



**INTERNATIONAL UNION FOR THE PROTECTION
OF NEW VARIETIES OF PLANTS**

SEMINAR ON ESSENTIALLY DERIVED VARIETIES

October 22, 2013 (Geneva, Switzerland)

SEMINAR ON
ESSENTIALLY DERIVED VARIETIES*
Geneva, October 22, 2013

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- 10.15 A technical perspective on essentially derived varieties
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- 15.30 Court decision concerning essentially derived varieties in Israel
Mr. Arnan Gabrieli, Seligsohn Gabrieli & Co., Israel
- 15.45 Experience on essentially derived varieties in Japan
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- 16.45 Possible role of future UPOV guidance in cases before the courts
Mr. Gordon Humphreys, Member of the Second Board of Appeal, Office for the Harmonization in the Internal Market (OHIM)
- 17.00 Possible role of arbitration, mediation and expert determination
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- 17.15 Discussion on Sessions II and III
- 17.50 Closing remarks by Ms. Kitisri Sukhapinda, President of the Council of UPOV
- 18.00 End of Seminar

WELCOME ADDRESS

Mr. Francis Gurry, Secretary-General, UPOV

Ladies and Gentlemen,

It is a pleasure for me to extend a very warm welcome to you all.

It is very gratifying to see so many of you here this morning. This is testimony to the importance that you attach and that we attach to the notion of essentially derived varieties which was introduced into the UPOV system with the 1991 Act. That is now 22 years ago, so to say that it is 'timely' to review its operation is perhaps an understatement. Essentially derived varieties are a fundamental concept. They are the means by which we strike a balance between the scope of the breeder's right, on the one hand, and the breeder's exemption, on the other hand. The concept shares in common with all intellectual property rights two fundamental principles. First the notion of derivation which you find not just in respect of plant varieties, but you find it throughout copyright law, for example, where the question of what constitutes a derivative work is pervasive. At what stage does a work become a derivative work and how do you assess that? Secondly, there is the question of balance. The UPOV system is there to provide an effective and an efficient incentive to innovation in plant breeding. How do you balance that effective incentive, which the system must provide, with the notion of allowing research to continue in innovation in plant varieties?

I think that we have a very interesting event ahead of us today. We will deal with technical and legal aspects in the first session; the second session is devoted to the experience of members in respect of essentially derived varieties; and the third session will deal with the very important question of the possible role of UPOV guidance or soft law in the future in respect of essentially derived varieties. We will be looking at what role alternative dispute resolution systems play in other areas of intellectual property or in other technical subject matters where there is a long history of using experts to be able to reach technical judgments with respect to technical subject matter. That is also an interesting area to explore.

Let me then welcome you once again and thank you all for attending. I now have pleasure in passing the floor to the President of the UPOV Council, Ms. Kitisri Sukhapinda.

OPENING

Ms. Kitisri Sukhapinda, President of the Council of UPOV

On behalf of the UPOV Council, I would also like to welcome everyone here today to this long-awaited Seminar on Essentially Derived Varieties. As many of you know, this topic is very important to all of us and I believe that is why you are all here. We should not expect any particular conclusions from the presentations today. Our aim is to gather the information we receive from the speakers and from today's discussions and use this information to help with the development of the information material on EDV to support our members and stakeholders.

SESSION I:
**TECHNICAL AND LEGAL ASPECTS OF ESSENTIALLY DERIVED
VARIETIES AND THE POSSIBLE IMPACT ON BREEDING AND
AGRICULTURE**

THE DEVELOPMENT OF THE PROVISIONS ON ESSENTIALLY DERIVED VARIETIES

Mr. Joël Guiard, Chairman of the Technical Committee of UPOV

One of the most important amendments of the UPOV Convention when it was revised in 1991 was the introduction of the concept of essential derivation.

Article 14 of the 1991 Act of the UPOV Convention, which defines the scope of the breeder's right, provides in paragraph (5)(a)(i) that the scope of the breeder's right *apply in relation to varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety.*

In paragraph (5)(b) of Article 14 there is a definition of an essentially derived variety from an initial variety:

- (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.*

Paragraph (5)(c) of Article 14 provides examples of breeding methods from which essentially derived varieties might be obtained.

The objective of the paper is to recall the development of the provisions on essentially derived varieties. Firstly, the main elements that were considered by the stakeholders when introducing this concept will be reviewed; then the background that led to the development of the definition in Article 14(5)(b) will be explained (see above).

The main elements considered by the stakeholders

When revisiting the reports of the preparatory meetings before the Diplomatic Conference of 1991, we observe that the main elements which had been considered were:

- The necessity to provide a more effective right to the breeder in order to provide adequate remuneration for the investment through royalties. Referring to the patent system where inventions which represent an improvement of an initial patented invention can be considered dependent on the latter, the stakeholders were in favor of introducing a similar possibility in the Plant Breeders' Rights system. In addition, since the beginning of the 80's, the development of new technologies in genetic engineering had offered the possibility to modify an existing variety by the introduction of a single gene. This introduction can lead to a new variety that can be protected independently, while containing the entire genome of the existing variety. Furthermore, with a patented gene, the new variety could be part of the claims of the patent, a situation which leads to an inconsistency between the two intellectual property regimes.
- Based on the experience gained since the beginning of the plant variety rights system in 1961, it became obvious that, at least for some species, the minimum distance between varieties was decreasing and so, although the varieties were declared distinct, the quality of the protection was decreasing. The introduction of statistical tests to establish distinctness, in particular for species with relative uniformity, was also questioned because the differences were not necessarily visible.
- In addition, the fact that characteristics used to establish the description and decide on distinctness were, in general, not linked with the value of the variety was increasing the concern of the breeders when very similar varieties were protected independently from the initial variety.
- Some breeding methods were also a source of concern because they were considered to lead to "plagiarism". In particular, this related to selection of mutants or use of repeated backcrosses to

result in differences in characteristics of minor importance for the value of the variety. In the case of mutations, this concern was increasingly sensitive in the ornamental sector. The introduction of minor changes by backcrossing was also observed in Maize. These new varieties were distinct according to the UPOV principles in force but again the quality of the protection was decreasing. In addition, as indicated above, the development of genetic engineering offered new tools with the possibility to transfer a single gene to an existing variety and to get new varieties very close to the initial one in a very short time. This issue was discussed in relation to the nature of the characteristics used to established distinctness. Some arguments were made to establish Test Guidelines with characteristics linked to the value of the varieties; so called “important characteristics”, in order to limit the risk of plagiarism. The discussions showed that this proposal was not really suitable knowing that the importance of the characteristics can be variable in relation to the use of a variety and can change over time.

In all these elements, it is important to underline that there was a strong support of all stakeholders involved in the preparatory meetings to introduce the concept of essential derivation in the new version of the Convention in order to provide more effective protection but with strong support for keeping one of the milestones of the UPOV Convention: the breeder’s exemption.

The background of the definition

During the preparatory work before the Diplomatic Conference of 1991, the discussions mainly dealt with the effect of the introduction of the concept of essential derivation. The following alternatives of dependence were considered:

[Alternative 1] may prevent all persons not having his consent from performing the acts described in paragraph (1) above in relation to the new variety.

[Alternative 2] shall be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.

[Alternative 3] may prevent all persons not having his consent from performing the acts described in paragraph (1) above in relation to the new variety. However, where the new variety shows a substantial improvement over the protected variety, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.

However, a precise definition of essential derivation was not discussed in depth.

The basic proposal which was discussed during the Diplomatic Conference was as follows:

(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, particularly through methods which have the effect of conserving the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety, such as the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant, backcrossings or transformation by genetic engineering,

(ii) it is clearly distinguishable from the initial variety and

(iii) it conforms to the genotype or the combination of genotypes of the initial variety, apart from the differences which result from the method of derivation.

This definition has three elements, based on technical elements: the origin of the essentially derived variety, its distinctness from the initial variety and the conformity in relation to the initial variety.

Nevertheless, except for distinctness which refers to Article 7, the terms of this definition remained generic, covering a wide range of situations depending on the species and breeding methods.

During the Diplomatic Conference, different proposals for amendments to the basic proposal were discussed:

- The fact that an essential variety is derived from only an initial variety. The first part of the definition clearly excludes the cascade of derivation, saying that an essentially derived variety is predominantly derived from the initial variety and the two following parts of the definition referring only to the initial variety. A variety C can be essentially derived from a variety B which is essentially derived variety from an initial variety A, but the dependency will only refer to the variety A.
- Numerous discussions on the clarification of the definition of the essential derivation took place considering that it would be difficult to decide if a variety was an essentially derived variety or not. It was clearly stated that the definition of the essential derivation could not be based on the breeding method.
- Depending on the objective of the breeder, any breeding method can result in an essentially derived variety and based on new scientific developments, it becomes easier to change small parts of the genome. So the reference to particular breeding methods was deleted from the first part of the basic proposal. Certain delegations were in favor of no indication of breeding methods considering that it could be misleading. Finally, paragraph (c) was added to Article 14(5) with breeding methods given as examples.
- The use of the word “conforms” in the third part of the definition clearly indicates that the evaluation of essential derivation is based on the similarity with the initial variety. A lot of discussions took place on the meaning of conformity but the large majority of delegations agreed to consider that an essentially derived variety should have only small differences compared to the initial one without wishing to provide a precise definition of the number and the size of the differences. It was decided during the Diplomatic Conference that UPOV will have to prepare guidelines on how essential derivation could be evaluated.

“Resolution on Article 14(5)

“The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requests 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.”

- In relation to the word “conforms” an important amendment was discussed. The basic proposal made reference to the conformity of the genotype or combination of genotypes. The amendment proposed to introduce the wording as it is in the definition of the variety (Article 1(vi)) which refers to the expression of the genotype or combination of genotypes, in other words the phenotype. The main reason for this change was that there was no clear method to assess the conformity at the level of the genome. This argument received good support and the amendment was approved.

After this very quick review of the discussion during the Diplomatic Conference, it is important to consider some elements of the definition of essentially derived variety as approved in the 1991 Act of the UPOV Convention, as reproduced in the introduction of this paper.

The first part of the definition states that the essentially derived variety has been predominantly bred on the basis of the initial variety. This means that the breeding scheme includes the initial variety with the aim of keeping a large part of its characteristics, so called essential characteristics, in the essentially derived variety. It excludes the case of a variety that is very similar to an initial variety but where the initial variety was not used in its breeding scheme. The breeder of a variety B, which is considered essentially derived by the breeder of variety A because it is too similar, has to prove the use of variety A in the breeding of variety B.

This paragraph does not make reference to any breeding method. Paragraph (c) of the Article 14(5) lists some examples of breeding methods which might lead to essentially derived varieties but this list is not exhaustive and doesn't mean that all varieties bred using these methods are essentially derived.

The main objective of this first part of the definition is to deal with the origin of the essentially derived variety.

The expression "essential characteristics" is not used in other articles of the Convention. In the same way as for characteristics used to establish distinctness, they result from the expression of the genotype but they are not necessarily the same. This point is essential in the interpretation of the condition "predominantly derived" which can be based on the characteristics used for assessment of distinctness but can also be based on other characteristics. For example, they might be linked to the value of the variety.

Paragraph (5)(i) of Article 14 says that an essentially derived variety cannot be dependent from a variety which is itself essentially derived from an initial one. This condition is designed to avoid a cascade of dependency resulting in a series of essential varieties for an initial variety. Hence, the evaluation of the essential derivation is always with reference to the initial one.

The second part of the definition requires that an essentially derived variety must be distinct from the initial variety. It clearly demonstrates that essential derivation relates to varieties which are distinct according to Article 7 of the Convention but nevertheless similar to the initial variety. It means that a variety with small differences from an initial variety can potentially be an essentially derived variety but not necessarily.

The third part deals with conformity, saying that, except for the differences resulting from the derivation, the essentially derived variety conforms to the initial variety in the expression of the essential characteristics.

This part seems to be a repetition of the first part, but the first part refers to retaining the essential characteristics and the second part refers to conformity, which is more precise.

In fact this part remains generic, because, as it was discussed during the Diplomatic conference, the assessment of conformity depends on the species, the structure of the varieties and the genetic variability available for the breeders.

