sup>17</sup> <https://www.ipaustralia.gov.au/plant-breeders-rights/understanding-pbr/pbr-detail/essentially-derived-varieties>;

<sup>18</sup> Additional Perspectives on Australia’s Implementation of Essentially Derived Varieties– Doug Waterhouse (2014);

<sup>19</sup> In commenting the Australian ‘bright line’ approach, Joel GUIARD acknowledged the following: ‘*The Australian approach is an interesting one because it allows for a specific case in varieties that could be an EDV, it provides a rule governing a decision and the idea of listing the essential characteristic I don’t think is realistic*’, UPOV Seminar on EDV (2013), p. 97  
[https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

can be effectively provided, by means of a mechanism that enables the owner of an initial variety to even effectively prohibit commercialization of plagiaristic/me-too varieties<sup>20</sup>.

The presence of a '*veto*' power against commercial usage of EDV in the Australian PBR legislation is also important in defining another unresolved and controversial issue in the European experience: the lack of agreement between the parties with regard to the commercial release of a variety having important and market valuable characters.

#### ***d) Enforcement of the EDV provisions in recent case-law***

Further to the final adoption of the UPOV Convention (1991), recent case-law has led to contradictory rulings above issues concerning the EDV assessment<sup>21</sup>.

For example, in *Van Zanten BV v. Hofland BV*<sup>22</sup>, the DNA tests showed no genetic difference, and the varieties were almost identical morphologically. This was, therefore, considered a clear-cut case of essential derivation.

Opposite to the above outcome, the case(s) of *Astée Flowers v. Danziger 'Dan' Flower Farm* showcase the challenge of examining and identifying EDVs<sup>23</sup>, allowing Courts to give genetic tests and morphology different weight, thus treating the question of derivation in diverging ways.

Based on the claims submitted by the opposing parties at first instance, the Civil Court of the Hague had to determine whether '*Blancanieves*' and '*Summer Snow*' were essentially derived from '*Million Stars*', pursuant to art. 13 (5)(a) and (6) of the Council Basic Regulation (2100/94).

The Court finally held that the varieties involved differed from each other, in the assessment of qualitative, yet morphological aspects, to the extent that '*Blancanieves*' could not be deemed

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<sup>20</sup> Clarification of plant breeding issues under the plant breeder's rights act 1994, p. 21; Australia (2002); <https://www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf>;

<sup>21</sup> Essentially Derived Varieties– Case Law in the Netherlands and Connected Observations, Tjeerd Overdijk, Vandosted Advokaten, Geneva (2013) [https://www.upov.int/edocs/mdocs/upov/en/upov\\_sem\\_ge\\_13/upov\\_sem\\_ge\\_13\\_ppt\\_10.pdf](https://www.upov.int/edocs/mdocs/upov/en/upov_sem_ge_13/upov_sem_ge_13_ppt_10.pdf);

<sup>22</sup> District Court Hague, 310918/KG KA 08-594 (2008);

<sup>23</sup> *Astée Flowers v. Danziger 'Dan' Flower Farm*, Case 198763, Court of the Hague (13th July 2005); *'Dan' Flower Farm v. Astée Flowers*, 105.003.932/01, Court of Appeal, The Hague (2009); *Danziger 'Dan' Flower Farm v. Azolay & Astée Flowers* 001228/03, District Court, Tel-Aviv-Jaffa (2009);

as essentially derived from the initial variety ‘*Million Stars*’. The genetic evidence was completely bypassed in the specific case, because it was viewed as unreliable and biased.

Furthermore, the decision of the Civil Court was appealed by Danziger, alleging an incorrect interpretation of the Council Regulation in the assessment carried out in the first instance. However, the Court of Appeal confirmed the decision, ruling that the DNA tests could not be relevant in order to declare any finding of essential derivation.

More specifically, the Court of Appeal described the genetic evidence as ‘*open to objections*’<sup>24</sup>, further stating that ‘*contrary to Danziger, the Court is of the opinion that the putative derived variety and the original variety must also be phenotypically similar to such a high degree that the one variety differs from the other variety only in one or a few inheritable characteristics*’<sup>25</sup>.

*Within this context, the 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 varietability*<sup>26</sup>.