The conformity is defined at the level of the phenotype of the essential characteristics, between the essentially derived variety and the initial variety, but the phenotypical conformity can rely on different genetic backgrounds. This point justifies the existence of parts 1 and 3 in the definition.

ESSENTIALLY DERIVED VARIETIES UNDER THE 1991 ACT OF THE UPOV CONVENTION: A BRIEF HISTORY

Mr. Raimundo Lavignolle, Plant Variety Register Director, National Seed Institute (INASE), Argentina

The objective of this presentation is to give a brief overview of the development of guidelines on essentially derived varieties (EDVs) after the Diplomatic Conference of 1991.

1 - Introduction: the mandate

The 1991 Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, in addition to the 1991 Act of the UPOV Convention, adopted further instruments, one of which was the following Resolution:

“Resolution on Article 14 (5)

The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requests the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines, for the adoption by the Council, on essentially derived varieties.”

2 - Development of EDV Guidelines: Following the mandate of the Diplomatic Conference

Following the Resolution, document CAJ/29/2 “Guidelines Relating to Essentially Derived Varieties” was prepared by the Office of the Union. The guidelines were considered by the Administrative and Legal Committee (CAJ) at its 29th Session in October 21 and 22, 1991, and at its 30th Session in April 8 and 9, 1992. At both sessions the CAJ considered the importance of involving breeders in the development of the guidelines, taking into account the role they were supposed to play in managing the system.

The guidelines were then presented to the Sixth Meeting with International Organizations (IOM/6), that was held in Geneva on October 30, 1992.

The full proposal is contained in document IOM/6/2, however we can summarize the key elements of the proposal as follows:

2.1 - Nature of the Guidelines:

At the time the guidelines were developed, the other guidance development by UPOV were Test Guidelines (TGs), TG/1/3 and the UPOV Recommendations on Variety Denominations. It was clear that the other guidance was in relation to the practice of the offices of the UPOV members and addressed to Governments of UPOV members. It was further clarified that matters related to EDVs were not included in the criteria to be satisfied prior to the grant of the breeder’s right. In the discussions for the preparation of the Diplomatic Conference and during the Conference it was a repeated view that the relationship between an essentially derived variety and an initial variety would be a matter between breeders. In consequence, the nature of the guidelines should be different to that for other guidance.

2.2 Provisions on Essentially Derives Varieties

The guidelines for consideration by the CAJ and by the IOM provided explanations to the text of Article 14(5). The main concepts contained in the explanations could be summarized as follows (full explanations in document IOM/6/2)

- Dependency:

The dependency is from the initial variety to its EDVs and not between EDVs themselves and provides an opportunity for the breeder of an alleged EDV to show that the initial variety is itself an EDV.

- Derivation - Art 14(5)(b)(i):

A variety can only be essentially derived from one variety, the initial variety, if it is derived while retaining the expression of the essential characteristics of the initial variety. It could only be an EDV from another variety when it retained virtually the whole genotype of the other variety. This was related to “retaining the expression of the essential characteristics” as provided in Art. 14(5)(b)(i). It also explained that “while retaining” required that the expression of the essential characteristics be derived from the initial variety, all characteristics should be taken into account, morphological, physiological, agronomic, industrial as well as molecular ones. These characteristics should, nevertheless, be those which were heritable genetically.

- Distinct - Art 14(5)(b)(ii)

EDVs can only be varieties that are clearly distinguishable from the initial variety and, accordingly, could be protectable independently from the initial variety.

- Conformity - Art 14(5)(b)(iii)

The guidelines explained that the provisions dealing with the conformity did not set a limit for the number of differences between the initial variety and the EDV. The limit was established when dealing with derivation, which required the essential characteristics of the initial variety be retained. The examples in Article 14(5)(c) made clear that the differences which resulted from the act of derivation should be one or very few.

2.3 Establishing the essential derivation of a variety

The proposed guidelines explained that establishing distinctness required no further comments. The same criteria as for other candidate varieties apply.

Establishing the origin would require the use of any information available (record books, genealogy, genetic knowledge, DNA analysis, etc.). In respect to the genetic origin, during the discussions it was proposed to provide in national laws for some modification of the burden of proof, but that was not taken up. The UPOV Convention was silent concerning the question of the burden of proof and this matter was left to UPOV members to decide.

When dealing with the question of similarity, the term “Essential” was considered to have the meaning of “fundamental” or “indispensable.” It was suggested that both the initial proposal, as well as the Japanese proposal which replaced it, called for the degree of similarity between varieties to be assessed on the basis of the characteristics of the variety taken as a whole and not characteristic by characteristic. It was also not desirable that decisions on whether a variety is or is not an EDV be decided differently in UPOV members. It was further explained that the intended interpretation had not been that the result from a crossing between two varieties could lead to EDVs.

Finally a series of examples were presented: the addition of a number of characteristics, one by one by genetic engineering; reselection from within a variety; backcrossing; transformation by genetic engineering; somaclonal mutants; natural or induced mutants; change in the chromosome number and cell fusion.

During the discussions of the guidelines, key concepts raised at the IOM/6 were the relationship between Article 14(5)(b)(i) and (iii); the need to establish distinctness before considering the EDV; and the EDV assessment, which may require a different approach to that for distinctness, in which case the notion of “distance” should be taken into account, which could be approached differently depending on the genetic structure of the varieties, and needed to be considered on a species by species basis. It was also expressed that an initial variety and its EDV should be very close varieties, in which case the principle of dependence would apply in a few cases.

The need for clarity was also raised, in particular for third parties that needed clear indication when they could be entering into the EDV concept when breeding new varieties.

2.4 Final conclusion

The draft guidelines and the discussions at the IOM/6 were considered by the CAJ at its 32nd Session in April 21 and 22, 1993 and by the Technical Committee (TC) at its 29th Session in April 21, 1993. Both Committees agreed that it was premature to set up examples at that time, and that the work of the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) could contribute to defining EDVs and, therefore, the discussion on guidelines for EDVs was adjourned *sine die*.

3 – Issues concerning the development of EDV varieties

3.1 Extending the protection from the initial variety to its EDV

Following the request of the TC, the CAJ at its 47th Session on April 10, 2003, discussed the cases of the possible extension of the protection of the initial variety to breeding results which conformed with the notion of an essentially derived variety. Even though the initial consultation took place at the Technical Working Party for Ornamental Plants and Forest Trees (TWO), it was agreed that the cases were possible in all crops. A Key element of this case was the need for the protection of the initial variety to be valid which required the need for the maintenance of the initial variety. Another element identified was the risk for the breeder of the EDV that the condition of EDV be challenged by third parties or, similarly, in the case that the EDV be obtained by a breeder different than the breeder of the initial variety (see final text in Annex III of document CAJ/47/18 “Report”).

4 – Development of the Explanatory Notes on Essentially Derived Varieties: UPOV/EXN/EDV

4.1 - Adoption of UPOV/EXN/EDV/1

In 2005, the CAJ agreed to the preparation of information materials concerning the UPOV Convention, including the development of information materials in respect of EDV. These information materials were to be discussed by the Administrative and Legal Committee Advisory Group (CAJ-AG) and, prior to drafting documents, the Office of the Union asked non-governmental organizations for information in that matter. Information from the International Seed Federation (ISF) and the International Association of Horticultural Producers (AIPH) was received.

Following the discussions at the first session of the CAJ-AG, the CAJ at its 55th Session, on March 29, 2007 agreed that there was no requirement for an initial variety to be protected in order to be considered an initial variety. The first draft for the explanatory notes on EDVs (UPOV/EXN/EDV Draft 1) was considered by the CAJ-AG at its second session. It was agreed not to develop guidance on licensing. Few editorial comments were made and a second draft (UPOV/EXN/EDV Draft 2) was presented at the CAJ at its 57th Session on April 10, 2008. At that session the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA) announced the development of its guidance on EDVs and requested that the CIOPORA guidelines be taken into consideration. ISF also requested some developments be incorporated into the EDV guidelines. Several UPOV members considered the information provided in document UPOV/EXN/EDV Draft 2 useful and indicated the urgent need for the guidance to be adopted, which would not hamper the consideration of the comments from CIOPORA and ISF when developing a future revised version of the guidance. At its 58th session, in October 27 and 28, 2008, it was agreed to propose document UPOV/EXN/EDV Draft 2 for adoption by the Council and to initiate the work for its revision. It was also agreed to consider the comments from CIOPORA and ISF in a future revision.

At its 43th Ordinary Session, on October 22, 2009, the Council of UPOV adopted UPOV/EXN/EDV/1 “Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention”.

A brief overview is provided in its table of contents:

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4.2 – Further elements for discussion and development of UPOV/EXN/EDV/2

The key elements proposed by CIOPORA and ISF for further discussion were:

- All examples in Article 14(5)(c) led to essentially derived varieties;
- Relationship between Article 14(5)(b)(i) and (iii)
- To insert a Variety “D” into the scheme of indirect derivation

The CAJ-AG at its 3rd Session CAJ-AG/8/3 considered the above matters and agreed that it would not be appropriate to consider all the varieties bred by the methods in the examples in Article 14(5)(c) to be essentially derived varieties; to further discuss the relationship between Article 14(5)(b)(i) and (iii) and requested the Office of the Union to develop a draft guidance for the situation with regard to a variety “D”. The CAJ, at its 59th Session on April 2, 2009, endorsed the conclusions of the CAJ-AG.

The CAJ-AG at its 4th Session CAJ-AG/9/4 did not discuss the relationship between Article 14(5)(b)(i) and (iii); and agreed to insert a Variety “D” into the scheme of indirect derivation. The representative of CIOPORA explained that CIOPORA did not agree with the statement in paragraph 12 of document IOM/6/2 that the “difference which results from the act of derivation should be one or very few”.

At its 5th session, on October 18, 2010, the CAJ-AG agreed with the scheme proposed for the inclusion of variety “D”.

At its 6th Session, on October 11, 2011, the CAJ-AG discussed the relationship between Article 14(5)(b)(i) and (iii); in particular it considered background information from discussions prior to the 1991 Diplomatic Conference, during and after the Conference. It also considered the first draft for the revision of the explanatory notes on EDV, UPOV/EXN/EDV/2 Draft 1. Other matters considered were the possibility of variety “D” being indirectly obtained by the use of information of the initial variety. e.g. DNA information and the possibility of including the issues concerning the development of EDV varieties (see item 3 above). It agreed to continue discussions on the above matters, to open the possibility of indirect derivation to varieties, “E”, etc. It also noted that clear rules on EDV may help breeders to benefit from the EDV protection, which would lead to cost savings for them. Information of how the Community Plant Variety Office of the European Union (CPVO) and the IP Australian Office deal with EDV would be circulated for 2012.

At its 7th Session, in October 29 and 30, 2012, the same issues were considered for discussion, jointly with a new version of the explanatory notes UPOV/EXN/EDV/2 Draft 2. Breeders’ associations considered it useful to incorporate guidance on “non protected” EDVs and that the assessment of EDV was a matter for the breeders, but UPOV should provide guidance. The European Coordination Via Campesina (ECVC) considered the EDV concept as a limitation of the breeder’s exemption and warned that traditional varieties should not be covered by the EDV concept. CIOPORA recalled its opinion that all mutants should be considered EDV, that it considered the provisions of Article 14(5)(b)(i) and (iii) inconsistent. ISF recalled that it had always been of the opinion that there should be a limited number of characteristics, one or very few, for a variety to be considered an EDV.

4.3 Summary of issues still under discussion

- Relationship between Article 14(5)(b)(i) and (iii)
- Use of information of the initial variety for indirect derivation
- Guidance on “non-protected” EDVs
- Number of differences to be considered an EDV

A TECHNICAL PERSPECTIVE ON ESSENTIALLY DERIVED VARIETIES

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Introduction:

The definition¹ of an essentially derived variety according to article 14 (5)(b) of the UPOV 1991 Act, clearly states (in general) that the *expression of essential characteristics* results from the *genotype or combination of genotypes*. This implies a direct correlation between the genotype and the appearance or phenotype of plants belonging to the variety with this genotype. Should changes in the genotype always be reflected in an altered phenotype? Or in contrast, are all plants with identical genotypes equally expressed in their essential characteristics? Do they look identical? Some examples will show us that this is not always the case.