In this case, representing a milestone within the case-law community system on EDV issues, both judgements relied on the CPVO’s assessment that found the variety ‘*Blancanieves*’ to be clearly distinguishable from all other varieties, since there were approximately 17 out of 21 observable phenotypic characteristics that were different between the two plant varieties involved.<sup>27</sup>

In contrast with the decisions provided by the Hague Court, Israel’s District Court of Tel-Aviv-Jaffa accepted the genetic tests submitted by Danziger, hence declaring essential derivation<sup>28</sup>.

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<sup>24</sup> *Ibid.*, p.16;

<sup>25</sup> ‘Dan’ Flower Farm v. Astée Flowers, 105.003.932/01, Court of Appeal, The Hague (2009), p. 20;

<sup>26</sup> *Ibid.*, p. 21;

<sup>27</sup> Plants, People and Practices – Jay Sanderson, Cambridge (2017) p. 224;

<sup>28</sup> Danziger ‘Dan’ Flower Farm v. Azolay & Astée Flowers 001228/03, District Court, Tel-Aviv-Jaffa (2009);

Moreover, the decision held by the Israel's Court was of great significance because the burden of proof was reversed, so that it was defendant's duty to prove the lack of derivation. According to the District Court of Tel-Aviv-Jaffa, Astée was not able to prove their claims about the way in which '*Blancanieves*' was created<sup>29</sup>.

In light of the foregoing, it's quite easy to find out that several conflicts on such sensitive topic could be potentially solved by reference to a generally accepted legal framework, therefore involving a qualitative approach that would enable the concept of EDV to meet its original mission as defined by UPOV Convention (1991).

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<sup>29</sup> *Ibid.*, p. 21;

#### 4. UPOV EFFORTS TO CLARIFY EDV: FROM 2009 TO 2017 EDV EXN

The International Convention for the Protection of New Varieties of Plants (UPOV, 1991) introduced the concept of ‘*Essentially Derived Varieties*’ (EDVs), although some of the key expressions, such as ‘*predominantly derived*’ and ‘*essential characteristics*’, remained uncertain for most of the members involved at the Diplomatic Conference, who formally requested the Secretary-General of UPOV ‘*to start work immediately after the Conference on the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties*’<sup>30</sup>.

Since then, all parties involved have been actively engaging with the intense debate before the Administrative and Legal Committee, in order to assess those issues related to the implementation of the UPOV obligations within the national IP systems.

Those efforts aimed at reaching a common view concerning the main topics on essential derivation, finally led to the release of the first version of UPOV EXN on EDV, in 2009<sup>31</sup>.

However, the clarifications provided within the above document didn’t manage to meet their main purpose, *i.e. ‘to provide guidance on ‘Essentially Derived Varieties’ under the 1991 Act of the International Convention for the Protection of New Varieties of Plants*’<sup>32</sup>.

In its closing remarks to the 2013 Seminar on EDV, the President of the Council of UPOV Ms. Kitisri Sukhapinda acknowledged, *inter alia*, the following points<sup>33</sup>:

- *Genetic distance measurements are not well correlated with phenotypic differences;*
- *Guidelines would need to consider the situation in different crops/ species and methods of breeding, e.g. mutants;*

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<sup>30</sup> 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) p 349;

<sup>31</sup> UPOV Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of The UPOV Convention (2009);

<sup>32</sup> Ibid., p.3;

<sup>33</sup> [https://www.upov.int/edocs/mdocs/upov/en/upov\\_sem\\_ge\\_13/upov\\_sem\\_ge\\_13\\_ppt\\_17.pdf](https://www.upov.int/edocs/mdocs/upov/en/upov_sem_ge_13/upov_sem_ge_13_ppt_17.pdf);

- *There is a need to consider the impact of the EXNs on breeders, including farmers, growers and society as a whole;*
- *Guidelines that would embrace a broad spectrum of stakeholders and interests may be more credible and persuasive to the Courts;*
- *Alternative dispute resolution mechanisms, such as mediation, arbitration and/or expert determinations could be useful tools for EDV assessments.*

It was, indeed, on those grounds that the Administrative and Legal Committee finally opted for the adoption of the current version of the UPOV Explanatory Notes on Essentially Derived Varieties, in 2017.



## 5. RELEVANCE OF THE ‘ESSENTIAL CHARACTERISTICS’ IN THE ASSESSMENT OF EDVs: THE PHENOTYPE PREFERENCE

The current version of the Explanatory Notes on Essentially Derived Varieties (2017) is nothing but the outcome of several years of negotiations to obtain a coherent, uniform set of rules that could finally entail the balance of diverging interests within the parties involved at UPOV, with regards to the main issues surrounding the EDV concept. As far as the scope of protection is concerned, the EXN on EDV deliver a set of provisions above the notion of ‘*essential characteristics*’ as per UPOV Convention (1991)<sup>34</sup>.

The crucial issue of the criteria for the ‘essential characteristics’ evaluation, and particularly of the importance of the phenotypical differences as opposed to the genetic conformity for the EDV assessment, has been clarified by the paragraph 6 of the Explanatory Notes, stating the following:

*UPOV/EXN/EDV/2*

*Par. 6*

*6. The following might be considered in relation to the notion of ‘essential characteristics’:*

- i. essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, **or other heritable determinants**, that contribute to the **principal features, performance or value of the variety**;*
- ii. characteristics that are **important** from the perspective of the **producer, seller, supplier, buyer, recipient, or user**;*

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<sup>34</sup> UPOV Explanatory Notes on Essentially Derived Varieties under the 1991 Act of The UPOV Convention (2017), par. 6 [https://www.UPOV.int/edocs/expdocs/en/UPOV\\_exn\\_edv.pdf](https://www.UPOV.int/edocs/expdocs/en/UPOV_exn_edv.pdf)

- iii. *characteristics that are essential for the variety as a whole, including, for example, **morphological, physiological, agronomic, industrial and biochemical characteristics**:*
- iv. *essential characteristics may or may not be **phenotypic characteristics** used for the examination of distinctness, uniformity and stability (DUS):*

In light of the statements as cited above, it is important to bear in mind that the scope of protection has to be determined by the characteristics which are the basis for grant of protection of a new variety.

Furthermore, proper defining the term ‘*variety*’ has represented one of the hottest cues since the adoption of UPOV Convention (1991), especially in relation to the ‘*breeder’s right*’, both as a threshold requirement for the grant of a PBR and determining the scope of the right. The term ‘*variety*’ can be defined as follows:

*‘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”<sup>35</sup>.*

The definition above 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*’.

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<sup>35</sup> International Convention for the Protection of New Varieties of Plants (1991), art. 1 (vi);

Both are technical terms that convey a particular perspective about the ways similarities and differences are considered and measured, and importantly, distinguished from others<sup>36</sup>.

The ‘*characteristics*’ of the variety are the features of the plant that define the variety itself<sup>37</sup>.

Consequently, such characteristics are of decisive importance in judging whether a new variety has to be regarded as an EDV. Extending the rights of an initial variety owner, regardless of how many distinct additional characteristics the new variety has, simply because it has been obtained by using one initial protected variety, would extend the scope of protection of a protected variety far beyond the scope determined by the characteristics, which was certainly not the intention of the legislator<sup>38</sup>.

*As it has been remarked, ‘It 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’.*<sup>39</sup>

Distinctness, as well as essential derivation, must be considered as two different concepts, implying the assessment of the former to be based on difference, by the expression of at least one characteristic, while essential derivation should be assessed on a conformity base, involving almost the entire genome and the relevant essential characteristics resulting from that genome.

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<sup>36</sup> Plant Breeder’s Rights and Essentially Derived Varieties: Still Searching for Workable Solutions - Charles Lawson, Griffith Law School (2016), p. 10;

<sup>37</sup> General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants – UPOV (2002), above n. 34 (2.4.1);

<sup>38</sup> Legal perspectives on Essentially Derived Varieties- Gert Würtenberger, Revista Eletrônica do IBPI – p. 204;

<sup>39</sup> ‘Why UPOV is Relevant, Transparent and looking to the Future: A Conversation with Peter Button’ – Jay Sanderson (2013); Journal of Intellectual Property Law and Practices, pp. 615, 618;

The determination of distinctness focuses on the *differences* in essential characteristics, whereas the determination of derivation focuses on the *similarities* of essential characteristics within the genome<sup>40</sup>.

In light of the aforesaid, the controversial definition of the EDV concept is bound to the criterion of ‘*essential conformity*’ with the initial variety.

Whereas a trivial, minor change between two varieties occurs, PBR law recognizes the right of the initial breeder through the possibility of a ‘*declaration of essential derivation*’.