The decision for a variety to be essentially derived from another (the initial) variety is thus based on the expression of the essential characteristics. The phenotype (defined as observable traits or characteristics) is decisive and should always be examined. However, investigation of the genotype can be very useful as a tool to predict essential derivation. According to the EDV concept, a putative EDV will differ in only the expression of one or a few essential characteristics compared to the initial variety. And, as these essential characteristics are resulting from the genotype, in most cases a strong genetic conformity between the initial variety and the putative EDV is to be expected. Therefore, genetic conformity can give a good indication for essential derivation.

When genetic conformity is used as a tool to predict essential derivation there are many questions to be answered on how to determine genetic conformity such as: what kind of genotyping methods or DNA marker technologies should be used, what genetic similarity indicates essential derivation? This paper pleads for a harmonized, general approach to give some technical guidance in EDV conformity studies on a crop-by-crop basis.

Proposed harmonized approach for genetic conformity studies:

Genetic conformity should be studied on a crop-by-crop basis since every crop has its unique peculiarities. A heterogeneous cross-pollinating crop for which all individual plants are genetically diverse will require a different approach compared to a vegetatively propagated crop for which all individual plants of a variety are genetically identical. In addition, for intensively bred species and/or species with limited genetic diversity in their gene pool more DNA markers are needed to reach the required discriminative capacity when compared to highly polymorphic species.

In general, to determine genetic conformity it is important to study a well-defined set of varieties that on the one hand are supposed to be known and accepted EDVs and on the other hand a set of varieties that are known or agreed on to be non-EDVs (see Figure 1). These sets of variety pairs represent two (distinct) groups. By using DNA markers we aim to define the minimum similarity of variety pairs that are supposed to be real EDVs (See Figure 1-arrow C) and in addition, the maximum similarity of variety pairs that are supposed to be non-EDVs (See Figure 1-arrow B). In this way we concentrate on the area of 'uncertainty'. The ideal situation will be that the similarity indicated by arrow B is (much) lower than the similarity indicated by arrow C. The gap between these similarities (See Figure 1-redbar) can, subsequently, be used by the breeders to set a threshold for EDV. Since such threshold is based only on genetic conformity and phenotypic characteristics are not taken into account, this should be used to shift the burden of proof.

¹ Article 14 (5)(b) of the UPOV 1991 Act:

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.

Before performing a genetic conformity study two major questions need to be considered:

1. How wide do we have to study the diversity (choices for framework of references and the relevance of references).
2. How deep do we have to look into the genomes that are compared (how many markers and what kind of DNA marker technology).

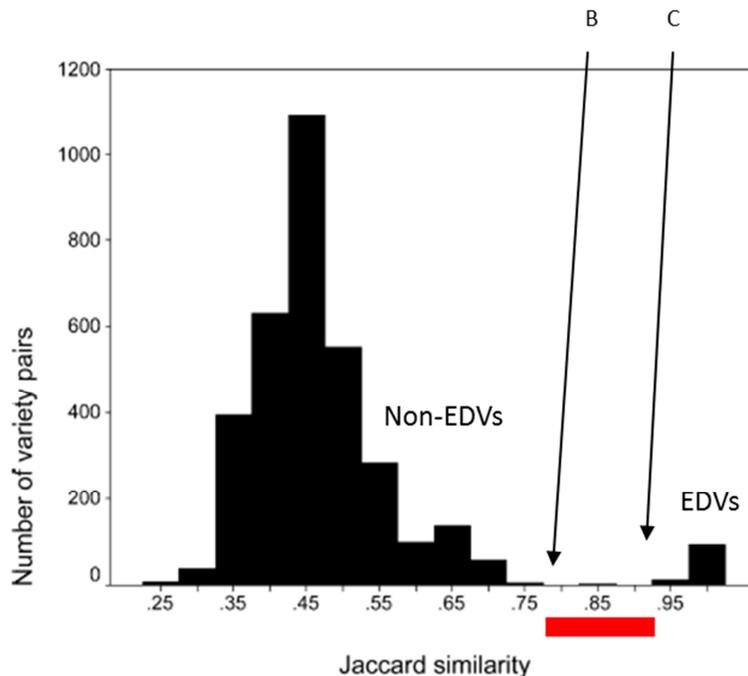


Figure 1: Graph from the EDV study for rose using AFLP® (Vosman et al. 2004) as an example. Distribution of similarities across all variety pairs. All mutant/EDV similarities are found between 0,95 and 1.0. All non-EDVs are found < 0,80 with 75% of the non-EDVs <0,50.

Genetic width – Choice of reference framework:

To investigate the genetic conformity it is of crucial importance to select reference varieties representing a relevant framework that guarantee representative sampling of the particular crop and gauge discriminative capacity of markers. Several categories for sample selection are proposed:

- a. To cover the complete genetic width, the reference collection to be used in the genetic conformity study must represent the complete phenotypic diversity within the species/crop currently available in the market. All relevant essential phenotypic characteristics should be present in comparative number of varieties.
- b. In addition to the genetic width, it is very important to zoom in on samples that are supposed to be genetically related with a well-known pedigree relationship. To fine tune the smallest genetic distance between related but not derived samples, we need to analyze varieties that originate from at least one common parent and/or progeny from a cross between two (non) related parents. Breeding material from breeding programs from the past 15 years will be very useful. It is of crucial importance to define the maximum similarity of variety-pairs in this category (see arrow B in Figure 1).
- c. The genetic analysis should include known and accepted mutant varieties and their original varieties. Varieties that are supposed to be EDVs and their initial variety. Although mutants are distinguishable from the original varieties based on phenotypic characteristics, their DNA fingerprints are expected to be nearly identical or completely identical. This is to define the reliable minimum similarity of variety pairs that are supposed to be EDVs (see arrow C in Figure 1).
- d. Different origins (from different independent growers) and/or different generations should be included in the analysis to investigate the allowed genetic variation within a variety due to selection or genetic drift.
- e. From all varieties included in the genetic analysis *duplo* samples should be analyzed. This means that from the same (leaf) material two independent DNA extractions should be performed. The two DNA samples will proceed through the whole technical procedure as

independent samples and serve as a measure for the intrinsic/technical error rate in the protocol.

The choice for the varieties that constitute a survey of the relevant width of genetic diversity and are likely to be encountered in future EDV determinations is a decision for the breeders of the particular crop.

For the determination of the maximum similarity of variety pairs that are supposed to be non-EDVs, varieties from category a and b will be used.

For the determination of the minimum similarity of variety pairs that are supposed to be real EDVs, varieties from category c and d will be used.

DNA profiles should be stored in databases in a way that they can be compared with all other profiles generated in the past and profiles that will be generated in the future. To assure the identity of the samples in the database, '*identity material*', that is original material used in the DUS trials and is granted PBR, can be used if agreed by the owners of the varieties.

Genetic depth - Choice of DNA marker technology:

Since the discovery of the double helix, the structure of the DNA molecule by Watson and Crick in 1953, the scientific area of molecular biology has developed very rapidly. Technologies like Polymerase Chain Reaction (PCR) and more recently Next Generation Sequencing (NGS) technologies have changed the world and also had great input on plant breeding.

For genetic conformity studies several genotyping or DNA marker technologies are suitable. In general, all DNA marker technologies generate information on just a fraction of the genome and not (yet) on the complete genome. Which technology is more powerful or more valuable is dependent on many factors. They all have their own advantages, disadvantages and unique properties. It is, therefore, not sensible or relevant to compare them (like apples and pears). Every case should be considered individually and the most appropriate technology should be selected after consideration of needs, purpose, crop and costs (it is not always necessary to shoot a fly with a cannon).

In an attempt to give a brief overview, we can distinguish random DNA markers and targeted DNA markers. The Amplified Fragment Length Polymorphism (AFLP®) technology developed by Keygene N.V. in Wageningen, the Netherlands and described by Vos et al. (1995) belongs to the first category. No prior DNA sequence information is required and therefore this technology is flexible and generally applicable to all crops. AFLP® is widely used for genetic conformity studies also in relation to EDV (Vosman et al., 2004; van Eeuwijk and Law, 2004; de Riek et al. 2001a and 2001b; Debener et al. 2000; ISF: Guidelines for the Handling of a Dispute on EDV in Lettuce). Although AFLP® is relatively old, it works well especially in polymorphic crops without prior sequence knowledge. This technology is less efficient when intensively bred crops and/or crops with a small genetic gene pool are involved. Most of the DNA fragments of the generated profiles appear then to be monomorphic (present in all varieties) and have no discriminative capacity.

An established and frequently used technology for genetic conformity studies is Simple Sequence Repeats (SSR; synonyms are Short Tandem Repeats (STR), Sequenced Tagged Microsatellite Site (STMS) or just Microsatellites). SSRs are targeted DNA markers. The highly polymorphic, multi-allelic markers are scored in a co-dominant way, discriminating homozygosity and heterozygosity, and appear to be very powerful in many crops. Several papers describe genetic conformity studies to determine essential derivation using SSR markers (Reid et al. 2011; Reid 2012: ESA-revised report on determining a threshold for genetic conformity in potato seedlings (2012); Vosman (2006) CPVO-final report on a European reference collection of rose varieties).

With the introduction of Next Generation Sequencing technologies the capacity to generate DNA sequence information increased enormously while the costs for this information decreased (indicated by the cost per raw megabase in Figure 2a and the cost per genome in Figure 2b). In these graphs the cost reduction in time is plotted together with the Moore's law for computers.

This enormous cost reduction for sequence information in time enabled genome wide screening and Single Nucleotide Polymorphism (SNP) discovery in a wide range of crops. After significant investments and research the location of informative SNPs is revealed, it is possible to systematically screen for these

particular (targeted) positions in the DNA in a simple and very cost efficient assay. Crop-specific SNP assays or arrays will reveal hundreds to millions of data points.

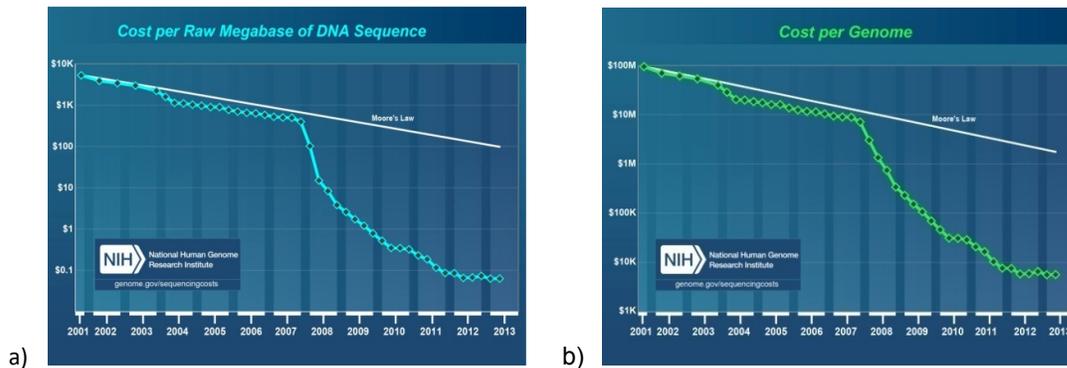


Figure 2a and b: Cost of DNA sequencing (cost per raw Megabase in Figure 2a; cost per Genome in Figure 2b) compared with Moore's law for computers. Moore's law says that computers double in power roughly every two years—an increase of more than 30 times over the course of a decade, with concomitant reductions in cost. (<http://www.genome.gov/sequencingcosts/>)

One step further is to perform the genetic conformity studies directly on genome sequence data. The approach of comparing complete genomic sequences or parts of genomes for every variety is called Genotyping based on DNA sequence information. Several recent papers show that this is also possible in plant species (Elshire et al. 2011; Lu et al. 2013).

The trend in DNA sequencing and technology development is: *More for less*. The advantage of more data points and high resolution of DNA sequence is that the genetic similarity is more fine-tuned: we have seen more of the complete genome. Another advantage is that DNA sequences reflect the genotype in a direct way: the DNA sequence *is* the genotype! Looking deeper into the genotype than knowing the order of all basepairs is not possible! For traditional DNA markers technologies additional technical steps are required to 'translate' the genotype into a DNA profile. When we know every basepair of a plant we know every potential marker.