In the context of PBR, the expression ‘*conformity*’ stands for a matching between the combination of genotype and phenotype of the varieties concerned. While genetic comparison is the traditional instrument in order to verify the ‘conformity’ requirement, this is not the only criteria for the EDV assessment, especially for mutants: ‘*mutations are related to the EDV concept, but not all mutants are EDVs.*’ *We should not discourage plant breeders in general or plant breeding by mutations, especially for certain species and even this might lead to innovative plant breeding. We need to find an equilibrium between the two systems to maintain plant breeders’ rights*<sup>41</sup>.

With the advent of new breeding techniques, such as genetic engineering, it’s been made possible to easily modify some important genetic characteristics concerning the new variety in only one go.

Therefore, it seems appropriate to acknowledge that several factors including the cultural, practical value of the variety, together with its characteristics are all to be considered in the assessment and identification of EDVs.

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<sup>40</sup> Court Decisions on Essentially Derived Varieties in The Netherlands - Tjeerd F. W. Overdijk -UPOV Seminar on Essentially Derived Varieties (2013) [https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

<sup>41</sup> Mr. Richard Brand, GEVES, France - UPOV Seminar on Essentially Derived Varieties (2013) p. 45 [https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

Some UPOV observers do believe that the characterization as an EDV is mainly determined by the genotype rather than by the phenotype of the varieties concerned.<sup>42</sup>

However, as a result of almost thirty years of intense debate, UPOV EXN on EDV (2017) reached the conclusion that distinctness in the phenotype plays a key role, as the putative EDV must conform essentially to the initial variety *‘in the expression of the characteristics that result from the genotype or combination of genotypes of the initial variety, except for the differences resulting from the act of derivation’*.

Phenotype can be defined as *‘the composite of the organism's observable characteristics or traits, including as its morphology or physical form and structure; its developmental processes; its biochemical and physiological properties; its behavior, and the products of behavior. An organism's phenotype results from two basic factors: the expression of an organism's genetic code, or its genotype, and the influence of environmental factors, which may interact, further affecting phenotype’*.<sup>43</sup>

As it has been pointed out by respected scholars *‘it is the phenotype which must give a first indication, allowing one to conclude (not to speculate!) that the new breeding result may be a derivation in the meaning of the EDV concept’*.<sup>44</sup>

This has been affirmed also by the (limited) existing EU case-law: in order to properly define and assert derivation, the putative EDV and the original variety must be phenotypically similar to such an extent that the one variety differs from the other variety only in one or few inheritable characteristics.<sup>45</sup>

Furthermore, from the definition of EDV *ex art. 14 UPOV Convention (1991)*, it follows that there should always be a particular act of derivation. Most notably, art. 14 (5)(c) rules that: *‘Essentially Derived Varieties may be obtained for example by the selection of a natural or induced*

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<sup>42</sup> Comments to the Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention – CIOFORA (2016), pp. 6-7 [https://www.UPOV.int/edocs/mdocs/UPOV/en/caj\\_73/caj\\_73\\_comments\\_ciopora.pdf](https://www.UPOV.int/edocs/mdocs/UPOV/en/caj_73/caj_73_comments_ciopora.pdf);

<sup>43</sup> <https://en.wikipedia.org/wiki/Phenotype>;

<sup>44</sup> Legal perspectives on Essentially Derived Varieties- Gert Würtenberger, Revista Eletrônica do *IBPI* – p. 207;

<sup>45</sup> Danziger ‘Dan’ Flower Farm v. Astée Flowers B.V., 105.003.932/01, Court Appeal, The Hague (2009), [20];

*mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing or transformations by genetic engineering'.*

A mutant could be described as a suddenly occurring change in an individual plant, which often can be preserved through multiplication and, as a consequence, can lead to a new and distinct variety.

## 6. A LEGAL PERSPECTIVE ON EDV ASSESSMENT

‘Essential characteristics’ are detailed under paragraph 6 of UPOV EXN on EDV<sup>46</sup>.

In particular, the differences between the initial variety and the putative EDV must not be such that the variety *‘fails to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety’*.

The expression above suggests a narrow scope of interpretation, assuming that varieties which do not retain all essential characteristics of the initial variety, are not to be considered as EDVs.