Comparing is relative:

The technological revolution, however, does not automatically solve the EDV challenges. The old questions remain valid: how deep do we have to screen to distinguish the EDVs from the non-EDVs? At which genetic similarity do we consider it likely for a variety to be essentially derived from the initial variety?

Screening and comparing whole genomes will reveal an increased number of differences between closely related varieties and probably enable us to find one or several differences between mutants and their initial varieties. But also the number of differences between non-related varieties will increase. The relative distances (and similarities) between these varieties will, however, not change. Comparing is relative. Therefore the choice for a DNA technology is *not* crucial. Any DNA marker technology can do the job as long as the technology has proven to be accurate.

To determine the adequacy of a technology or DNA marker set several points should be considered:

- i. Discriminative capacity/informativeness: This can only be determined by an extensive study including the relevant reference framework representing all categories (a, b, c and d) mentioned above. Is it possible for the defined marker set to discriminate the variety pairs that are agreed on to be real EDVs from the variety pairs that are supposed to be non-EDVs? Diversity statistics such as Polymorphism Information Content (PIC)-values, expected heterozygosity (H_e), Effective Multiplex Ratio (EMR), Marker Index (MI) and/or Resolving power (Rp) can be calculated to

illustrate the informativeness of a marker or marker system². The number of markers used should be an excess (exhausted number of markers). Analysis with a random selection of markers should not lead to different conclusions.

- ii. Representative sampling of the genome: No matter the number of DNA markers that are used in a genetic conformity study, it is important that they are uniformly distributed over the genome and representative for the DNA content of the variety. Markers are preferably not linked.
- iii. Reproducibility: Once chosen for a particular technology or DNA marker set this should repetitively reveal the same DNA profile for a variety. This is essential especially when the DNA profiles are stored in databases.
- iv. Error-rate: Every technology and every machine or platform has its imperfections and deficiencies. It is crucially important to be able to distinguish the technically induced variation from the real genetic diversity. This can be determined by the analysis of *duplo* samples.

So far, several genotypic conformity studies have been published using different techniques. (De Riek et al. 2001a; Heckenberger et al., 2005a, 2005b and 2006; Vosman et al. 2004; van Eeuwijk and Law, 2004; Borchert et al. 2008; Noli *et al.*, 2012). The International Seed Federation (ISF) has adopted guidelines for dealing with disputes on essentially derived varieties (see <http://www.worldseed.org/isf/edv.html>) and the ISF Crop Sections have set EDV thresholds for perennial ryegrass, maize, oilseed rape, cotton and lettuce based on genetic conformity studies in these crops. In common with ISF, we recognize that marker systems and specific marker sets will change over time as the technologies develop. In addition, genetic diversity within a crop is not static. It is living material and it will evolve, develop and change over time as new varieties are developed. Therefore, thresholds and measurement techniques described in these guidelines should be reviewed periodically and adjusted if necessary.

Summarizing remarks:

- Genetic conformity can, in addition to morphology assessment, be used as a tool to predict essential derivation.
- To determine the genetic conformity on a crop-by-crop basis we propose a harmonized approach.
- In general, to predict EDV the minimum similarity of variety pairs that are supposed to be real EDVs should be defined. In addition, the maximum similarity of variety pairs that are supposed to be non-EDVs should be defined. The range/gap between these similarities (See Figure 1-redbar) can, subsequently, be used by the breeders to set a threshold for EDV.
- To allow reliable determination of an EDV threshold the choice of a relevant reference framework is crucial.
- The choice for a DNA marker technology is, in our view, not crucial. This choice is dependent on many factors like purpose, crop, prior available knowledge on DNA sequence level and costs.
- For the determination of a suitable, accurate marker set it is important that the number of markers is exhaustive and the discriminative capacity is sufficient. The produced DNA profiles should be reproducible and the technical error-rate should be clearly distinguishable from the genetic diversity by using *duplo* samples.

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A LEGAL PERSPECTIVE ON ESSENTIALLY DERIVED VARIETIES

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I. Introduction

A plant breeder's right will be granted upon application if the variety is new, distinct, uniform and stable¹.

The distinctness criterion is the relevant criterion in relation to other varieties that are commonly known at the time of the filing for grant of a plant breeder's right². It determines the scope of protection. Distinctness must be established with regard to one or more important characteristics. Any new breeding result which is not clearly distinct from varieties of the same species, with regard to characteristics being the basis for grant of protection, falls into the scope of protection of a protected variety.

The rights granted to the holder of a breeder's right are determined by Article 14 UPOV 1991 and Article 13 of Regulation 2100/94. In summary, the rights of a breeder in a variety cover the entire field of commercial production and commercial distribution of the propagating material and, under certain circumstances, of the harvested material and products obtained from harvested material.

Any material of protected varieties may be used for the purpose of breeding other varieties, without the possibility of intervention by the owner of the rights in the material used (forthwith called initial variety). As, due to the nature of living material, the breeding of a new variety inevitably requires that freely available material is used, one of the fundamental principles of the plant variety protection system is the breeder's exemption which allows everybody to use plant material released into the public domain, even if the plant material is protected by a PVR. If the use of such material led to a new variety, the rights granted in the same were, up to the 1991 Agreement, totally independent from any rights related to the material used.

In order to balance the interests of a holder of a plant breeder's right and the need to have free access to protected material, safeguarded via the breeder's exemption, the UPOV Convention 1991 introduced the concept of EDV. It extends the scope of rights of a PVR owner to new varieties created by third parties by making the commercialisation of such new varieties dependent upon the consent of the owner of the initial variety.

This article tries to shed some light on what an EDV may be, as the wording of the relevant legal provisions cause great uncertainty.

II. Background for Introduction of the EDV Concept into UPOV 1991

The EDV concept lies in the area of conflict between sufficient scope of protection for a new breeding result and the principle of independence (breeder's exemption), one of the main principles in the plant variety protection system.

As the distinctness criterion can usually be easily fulfilled due to minimal distances and, moreover, in many instances the development of something distinct to fulfil the uniformity and stability requirement may not go beyond the average ability of persons skilled in the art of breeding, the scope of protection of a PVR appears to be rather limited. This is emphasised by the fact that Art. 1 of the UPOV Convention defines, in No. IV, a breeder as being not only the person who has created, but also somebody who has discovered and developed a variety. Thus, even a spontaneous mutation of a protected variety may be open for protection in favour of its finder.

Moreover, due to the breeder's exemption, any plant material which includes that of protected varieties available on the market may be used for breeding purposes. Due to the nature of living material, something new - in the sense of the protection system - may be created without too much intervention by man. In these cases it may not be fair in all circumstances to unconditionally attribute rights in such new plant material produced by nature's capriciousness solely to the breeder, without participation of the breeder of the material used from which something new has emerged.

¹ (Article 5(1) UPOV 1991; Article 6 of Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights)

² (Article 7 UPOV 1971; Article 7 of Regulation 2100/94)

It is evident that such an unconditional exemption enormously restricts the value of a right, in particular in cases in which a person makes use of protected material without having to invest time and money, as the material, as such, creates something distinct by its nature rather than by the intervention of man, thus exploiting the investment of the breeder of the initial plant material. One must take into account that the initial material used is very often the breeding result involving extensive time and monetary investment by the breeder of the initial variety. If such material can be used by other breeders - without equal substantial time and financial investment - to produce a variety which, as such, is protectable as it fulfils the DUS requirements, such a breeder bases his activities solely or mainly on the time and monetary investment by the breeder of the initial variety.

In addition to these two aspects in the PVP system, restricting the value of PVRs significantly, possible claims by patent owners for gene and gene combinations introduced into material of protected varieties, causing a one-sided dependency of breeders, were the motives for introducing the EDV concept.

III. Aspects to be observed in the interpretation of the legal provisions on EDV

It is essential to note that the provisions related to EDVs are listed under Chapter V of UPOV 1991, headed "Scope of the Breeder's rights". This indicates that what has to be regarded as an EDV falls into the scope of rights granted to the holder of the rights to the initial variety and for this reason it is dependent on those rights to a certain extent, however, without restricting the breeder's exemption fundamental to the system. Thus, any activities with a breeding result essentially obtained from a protected initial variety, which endanger the commercialisation possibilities of the owner of the initial variety, have to be regarded as dependent on his consent, whereas any activities to be regarded as activities in developing a new variety such as crossing, but also testing to find out whether it could already be used for marketing or whether it still has to be improved for later marketing, fall under the breeder's exemption, excluding any intervention possibilities by the owner of the rights in the initial variety.

On the other hand, one has to bear in mind that the scope of protection is determined by the characteristics which are the basis for grant of protection of a new variety. 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 owner of an initial variety, 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. As becomes evident from the preparatory documents for the 1991 UPOV Convention, one of the main aims of the introduction of the EDV concept was to diminish the problem of plagiarism. Plagiarism, however, occurs only if the contribution by a breeder of a new variety is mainly based upon the work of the breeder of the initial variety, not contributing something essential which would justify total independency of the new breeding result from the initial variety.

IV. What is an EDV

The wording of the provisions on EDVs has been criticised as difficult and complicated. The essential concept is: a breeder basing his activities to create a new variety mainly on the working result of another breeder cannot exploit his achievement solely to his advantage, unless the breeder of the initial variety gets his share, whereas the holder of an EDV may obtain a PVR if it satisfies the DUS requirements. This seems to be a fair balance of interests of both parties involved: on the one hand the need of the breeder of the EDV to seek the owner's consent of the initial variety for any marketing activities and direct preparatory activities as defined in Art 14 (1) UPOV 1991 and, on the other hand, the EDV breeder's right in a PVR on its own which may be exercised/enforced against third parties which make use of the EDV without his consent when he has obtained a PVR.

If one looks at the wording of the legal provisions, the following terms are decisive for the judgement of whether a new variety is an EDV:

- **Predominantly derived**
 - from the initial variety with regard to which **a right has been granted**, or
 - from a variety which itself is a derivation of a protected variety

- **Distinctness** from the initial variety, whereas the distinctness is the **result of the act of derivation**
- **Conformity**, essentially with the initial variety, in the expression of characteristics **that results from the genotype** or a combination of genotypes of the initial variety

Dependency can only be given in relation to one protected variety (see wording of Art.14 (5)(a)(i) UPOV 1991): essentially derived from the protected variety). As the application for grant of a PVR already creates a contingent right (*Anwartschaftsrecht*) if it fulfils the DUS requirements, an applied-for variety needs to be regarded as protected in the sense of the EDV provisions. Thus, use of material of a variety at the time protection has been applied for creates dependency, if the applied-for right will be granted.

Does use of **one** protected variety always lead to an EDV regardless of the contribution of the breeder in developing it further into a new variety? It seems that this is suggested by the EDV provisions. If the extent of contribution by the breeder of the EDV would be of relevance, it would be next to impossible to determine, by objective criteria, the threshold as to when his contribution makes the result a new variety on its own.

It appears that no predominant derivation can be given in cases in which two varieties are crossed. Both parents equally influence the population resulting from the crossing, even if the new variety shows essential conformity in the expression of characteristics with one of the two parents. It should be without any doubt that also at least sister-lines emanating from a population caused by crossing cannot be essentially derived from each other.

Bearing the foregoing in mind, the controversial battleground of the EDV concept is proof of the criterion “essential conformity” with the initial variety.

From the wording of the EDV provisions, it follows that the characterisation as an EDV is mainly determined by the genotype rather than by the phenotype. As the distinctness requirement does not ensure sufficiently broad protection in cases in which the breeder of a new variety has built his contribution to create something new mainly on the investment of the breeder of the initial variety, it is the genotype comparison established as one of several conditions which qualify a new breeding result as an EDV. However, distinctness in the phenotype still has an important role, as the derivation must

- **conform essentially** to the initial variety
- in the **expression of characteristics**
- that result from the genotype or combinations of genotypes **of the initial variety**,

except for the differences which result from the act of derivation.

To my understanding it is, to a wide extent, yet unknown which genes or combination of genes are responsible for certain phenotypical characteristics. Thus, the phenotype retains its indicative function as long as it is not possible to prove that a certain gene or combination of certain genes is responsible for certain characteristics in the phenotype. Even then, it is most doubtful whether solely genotype conformity is sufficient to qualify new breeding results as an EDV since, as becomes apparent from the above extract of the legal provisions, in this concept the phenotype is, at least, of equal importance. Thus, 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. The owner of an initial variety is obliged to prove that, due to certain common characteristics unique to the initial variety, the new variety is an essential derivation of his protected variety. If he cannot establish evidence that the characteristics of the new variety, in which it essentially conforms to the initial variety, he must at least prove that, to a wide extent, the new variety is identical to those characteristics which qualify the initial variety as an outstanding or remarkable new breeding achievement. Therefore, the decisive question is what essential conformity means.

With all probability, essential conformity is regularly given with regard to new varieties which encompass the same characteristics of a known variety which qualify that variety as something really new. Let me give you a few examples for illustration purposes:

- a *Calluna vulgaris* variety, which is the first with white flower buds.
- an *Osteospermum* variety, which is the first of such species which does not need a cool period during summertime to gain forces to develop the full flower bouquet, for a second time.
- a *Leucanthemum x superbum* variety, being the first variety of such species which is characterised by lateral flower stems.
- a grape variety, which is the first without seed kernels.

If in any such cases a new variety appears showing this unique character, whereas distinctness is founded by any other characteristic common for certain other varieties of this species, it would be a strong indication that it is an EDV.

In all other cases the existing differences must not be so significant that an expert must conclude that the variety was bred independently. If there exists for an expert the likely possibility that, despite the differences in the phenotype, mainly material of the initial variety had been used, the owner of the initial variety should have fulfilled his burden of proof. It is then incumbent upon the owner of the assumed EDV to establish counterproof.

The statutory definition determines that the substantial concurrence in the protected characteristics must be caused by the genotype or combination of genotypes of the initial variety, that is they must originate in the genes that constitute the morphological and physiological basic structure of the relevant plant material and determine the outer appearance of the initial variety (phenotype). Where a substantial concurrence in the phenotype exists in the plant material in question, it is generally to be assumed that it stems from the same genotype.

The question of genetic conformity becomes relevant only when it is clear that the outer appearance, i.e. phenotypic characteristics, is of such similarity to the protected variety that a predominant derivation is likely. In such a case, apart from the question of whether the deviations in the phenotype are within the tolerable thresholds for the relevant type, in order to speak of a genetic conformity it is also crucial from which varieties, and based on which characteristics, the deviating plant material was obtained. This will force the holder of the assumed EDV to reveal the origin and basis of the breeding achievement.

This contribution to the Seminar is based upon an article which will be published in the Brazilian online IP journal "Revista Electronica" at the end of November 2013.

VIEWS OF THE INTERNATIONAL COMMUNITY OF BREEDERS OF ASEXUALLY REPRODUCED ORNAMENTAL AND FRUIT-TREE VARIETIES (CIOPORA) ON ESSENTIALLY DERIVED VARIETIES

Mr. Edgar Krieger, Secretary General, CIOPORA

Mr. Jan de Riek, Molecular Genetics & Breeding - Group Leader, Institute for Agricultural and Fisheries Research (ILVO), Belgium, Board member of CIOPORA

The EDV concept is a significant part of the horizontal protection of Plant Breeders' Rights, which concerns the relationship between breeders (vs. the vertical scope, which concerns the relationship between the title-holder and the downstream production- and trade-chain, such as propagators, growers, wholesale and retail).

Art.14 (5) of the UPOV 1991 Act extends the protection of a protected variety inter alia to EDVs thereof. In other words: The scope of protection covers the protected variety as well as EDV thereof. By making a reference to Article 14 (5) in Article 15 (1) (iii) the EDV concept also limits the so called breeders' exemption: Everybody can breed new varieties by using a protected (initial) variety, but shall not commercialize these new varieties if they are EDV thereof.

The main issue for breeders of vegetatively reproduced ornamental and fruit varieties is mutants (and GMOs). New mutants are often developed on the basis of new initial varieties. Mutants have several commercial advantages for their finder: There is not much discovering and developing work required, they have a short process of evaluation, they take the benefit of the already known variety and they are easy to launch. But there is also the other side of the coin: mutations of an innovative initial variety can take a big market share from the initial variety, with low costs, and the breeder of the innovative initial variety will not earn a similar return on investment if his market is shared by low-cost mutations.

In the opinion of CIOPORA it is therefore fair that the breeder of the innovative initial variety receives his share from the commercialization of the mutations of his variety. A good protection system protects the innovative breeder, but also allows EDVs to be developed - for the benefit of the original breeder, the developer of the EDV and the growers.

The breeders of vegetatively reproduced ornamental and fruit varieties need clarity in regard to EDVs, particularly in respect of mutants and GMOs. It is e.g. not acceptable that two courts making a judgment about the same varieties come to different results as regards their classification as EDV.

The reason is that, although in place for 20 years already, the EDV concept still causes disputes and discussions about its meaning and purpose and about its scope. The main reason is the unclear language of the EDV provision and the erroneous entanglement of dependency and plagiarism.

Especially the wording "*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*" gives rise to interpretation differences. What is meant? Is it the genotype i.e. aiming at genetic conformity, or, because of the use of the word "expression", the phenotype? In our view, the EDV definition should aim at varieties sharing a high genetic conformity with the Initial Variety.

Some try to introduce erroneous simplifications or interpretations of the EDV concept by classifying EDVs according to the supposed biological or genetic mechanisms involved – *small* versus *large* mutations, *single* mutations/GM events versus *accumulated* ones creating a series of EDVs that at a certain level should become non-derived, involving meiosis or not, etc. –, or by limiting the set of "*essential characteristics*" to major or important characteristics. In our view, the wording "*essential characteristics*" is in the Convention to indicate any characteristic that is typical to the Initial Variety and not to differentiate them from any kind of *non-essential* ones.

Predominant derivation, of course, is always a prerequisite and is in the view of CIOPORA limited to the physical use of the Initial Variety.

Mutants and GMOs –if clearly distinguishable from the Initial Variety– always need to be considered to be EDVs irrespective of the number of phenotypic differences in comparison to the Initial Variety, because they are solely derived from the Initial Variety, retain a very high genetic conformity and all differences from the Initial Variety result from the act of derivation.

However, some want to limit the EDV concept to varieties which can be distinguished from the Initial Variety by a very limited number of phenotypic characteristics ("*typically by one*")¹. Such interpretation limits the EDV concept as much as possible. Taking into consideration that an EDV by definition must be *clearly distinguishable* from the Initial Variety, which requires at least a difference in one characteristic (even under the small minimum distances currently applied by UPOV and the examination offices of its member countries), under such interpretation only varieties which have exactly one difference compared to their Initial Variety could be considered to be an EDV – a contradictory and useless approach.

In fact, the entanglement of dependency and plagiarism was and is a mistake in the conception of the EDV provision. Plagiarism is not a question of derivation or dependency, but rather a question of Minimum Distance and direct infringement. If a variety in its phenotype is almost identical (not clearly distinguishable) to a protected variety, its commercialization is a direct infringement, irrespective whether it is derived from the protected variety or not.

In vegetatively reproduced ornamental and fruit varieties, when mutants and GMOs are concerned, it is necessary that the EDV concept establishes dependency for each variety which is derived from one Initial Variety only, irrespective of the degree of the phenotypic similarity between the dependent and the Initial Variety. Then the issue could be limited to establishing derivation only i.e. was the Initial Variety used or not. Such approach would immediately bring clarity into the EDV concept and would allow the breeders to effectively enforce the PBR titles of their Initial Varieties.

VIEWS OF THE INTERNATIONAL SEED FEDERATION (ISF) ON ESSENTIALLY DERIVED VARIETIES

Mr. Marcel Bruins, Secretary General, ISF

Mr. Stephen Smith, DuPont Pioneer, United States of America, Chairman of the ISF Intellectual Property Committee

The International Seed Federation (ISF) strongly supports the concept of essential derivation which allows new technological developments to be taken into account thereby supporting the intellectual property rights of both those who initially develop improved varieties and those who later use those varieties to make specific improvements on them. ISF considers that this principle, whilst appropriately strengthening PBR, does not restrict the breeders' exception, a key feature of the UPOV Convention.

The concept of EDV also has the effect of drastically decreasing plagiarism in plant breeding because in our view, all plagiaristic varieties fall under the EDV principle. ISF is opposed to plagiarism, i.e. any act or use of material/technology in a breeding process that purposely makes a close imitation of an existing plant variety. Plagiarism does not contribute to plant improvement and should be seen as an abuse of the breeder's exception.

The principle of essential derivation involves questions of scope of protection and enforcement under breeders' rights; for both the breeder of the initial variety and the breeder of the EDV. Since it is a matter of enforcement of breeder's rights, then it is left to the initiative of the initial breeder to enforce those rights. At this point it is important to stress that the determination of essential derivation is not part of the procedure of the granting of the PBR. Determination of EDV status comes after the DUS process. If a variety cannot be determined to be distinct then it cannot be granted a PBR and therefore does not exist as a variety per se. Nonetheless, official description data of varieties based on UPOV guidelines should be available after granting of rights to enable breeders to compare their varieties.

ISF actively promotes internationally agreed-upon professional rules and usages for assessing essential derivation and for solving disputes for all crops. Otherwise, there would be, at best, a series of published scientific papers on how to determine EDV status with no industry consensus on how to apply those academic principles. For many crops, there would remain no published scientific basis to help guide determination of EDV status. In order to address this issue, ISF started more than 10 years ago to develop guidelines for specific crops that would help in the determination of EDV status. So far ISF has developed guidelines for EDV disputes pertaining to perennial ryegrass, maize, oilseed rape, cotton and lettuce. ISF notes that even if there are not yet internationally agreed-upon professional rules and usages for assessing essential derivation and for solving such disputes for all crops, the concept has already provided greater clarity for breeders in their research and product development programs and has contributed to reduce infringements.

Proof of predominant derivation

To determine proof of predominant derivation various criteria or a combination thereof can be used, such as:

- Morphological characteristics
- Molecular characteristics
- Breeding records
- Combining ability

As the determination of DUS under UPOV guidelines is largely based on morphological analyses, the question arises whether conformity should continue to be established based on morphological characteristics or might molecular characteristics have a special role to play. In this regard, it is pertinent to note that the question of conformity can be addressed by establishing Distance (or Similarity) Coefficients that define a threshold that serves as a trigger point for the reversal of the burden of proof. Geneticists and statisticians agree that it is technically possible to measure distance coefficients using morphological markers, however these distances are not always reflective of genetic distances or of pedigree relationships. In addition, the use of morphological characteristics could be more difficult due to environmental factors, and often much more expensive. Consequently, ISF has mainly worked on thresholds (distances between varieties) measured by molecular markers.

Requirements for an EDV study

First of all there needs to be a good reference population to assess genetic diversity in a crop. Secondly there needs to be an EDV specific population that will allow investigation of potential EDV / non EDV cases. It is also necessary to choose an appropriate marker system. And last but not least, a type of measurement needs to be agreed upon for the genetic similarities.

Choice of markers

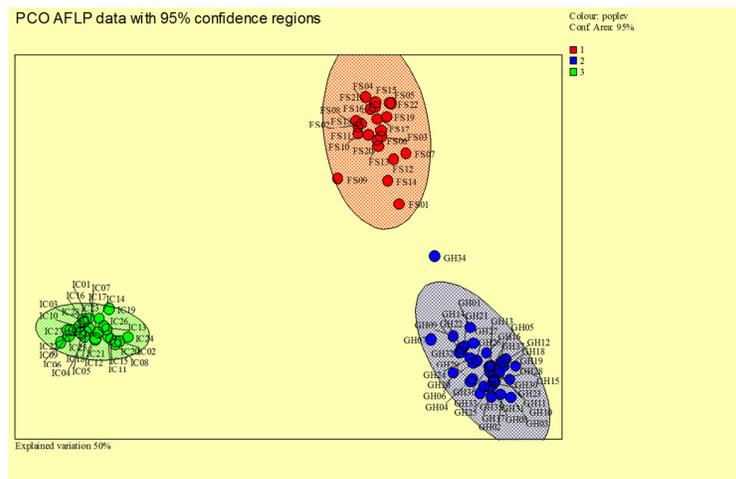
The markers must comply with several requirements, for example they must be “freely” available and must meet several technical criteria which are addressed in an ISF document “Issues to be addressed by technical experts to define molecular marker sets for establishing thresholds for ISF EDV arbitration”.