As Mr. Würtenberger correctly brought to the audience’s attention at UPOV Seminar on Essentially Derived Varieties (2013): *‘One should not forget that the UPOV system is based on phenotype. I try to emphasize that the differences in the phenotype are the starting point and the starting point for UPOV was also variations in the appearance, which are regarded more or less minimal in comparison to the initial protected variety. The genetic analysis is a very important means at a later stage. Of course, one should not strictly concentrate on the phenotype and on the genetic side, but the genetic side only comes once there are indications caused by the phenotype that there may be essential derivation’*<sup>47</sup>.

The exclusive use of genetic distances to determine essential derivation is therefore not suitable for all plant varieties, as there is a need for phenotypic variations to be based on genotypic variation.

Absolute measures of genetic similarities are not scientifically feasible. Quantitative thresholds have to be constantly monitored in order to comply with the innovations concerning new breeding technologies.

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<sup>46</sup> UPOV: Explanatory Notes on Essentially Derived Varieties under the 1991 act of the UPOV Convention (2017), p. 6;

<sup>47</sup> UPOV Seminar on EDV (2013), p. 47 [https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

The limitations of quantitative approaches are a consequence of the nature of science, which erroneously tends to assume that essential derivation is a merely scientific fact that can be quantitatively determined.

Indeed, some of the scientific uncertainty has been overcome by a consideration of the quality of the differences between the plant varieties involved.

A juridical approach is dynamic, as it can adapt to the evolution of plant breeding practices and variety production. The legal assessment of essential derivation can provide a more in-depth and comprehensive decision<sup>48</sup>.

As a consequence, we can firmly assume that legal and scientific approaches are to be deemed as interdependent factors within the examination and identification of EDVs.

In a nutshell: derivation cannot and should not be examined and identified purely on quantitative grounds. Cultural and practical values are also important in examining and identifying EDVs.<sup>49</sup>

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<sup>48</sup> Plants, People and Practices – Jay Sanderson, Cambridge (2017), p. 227;

<sup>49</sup> *Ibid.*, p. 230;



## 7. EDV AND COMPULSORY LICENSING

The important innovations, as described under the current version of the UPOV Explanatory Notes on Essentially Derived Varieties (2017), represent a milestone for the whole PBR system. In such contest, they constitute a more detailed degree of legal certainty for practitioners involved in the interpretation of the EDV concept, with reference to those biotechnological improvements capable of contributing to the benefit of both consumers and society. As we noted above, paragraph 6 of the Explanatory Notes comprehensively defines the fundamental concept of ‘*essential characteristics*’, with evident reference to the importance of phenotypic characters, including the non-DUS relevant ones as they could be able to bring valuable characterizing features to the variety ‘as a whole’.

Such a remarkable step forward a clear and uniform interpretation is able to be part of the interpretative ‘*acquis*’ in international Plant Breeders Rights, in order to encompass the difficulties flowing from the adoption of quantitative and/or dogmatic criteria.

Reference to substantial value of the improved variety may also be inferred by the ‘compulsory licensing’ procedure introduced by art. 29 of EU Council Regulation no. 2100/94 (the Basic Regulation), which in itself constitutes a limitation of the exclusive rights granted to the owner of a protected variety. Such limit is also contemplated to assist the owner of an EDV against the IV owner refusal to issue a license on unjustified reasons.

Notwithstanding the profound differences between the EDV concept and the Compulsory Licensing scheme, it is worth noting how both introduce limits in the exclusive rights conferred to the owner of a protected variety, so that while in the EDV case it is appropriate that he is compensated from the commercial exploitation of a variety bearing minor and/or

cosmetic differences<sup>50</sup>, the compulsory licensing scheme offer a remedy against the abuse of an Intellectual Property Right to the detriment of the Society at large.

Pursuant to art. 37(2) of Regulation no. 874/94 (laying down the implementing rules to the Basic Regulation (2100/94)), even the owner of an EDV is entitled to formally request the CPVO office to be granted with a compulsory license pursuant to the above-mentioned art. 29 (5), in presence of ‘*significant technical progress of considerable economic interest*’.