How to fix the threshold

In all ISF studies we have used variety pairs with a known genealogy. While investigating the genetic diversity it is crucial to compare the global versus closely related pairs. Cut off thresholds are best determined by breeders on a crop specific basis so that an understanding of the diversity and breeding approaches can be brought to bear on this determination.

Lettuce

ISF has investigated three lettuce types: 35 varieties of the Greenhouse Heated, 21 varieties of the Field Summer, and 27 varieties of the Iceberg type. The study included the most widely commercialized varieties together with additional varieties to allow maximum variation to be shown for each type. In all ISF studies the names of both the varieties and companies are coded anonymously.



This figure shows associations of the varieties based on their genetic distance measures. The three lettuce types grouped according to their morphologies and pedigrees when assessed with AFLP markers following a Principal Coordinates Analysis.

zone	q	genox	genoy	compx	compy	all	erromargin
2	0.9990	22	21	5	5	0.9985	0.0028
2	0.9973	19	15	4	4	0.9878	0.0079
2	0.9956	11	8	3	3	0.9850	0.0073
2	0.9939	13	11	3	3	0.9816	0.0093
2	0.9922	10	8	3	3	0.9759	0.0095
2	0.9906	35	30	6	6	0.9740	0.0159
2	0.9889	13	8	3	3	0.9717	0.0135
2	0.9872	27	25	5	5	0.9702	0.0132
2	0.9855	12	8	3	3	0.9686	0.0154
2	0.9838	11	10	3	3	0.9684	0.0120
2	0.9822	18	16	4	4	0.9671	0.0128
2	0.9805	35	31	6	6	0.9669	0.0109
2	0.9788	12	2	3	1	0.9667	0.0141
2	0.9771	31	30	6	6	0.9651	0.0107
2	0.9754	30	18	6	4	0.9651	0.0138
2	0.9738	13	12	3	3	0.9650	0.0158
2	0.9721	12	10	3	3	0.9639	0.0142
2	0.9704	20	16	4	4	0.9619	0.0108
2	0.9687	16	14	4	4	0.9618	0.0124
2	0.9670	12	11	3	3	0.9612	0.0129
2	0.9654	35	18	6	4	0.9593	0.0169
2	0.9637	8	2	3	1	0.9587	0.0160
2	0.9620	13	10	3	3	0.9582	0.0160
2	0.9603	33	18	6	4	0.9580	0.0196
2	0.9586	35	33	6	6	0.9579	0.0154
2	0.9570	30	14	6	4	0.9570	0.0159
2	0.9553	31	16	6	4	0.9565	0.0099
2	0.9536	27	24	5	5	0.9553	0.0154
2	0.9519	20	14	4	4	0.9538	0.0165
2	0.9502	17	15	4	4	0.9536	0.0185
1	0.9486	10	2	3	1	0.9534	0.0208
1	0.9469	33	31	6	6	0.9524	0.0201
1	0.9452	33	30	6	6	0.9519	0.0152
1	0.9435	31	29	6	6	0.9511	0.0208
1	0.9418	12	3	3	1	0.9507	0.0181
1	0.9402	35	16	6	4	0.9503	0.0146
1	0.9385	30	16	6	4	0.9501	0.0161

The above Table shows examples of genetic distances and known genealogies for the Greenhouse Heated type of lettuce, when marker data are analyzed using the Jaccard Index: GH21 and GH22 were selected from the same F4 generation; GH8 and GH11 come from same F3; GH30 and GH35 come from same F3 and GH27 is from a cross involving GH25.

After several analyses, it was decided that a 0.96 Jaccard similarity for all 3 cultigroups would be used. Passing this threshold should serve as a trigger to initiate EDV discussions. If the dispute could not be resolved, an amicable settlement should be attempted, followed by arbitration and as a last resort going to court.

Oilseed rape

Four studies were carried out, and these analyses showed that marker profiles using bulks of 40 plants have a very high repeatability, and also lead to a clear separation of all the varieties. On the basis of this it was decided that a Dice distance of 0.85 is the trigger to start discussions. Needless to say, the assessment should be done according to the scientifically based and agreed upon ISF-protocol.

Ryegrass

Ryegrass varieties were analyzed using SSR's. The first phase of the research showed that bulks provide the same result as individual plants. In the second phase the variability among current commercial varieties was analyzed and this resulted in a set of guidelines. The threshold was set at a Jaccard similarity of 0.6 that serves for the reversal of the burden of proof. These guidelines apply to all ryegrass varieties, so have a retroactive effect and they stipulate that besides arbitration also going to court should be possible.

Cotton

After a detailed literature review on the use of molecular markers in cotton ISF took a slightly different approach compared to those previously mentioned. Through the literature review it became apparent that

there is a high degree of genetic diversity within current commercialized allo-tetraploid cotton varieties thereby making it very difficult, or impossible, to assign a specific EDV threshold. After thorough discussion it was agreed to use parentage as the main parameter of determination of potential EDV status. It was decided that if the phenotypic or genotypic characteristics suggest that two or more backcrosses were used to develop the putative EDV or in case the coefficient of parentage value is higher than 87.5%, then the resulting variety could indeed qualify as a putative EDV. This threshold is to be used as a trigger point for discussions, and if no settlement can be reached, parties should go to arbitration.

Tomato

This study is not as such an EDV study, but instead a study to investigate how to detect the use of a proprietary inbred line in a hybrid. In phase 1 (2006 – 2007) the Daniela type was used, of which 21 hybrids, 35 parental lines from 5 companies were analyzed with 93 SSR markers. In phase 2 (2008 – 2009) the Cherry tomato type was used of which 17 hybrids, 34 parental lines from 6 companies were analyzed. The same set of markers was used as for the Daniela type. In phases 3 and 4 (2010 – 2011) a comparison was made between SSR versus SNP markers. Different indices of similarity were investigated: Dice, Rogers and the Simple Matching Percentage (SM%). This SM% is an index of genetic similarity that measures the match between alleles in the hybrid and the inbred line. It could be concluded that SNP markers (7720 publicly available markers in the SOLCAP 10K Array) deliver data of excellent quality to detect the use of a proprietary inbred line as a parent, and that compared to SSR, SNP markers are less sensitive when used with inbred lines that are not fixed or had some residual heterozygosity. A threshold for the Simple Matching Percentage (SM%) could be set to a value as high as 99.95

ISF recommendations

In case of a dispute, ISF recommends to its members to first enter into a conciliation or mediation procedure. If that does not provide satisfactory results, it is advised to enter into (binding) arbitration, according to ISF Procedure Rules for Dispute settlement. More information can be found on the ISF website: www.worldseed.org

Maize EDV Case Study

With regard to determining EDV status the issues to be considered are not Distinctness, Uniformity, or Stability. Those criteria have already been tested using established UPOV protocols and a determination that the variety is eligible for PBR because it has passed the DUS evaluation criteria has already been made. If this were not the case then there could be no issue of possible EDV status as a prior issue of non-distinctness would have rendered the test variety as ineligible for protection under PBR due to lack of novelty.

In determining EDV status the primary question to be answered is: Has the putative EDV been predominantly derived from one of its parents? Determining not only pedigree, but closeness of pedigree or degree of genetic similarity become primary questions to be addressed. Molecular marker data have an important role to play in determining genetic similarity and pedigree. First, it is well established in the scientific literature that molecular marker data can provide a genetic measure of similarity (or difference) between varieties of the same cultivated species. Second, it is often, if not always, impossible for the breeder of the initial variety to themselves obtain prime facie evidence of EDV status. Varieties of self-pollinated species (e.g. wheat, barley, soybean) are usually available through commercial channels to allow comparisons to be made. However, it is well established that morphological comparisons can obscure genetic differences because of genotype x environment interactions and due to complex genetic control of many morphological characteristics which can lead to similar genetics causing similar morphologies which then belie those underlying genetic differences. In any event, obtaining reliable morphological data is resource and time-consuming requiring replicated field plots across environments. With regard to parental lines of hybrids since the parental lines are usually, if not always, maintained as proprietary trade secrets and not publicly available then it is impossible for the breeder of the initial varietal parent line to make any comparisons with a putative EDV inbred line because only the hybrids will be commercially available for comparison purposes. Morphological comparisons using hybrids cannot be interpreted in terms of comparisons of their inbred parental lines. When the issue is one of determining putative EDV status of parental lines of hybrids then the only possible means of at least initially approaching the issue is to make comparisons using molecular marker data.

With these factors in mind, and as already described, members of national and international seed associations, including experts in breeding and molecular markers, have developed crop specific criteria to 1) determine thresholds of genetic similarity to help determine EDV status and 2) determine protocols

to measure genetic similarities between pairs of inbred lines or varieties in order to ascertain where those inbred lines or varieties are placed in respect of the agreed upon thresholds. US and European members of ISF had previously developed guidelines using Restriction Fragment Length Polymorphisms (RFLPs) and then for a subsequently developed and superior molecular marker technology known as Simple Sequence Repeats (SSRs). Using industry agreed sets of SSRs thresholds had been agreed to define three zones to help determine if there had been predominant derivation: 1) A Red zone (90% or greater similarity) which provided “a strong indication of predominant derivation” (ISF, 2008); 2) an orange zone (83-89% similarity) where “other criteria should be evaluated including combining ability, phenotypic characteristics and breeding records”, and 3) a green zone (below 82% similarity) where there is no predominant derivation. For both the orange and red zone cases ISF (2008) guidelines state that “the burden of proof shifts to the breeder of the putative essentially derived variety” i.e. it is then the burden of the breeder of the putative EDV to prove that it is not predominantly derived and therefore not an EDV of the initial variety.

When the US (under the auspices of ASTA) and European experts (under the auspices of the French Maize Breeders Association [SEPROMA] and members of the University of Hohenheim teams) had completed their work on SSRs they decided that rather than continue their work to define one set of SSRs to in EDV determination for both the US and Europe they would combine their resources with the aim of accomplishing such a goal but using the recently introduced and superior technology of Single Nucleotide Polymorphisms (SNPs). The scientific team for this SNP-EDV maize project comprised Yves Rousselle (post-doc), the INRA plant genetics group (Alain Charcosset), Rex Bernardo (University of Minnesota) and Benjamin Stich (Max Planck Institute). ASTA and Union Française des Semenciers (UFS) (French Seed Producers), previously known as SEPROMA Representatives from the following companies participated in the scientific review team: AgReliant, Biogenetics Services, Caussade Semences, Dow, Euralis, KWS, Limagrain, Maisadour, Monsanto, Pioneer Hi-Bred/DuPont Pioneer, RAGT, and Syngenta.

Similarity thresholds using SSRs had already been agreed upon and most of the same US and European inbred lines that had been used to determine EDV status using SSRs remained available. The goal therefore was to use these same inbred lines to: 1) screen publicly available maize SNPs, 2) identify those that could reliably be used to profile at least these maize inbreds, 3) determine the degree of correlation in terms of genetic similarity measures revealed by the set of agreed upon maize-EDV SSRs compared to the SNPs. 4) use that measure of correlation to adjust the SSR based EDV thresholds to an equivalent SNP based threshold, and 5) to determine how many SNPs would be required to provide genetic similarity measures with an appropriately high degree of precision. This was essentially an exercise in recalibrating SSR thresholds previously agreed upon by members of the maize breeding industry so that an equivalent method to help determine EDV status in maize using SNPs would also be available. This exercise was necessary because the practical advantages afforded by SNPs were leading many, and ultimately most probably all maize genetic marker laboratories to SNP or sequence based marker platform technologies.

SNP-EDV maize research began with a set of 50,000 SNPs assembled on an Infinity chip. Quality control testing using the set of EDV inbreds and removing those that might lead to bias because they had been selected solely on the basis that they could differentiate between public inbred lines B73 and Mo17, established a working set of 26,784 SNPs. SNP profiles of each member of the EDV inbred set were created using these 26,784 SNPs. Genetic similarity-distances were calculated from comparisons of the SNP profiles for each pair of these inbred lines. These pair-wise inbred SNP distances were compared with those obtained using the agreed upon SSR EDV sets. It was also decided to maximize coverage of the genome to equal numbers of SNPs using the genetic map and the physical maps. Using the most discriminative SSR set x laboratory protocols (SEPROMA set assayed by Trait Genetics, Max Planck Institute) then the correlation for distances between pairs of inbreds with SNP data was 0.94 with a slope of 0.5 (Figure 1). When varieties that are 90% or more similar by SNPs are considered then the correlation with SSR based genetic distances rises to 0.99.

- This SNP evaluation and calibration exercise provides the scientific basis enabling SNPs to be used to help determine predominant derivation, and thus EDV status in US and European maize. Using these data the SSR thresholds then are recalibrated using these SNPs with US and European maize inbred lines to: 95% + similarity = red zone
- 91%-94% similarity = orange zone
- <90% similarity = green zone

- 1536 or 3072 SNPs provide an adequate level of precision (SD 0.006 and 0.004, respectively)

Final tests of SNP sets are underway now. The next steps will be to present these data to ASTA and UFS. A manuscript will be written for peer review and publication in the scientific literature. It is anticipated that guidelines will be posted on the ISF website.

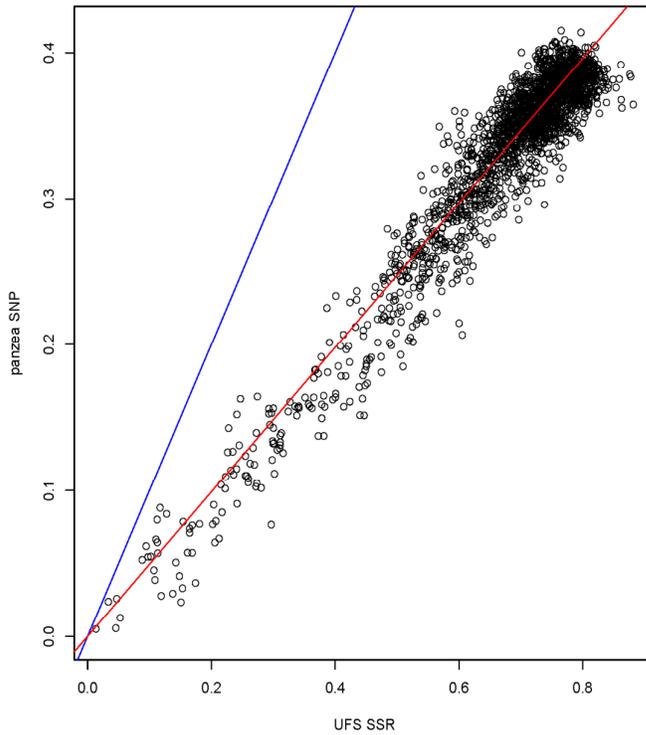


Figure 1. Correlation of pairwise distances of maize EDV test inbreds profiled by SEPROMA agreed EDV SSRs and 26,784 SNPs.

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ESSENTIALLY DERIVED VARIETIES AND THE PERSPECTIVE OF FARMER-BREEDERS

Ms. Normita Gumasing Ignacio, Executive Director, South East Asia Regional Initiatives for Community Empowerment (SEARICE)

Smallholder men and women farmers across the world have historically been the original plant breeders since the dawn of agriculture more than 10,000 years ago. For most developing countries, where most of the plant genetic resources come from, smallholder farmers continue to consciously or unconsciously breed new plant varieties with two motivations: attain food security for all, and increase agricultural biodiversity. On account of these farmers' enormous contribution, the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA) obliges its 128 members¹ to develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture².

It is significant to note that more than two-thirds or 68% of UPOV's 71 members³ are contracting parties to the ITPGRFA, and consequently they are enjoined to protect farmers' rights, which is articulated in Articles 9.2 and 9.3 of the ITPGRFA, thus:

9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;

(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and

(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

It is also important to note that Article 6.2 of the ITPGRFA stresses the need to promote farmers' breeding efforts, to wit:

6.2(b) strengthening research which enhances and conserves biological diversity by maximizing intra- and inter-specific variation for the benefit of farmers, especially those who generate and use their own varieties and apply ecological principles in maintaining soil fertility and in combating diseases, weeds and pests;

6.2(c) promoting, as appropriate, plant breeding efforts which, with the participation of farmers, particularly in developing countries, strengthen the capacity to develop varieties particularly adapted to social, economic and ecological conditions, including in marginal areas;

6.2(d) broadening the genetic base of crops and increasing the range of genetic diversity available to farmers;

6.2(e) promoting, as appropriate, the expanded use of local and locally adapted crops, varieties and underutilized species;

¹ http://www.planttreaty.org/list_of_countries?field_cp_status_value_many_to_one=Yes&field_cp_contracting_value_many_to_one=All&field_cp_signature_by_value_many_to_one=All&field_cp_faoregionone_value=All&field_cp_faoregiontwo_value=All&field_cp_income_value=All. Last updated on 30 August 2013. Last accessed on 1 September 2013.

² Article 6.1 of the ITPGRFA reads: The Contracting Parties shall develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture.

³ Status of UPOV members as of December 31, 2012. <http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf> Last accessed on 1 September 2013.

6.2(f) supporting, as appropriate, the wider use of diversity of varieties and species in on-farm management, conservation and sustainable use of crops and creating strong links to plant breeding and agricultural development in order to reduce crop vulnerability and genetic erosion, and promote increased world food production compatible with sustainable development

SEARICE or the South East Asia Regional Initiatives for Community Empowerment, for more than thirty years now, have been partnering with smallholder farmers in at least five countries including Viet Nam, which is a UPOV member, through governments, NGOs, and schools to implement these provisions on smallholder farmer participation in plant breeding, and in implementing farmers' rights; as well as advocating the exclusion from patentability, PBRs and other proprietary rights, plants and other life forms; inasmuch as these proprietary rights limit the materials that smallholder farmers use in breeding. SEARICE also continues to develop *sui generis* systems with the aim of protecting farmers' varieties from exploitation and unconscionable appropriation. These efforts have led to the recognition of farmer breeders and farmers' varieties that are adaptable to local conditions, varieties that can best meet their needs, and varieties that are resilient to shifting climatic changes and economic trends. When UPOV 91 and the system of EDV was developed, nobody thought of possible impacts on the innovation system of farmers who are doing breeding by selection. And it seems that the knowledge on this has not improved since then. Nevertheless, UPOV 91 is widely promoted as the right system for developing countries where the informal seed sector and breeding by farmers play an essential role. There is a need to look into this. Moreover, since 68% of UPOV members need to implement farmers' rights and sustainable use of PGRFA, there is need to consider the following conditions in determining EDVs, whether in the technical or legal discourse:

1. Farmers' varieties, especially those bred in developing countries should never be considered EDVs or unprotected initial varieties that can be appropriated by anyone. Farmers continue to develop varieties adapted to changing local conditions through evolutionary breeding and adaptive selection. For them, all PGR materials are raw materials for adaptation and development regardless of whether these materials are DUS or not. The introduction of high yielding varieties has already displaced many traditional varieties and has tremendously reduced the diversity of PGR materials available for farmers breeding. EDVs will exacerbate the situation and this will have serious implications on farmers' capacity to adapt to all the challenges that they face including climate change.
2. Plant Variety Protection, like patents, are artificial monopolies on a public good. Although economists rarely come to a consensus, they agree on one thing: monopolies lead not just to inequities but also to major distortions in resource allocations. As a society, we tolerate this distortion in the hope that it will promote innovation that would, in the end, lead to social benefits that would outweigh the costs.⁴ Plant breeders are given incentives through privatization of property not only to compensate them for their efforts and investment, but ultimately, to give society the benefits of new discoveries and the expansion of our collective knowledge. Therefore, in any policy issue such as this, the ultimate question that must be answered is this: does the social benefit outweigh the social cost? Given the important role of farmers in innovation and the adaptation pressures posed on them and our food supply by climate change, the costs to society of limiting farmers' ability to create so-called "essentially derived varieties" would be devastating and would far outweigh the benefits. For the regular consumer, the farmers and even the breeders, it is just not worth it.
3. Formal breeders do not have a monopoly on innovation. Innovation is done by the farmer every day. Indeed, in agriculture, necessity is the mother of invention. The farmer must invent new practices and breed new varieties because he or she must. New farming practices and new farmer bred varieties enable them to adjust to environmental challenges, to put food on the family's table, and, we as non-farmers must always remember, to put food on the tables of the rest of humankind. Studies indicate that 60-70% of farmers in Southeast Asia use seeds saved on-farm, even though the government has been aggressive in promoting the use of certified hybrid seeds. The remaining seeds are obtained from local sources: government, seed exchanges, and, to a limited extent, private growers.⁵ Within the same period of time, farmers breed or discover far more varieties than formal breeders. Formal breeders, on the other hand, source breeding materials from farmers who, in good faith, provide them with little or no restriction. All of formal breeders' discoveries were built

⁴ Joseph Stiglitz. "Economic Foundations of Intellectual Property", 57 Duke Law Journal 1693-1724 (2008).

⁵ Improving Food Security Through Community-Based Seed Systems in Rainfed Rice Areas of Asia, SEARCA

on the hard work done by farmers, one way or the other. Many important so-called scientific breakthroughs in plant breeding are in fact not objective discoveries, akin to saying that Christopher Columbus “discovered” the Americas when the natives have made it their home for thousands of years.⁶ The current trend of scouring the wild and small farmers’ farms for native traits underlines the richness and potential of informal breeding. These original native strains were often grown in less than ideal environments and not surprisingly, are a rich source of traits such as cold tolerance or drought resistance.⁷

In short, farmers are an indispensable part of the innovation system that sustains formal breeders. Cutting off farmers from this process by restricting their right to freely generate “essentially derived varieties” from a protected variety is inequitable and unwise. It is inequitable because, as stated above, 1) all of formal breeders’ breeding materials are derived, to some extent, from a farmers’ variety, 2) these breeding materials are usually obtained from farmers with little or no restriction, not even a restriction against essentially deriving a variety from these.

It is also unwise, especially for the formal breeder and humanity in general, because farmers’ use of a diverse set of germplasm is an essential component of on-farm conservation that ensures agricultural biodiversity. In restricting the farmers’ right to essentially derive varieties from protected varieties, one limits the potential of farmers to incorporate a protected variety’s traits into the informal system and the local and indigenous genetic pool, which is recognized as an essential means of adaptation to the many varied effects of climate change that hits a locality. Plant breeding is not just the province of formal plant breeders. It has been done by farmers for millennia. It continues as a practice among small farmers, although the practice has been greatly eroded by the Green Revolution to the detriment of agricultural biodiversity and small farmers’ survival. SEARICE seeks to revive and strengthen the breeding tradition through the Farmers Field School and by advocating Participatory Plant Breeding and Varietal Selection. Through this process, farming communities are able to adapt and survive the huge challenge of climate change. In Viet Nam for instance, farmers are able to develop rice varieties that are saline tolerant through selection from promising lines and stable materials provided by our partner research institutions. Similarly, in the Lao People’s Democratic Republic, farmers are able to produce drought tolerant varieties through adaptation trials. In Thailand, some very good rice varieties that are now popular in one region were developed by farmers through off-type selection and in Bhutan farmers are able to overcome the serious rice blast infestation through participatory varietal selection of rice blast resistant varieties from our partner research institution. In the Philippines, farmers, through evolutionary breeding, are mixing even hybrid maize seeds with traditional varieties to develop varieties that meet their needs and preferences. There was even a case of a red rice variety, which is very popular in one of the islands in the Philippines, which was selected by a farmer and became popular in the island. It was selected from a plot planted with IRRI white rice variety so it resembles the IRRI variety except for the red color. Upon analysis, it was found out that the variety came from a hybrid between IRRI white variety and local red rice variety. The farmer had consciously picked and selected such red variety because of its combined traits of high yield of the IRRI white variety and the preferred taste of the traditional red variety. This could be a case of an essentially derived variety, and it is just inconceivable that the farmer who developed the high-yielding red rice variety which benefits many farmers in the island would be penalized for his innovation.