According to the procedural rules, the applicant shall provide ‘*documents evidencing that the applicant has applied unsuccessfully to obtain a contractual license from the holder of the plant variety right*’, where ‘*a request for a contractual license*’ shall be considered unsuccessful in case:

- *The opposite holder has not given a final reply within a reasonable period;*
- *The opposite holder has refused to grant a contractual license;*
- *The opposite holder has offered a license on obviously unreasonable fundamental terms.*

In other words, the current EU legislation seems to protect the underlying public interest in the exploitation of the EDV’s characters, by means of an additional source of legal protection, devolving this important role to the CPVO and the European Court of Justice<sup>51</sup>.

As a result, both EDV and Compulsory Licensing may play a delimitation function of the Initial Variety owners’ rights: (i) EDV, especially under the current version of the UPOV 2017 EXN, by preserving the essential scope to provide the society with improved varieties concretely and measurably differentiated from the Initial Variety; and (ii) the Compulsory Licensing avoiding the risk of an abuse of the granted PBR.

So far, the EU case-law is very limited (just one case) and further developments (which include also the EUCJ) with regards to the legal requirements for the granting of a

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<sup>50</sup> Most coherently, under the Australian ‘*bright line*’ approach, the IV owner has a ‘*veto*’ power against commercial exploitation of a ‘*me-too/copycat*’ variety (EDV), which are therefore excluded from any ‘*compulsory licensing*’ scheme.

<sup>51</sup> In spite of the ‘*Community*’ nature of EU PBR law, EDV judicial assessment is carried on a national basis, as for the ‘*European Patent*’ model, while Compulsory Licensing assessment follows the standard unified judicial system.

compulsory license in the PBR field would be helpful to give a clear picture of the fair interpretation to be followed for the granting of a compulsory license.

Including, which constitutes in most cases the real issue in the EDV cases, the fair determination of the '*equitable remuneration*' due to the Initial Variety owner if and when the alleged variety is an Essentially Derived Variety.

## 8. CONCLUSION

There is an ongoing, ever increasing, need for plant improvements to keep pace with more demanding properties that crop plants have to satisfy.

As we know, the establishment of a new trait may take up to several years, depending on various contingent factors, with enormous capital input.

Such investments require adequate protection, and if the trait is one that may be employed in various genetic backgrounds of a given crop species, any PBR mining innovation process is certainly not suitable to achieve broad protection.

UPOV and its members should apply a fair EDV approach, directed at establishing the right balance between breeder's rights and those of farmers and the society at large.

In Mr. Waterhouse's own words: *'I think that one of the metrics is that the development and release and availability of new varieties that are of better value to that society. So, whatever we do with EDV, whatever we do with the other elements of UPOV, that should be the outcome: that we get more varieties. EDV was an attempt conceptually to balance the rights of the first breeder and the second breeder and there is a dilemma for breeders themselves. We as policy makers are trying to adjust the balance listening to what the breeders say'*<sup>52</sup>.

The concept of derivation occupies a legal space and raises distinct legal issues; while science can quantify the ways in which plant varieties are the same, it cannot tell us whether there are substantial or important differences between plant varieties, or whether that sameness should have any meaning.

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<sup>52</sup> UPOV Seminar on EDV (2013), p. 97 [https://www.upov.int/edocs/pubdocs/en/upov\\_pub\\_358.pdf](https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf);

Taking into account the purposes of the definition of ‘*conformity*’, as provided in the Community Basic Regulation, the assessment of conformity itself shall rely on the phenotypical differences of the varieties concerned.

Consequently, the assessment of substantial and important differences in relation to the relevant, different crops involved in any specific case concerning derivation, may increase the degree of certainty.

Such differences represent the embodiment of the characteristics expressed by any organism such as, *inter alia*, morphology, development, biochemical and physiological properties, including behavior.

On this respect, any attempt to widen the boundaries concerning derivation, by means of a merely scientific/quantitative approach, is aimed at bypassing, *a priori*, any legal/qualitative method. This would empower the scope of protection granted to the breeder of the initial variety, by creating a breach in the traditional IP system, caused by an unfair advantage in favor of the initial PBR holder.

The innovations within UPOV EXN (2017) represent a considerable step toward legal certainty and predictability, as per the Australian ‘*bright line*’ approach. Each and any effort to depart from the EDV scope, with particular reference to the construction of the ‘*essential characteristics*’ as per paragraph 6 within the current version of UPOV EXN, would ultimately go against the main objective of PVR, namely to provide and promote effective system of protection, to the society welfare, in the name of innovation.