Intellectual property, particularly plant variety protection and patents, is not the only form of incentive for innovation. It may even be counterproductive because sometimes the best or easiest way of making money is not to come up with a better idea but to form a monopoly or cartel and restrict competition.⁸ Many developing countries have emerged as centers of agricultural biodiversity even prior to the

⁶ Writing in the journal *Nature Genetics*, a team led by Yusaku Uga of the National Institute of Agrobiological Sciences in Tsukuba, Ibaraki Prefecture, describes finding a remarkable gene in a rice plant cultivated in the dry uplands of the Philippines. This strain, also called cultivar, is called Kinandang Patong. Its big characteristic is roots that are deep and grow straight downward, boring into parched soil for water, as opposed to root systems that are shallow and grow out laterally in typical water-rich paddy fields. (“Roots breakthrough: drought resistant.” *Japan Times*. Available at <http://www.japantimes.co.jp/news/2013/08/05/national/roots-breakthrough-drought-resistant-rice/#.UikEFrsYy2U>. Accessed on September 4, 2013) The RIL parent lines, IR64 and Kinandang Patong, were obtained by Dr. Yusaku Uga from the International Rice Research Institute (IRRI) and propagated in compliance with the Standard Material Transfer Agreement (SMTA). (Uga Y., K. Okuno and M. Yano (2011) *Dro1*, a major QTL involved in deep rooting of rice under upland field conditions. *Journal of Experimental Botany* 62: 2485-2494)

⁷ Dr. James W. Friedrich. “Native traits: Technology Developed From the Natural Abundance of Ancestral Strains of Corn.” Available at <http://nativetraits.blogspot.com/p/introduction.html>. Accessed on September 4, 2013.

⁸ Joseph Stiglitz. “Economic Foundations of Intellectual Property”, 57 *Duke Law Journal* 1693-1724 (2008).

introduction of plant variety protection or patents. A study done by the SEARICE Community Biodiversity Development and Conservation Programme on plant genetic resources diversity and seed supply system of Bohol⁹ found that crop diversity was the result of both natural and human factors. On the human end, farmers' preferences and selection process play a key role. Crop varieties are selected according to factors such as cooking and eating quality, flesh texture, yield, early maturity, plant height, and resistance to pests and drought. Because most of their crops are used for personal consumption, a variety of crops are maintained by each farmer. Further, farmers can be driven by the quest for mastery and the delights of discovery, just as in basic research where free sharing of knowledge is the norm even if the discoveries later turn out to be profitable.¹⁰ Moreover, farmers' innovation can be driven by the necessity of creating varieties that can adapt to the peculiar challenges of his or her farming locality and the effects of a changing climate thereon. Plant variety protection is a tool of private industry, to justify investments in capital. Therefore, it does not address the needs of farming areas where private seed growers find a limited market and few economic incentives. Where there is little chance for a return on investment, private seed growers cannot be relied on, much like the pharmaceutical industry's neglect of diseases that affect only a few people. Applying the EDV restriction to farmers in these areas again limits the potential for farmers to adapt protected modern varieties to local conditions and needs. Yet the varieties locally bred by farmers under very challenging natural conditions continue to be a source of livelihood for the farmers and a source of breeding materials for formal breeders.

Applying EDVs to farmers is an overreach. In the test of whether extending the protection to EDVs, particularly with regard to acts of farmers, leads to a net social benefit, it comes up short. In addition to the above social costs, the transaction costs that would be required for a small farmer-breeder to obtain a license would put it out of the small farmers' reach. Policymakers must not forget the collaborative nature of innovation. The marginal social return of having plant variety protection, especially given its low requirement of novelty and the absence of a requirement for non-obviousness, is only having innovation earlier than it otherwise would have been. The plant variety protection system does not reward people on the basis of the marginal social return of their contribution. It gives the individual or firm that is first the entire value of the innovation, which obviously can well exceed the marginal social contribution.¹¹ Policymakers must keep in mind that the design of an intellectual property system demands a balancing act, and that monopoly profit is justified only if it ensures a net social benefit.

⁹ Community Biodiversity Development and Conservation Programme - Bohol Project. 2001. A Study on the Plant Genetic Resources Diversity and Seed Supply System of Bohol Island, Philippines. Technical Report No. 1, Southeast Asia Regional Institute for Community Education. Quezon City, Philippines.

¹⁰ Most important ideas are those that are generated in universities, and many of the most important intellectual advances are not covered at all by the patent system. Look at the basic idea underlying the computer, Alan Turing's "Turing Machine": it was not protected by the patent system.⁹ Ideas like asymmetric information are not covered by intellectual property. (Joseph Stiglitz. "Economic Foundations of Intellectual Property", 57 Duke Law Journal 1693-1724 (2008).)

¹¹ Joseph Stiglitz. "Economic Foundations of Intellectual Property", 57 Duke Law Journal 1693-1724 (2008).

ESSENTIALLY DERIVED VARIETIES AND THE PERSPECTIVE OF GROWERS

Ms. Mia Buma, Secretary, Committee for Novelty Protection, International Association of Horticultural Producers (AIPH)

The International Association of Horticultural Producers is honored to contribute the perspective of ornamental growers at this EDV seminar.

1. I will first give a short overview of the arguments for the introduction of the EDV provision in the 1991 Convention. To understand this provision it is necessary to know why it was introduced.
2. Secondly I will evaluate the EDV provision: has it brought the benefits that were intended when it was introduced?
3. Following this I will give AIPH's opinion on the EDV provision.
4. Finally I come to a resume and conclusions.

1. The arguments for the introduction of the EDV provision in the 1991 Convention

To understand the EDV provision it is necessary to know why it was introduced. What was the reason for introducing an extension of the breeder's right to varieties which are essentially derived from varieties to which PVR had already been granted?

The main reason was the fact that under the system of the former Conventions (1961 and 1978) one difference between the new and the initial varieties was enough to get the grant of a breeder's right. One of the consequences of this system was that a new and successful protected variety was used by other breeders to develop a new successful variety just by adding a very small different detail to the successful variety and to ask for a new breeder's right. For that reason some people already warned that to grant a breeder's right, wider distances were needed and that criteria for acceptance of and agreement on distances between varieties had to be made. The existing situation could damage the position of the holder of the first existing breeder's right seriously. The opinion was that the distances between varieties had to become wider to be able to grant a breeder's right. For that reason in the years before 1991, UPOV was busy formulating and describing the main characteristics for 10 to 12 important varieties with the goal of helping to decide if the criteria for distinctness had been reached. Supporting this work the Royal Horticultural Society (RHS) helped in cooperation with the Dutch ornamental industry to formulate criteria. They developed the RHS Colour Chart. This chart had and still has two positive effects: all UPOV countries could use the same colour criteria for the decision for the grant of a breeder's right and it provided clarity about the needed distances between the colours of the initial and the new variety to decide if a new independent breeder's right can be granted.

Secondly the existence of mutants in propagating material was another reason to find clearer and fairer criteria for the decision to grant a new breeder's right. A mutant hardly differs from the initial variety except by one or two characteristics. However the mutant finders could still apply for their own PVR for this mutant, if it could be distinguished from the initial variety. The fact that this competitor hardly did any breeding work, was felt in the breeding world to be unfair. A third development asked for a solution that created more clarity and fairness in deciding on whether to grant a new breeder's right. This was the development of biotechnology, which made it easier to create mutants with the use through genetic manipulation. For those reasons the EDV concept was introduced in the UPOV Convention 1991. The EDV provision defines that if a breeder brings a new variety onto the market that is not significantly different from its parent variety, he can apply for a breeder's right but still needs permission from the owner of the already existing protected variety, who can exercise full rights against the breeder of the EDV. In other words this new variety can have breeder's right protection but the finder has to ask permission from the breeder of the initial variety if he wants to sell material from this new variety.

Since the introduction of the EDV concept in article 14.5 of the Convention 1991, AIPH has raised the question: can the problems as mentioned be solved by the EDV provision? Or stronger: is the EDV provision the suitable juridical solution for these problems? Is there even a juridical solution for these problems? I'll come back to this under point 3.

2. Evaluation of the EDV provision: have they brought the benefits that were intended when it was introduced?

I explained the arguments for the introduction of the EDV. These arguments were rather clear and understandable. But the working-out of it in the UPOV Convention was quite problematic, because if the protection of a protected variety has to be extended to material which is not the variety itself, how and where do you draw the dividing line?

In the UPOV diplomatic conferences of the 1991 Convention, much hectic debate took place as to what the right formulation of the EDV provision should be. The same happened during the legislative progress of the European Regulation on Community Plant Variety Rights (EC NO 2100/94 of 27 July 1994). This explains why the definition of EDV is not clear in any law text, nor in the UPOV Convention, nor in the national legislations. The definitions used do raise a lot of new questions. For that reason in 1991 the UPOV members agreed that UPOV would develop guidelines (explanatory notes) to determine whether a variety is essential derived or not. Because of the complicated issue of EDV those guidelines are still under discussion. The most important discussion points still deal with the following key issues of EDV: - how can it be proven or determined that a variety is essentially derived from another variety?

- what is the degree of genetic relatedness? Or in other words: when is a variety predominantly derived?
- what degree of phenotypic similarity between two varieties may lead to the conclusion that the new variety is derived from the parent variety? When is there similarity in the essential characteristics and which characteristics are to be considered essential?

Many involved parties in the breeding world have tried to give answers or guidelines on these questions. For example, ISF has given guidelines in its Views on Intellectual Property, CIOPORA International has published its Position Paper on EDV in 2008 and has announced that it will publish its reviewed positions in The Green Paper 2014. Member states have tried to give answers and explanations of the EDV provision in the explanatory memorandum within their own legislative implementation processes. UPOV is busy completing its own explanatory notes on EDV (UPOV/EXN/EDV/2 Draft 3, date February 7, 2013).

Nevertheless to litigants, judges and lawyers these guidelines have not given much help as can be seen from the jurisprudence in the very few Court cases, which are published so far:

- Danziger-Astee, Judgment of the Appeal court in the Hague (NL) December 29, 2009 and the earlier judgment in this case: Court The Hague (NL) July 13, 2005.
- Van Zanten-Hofland, Court The Hague (NL) August 6, 2008
- Danziger-Biological Industries, Court The Hague (NL) September 7, 2007
- Exotic Plant– Deroose Plants, Court of Commerce Gent (Belgium), December 3, 2012

I only briefly mention the court cases here, as this afternoon, Tjeerd Overdijk will go into detail in the jurisprudence in his presentation about the Court decisions on EDV in the Netherlands.

3. Opinion of AIPH on the EDV provision.

As said before: since the introduction of article 14.5 Convention 1991, AIPH has raised the question: can the problem of EDV be solved with a juridical solution? AIPH opinion is that essentially the EDV issue is not a juridical one for several reasons.

To understand why the solution is not a juridical one I first want to give three general statements on behalf of AIPH:

1. Statement: The goal of PBR is to stimulate plant breeding by an intellectual property rights system. This ensures that we (society) accept that certain entrepreneurs can for certain products, during a certain period of time and under strict conditions, gain a monopoly. The only reason for this is that we as society have the opinion that it is important that certain intellectual and/or economical activities are stimulated, because these activities contribute to technical and intellectual progress, which subsequently supplies important and useful products to our society.

2. Statement: Innovation and product renewal is the basis for progress in the ornamental sector. Therefore plant breeding is fundamentally important. AIPH supports a Plant Breeder's Rights system that stimulates breeding. An effective working Plant Breeder's Rights system is very important. However the

EDV provision seems to favour existing breeders above new breeders by making it more difficult for new breeders to receive a new independent breeder's right. Society in general and the growers in particular have an interest in new varieties and do not question where these varieties come from: breeders or new breeders.

AIPH supports rules and regulations that stimulate product renewal.

3. Statement: One of the main principles of PBR is the so called breeder's exemption. This allows breeders to use protected varieties for their breeding programs. As we all know, new varieties obtained by breeding sometimes hardly differ from the parent varieties. AIPH is of the opinion that the provision on EDV should not restrict this breeder's exemption in any way.

Against the background of these statements you will understand the following arguments of AIPH that essentially the EDV issue is not a juridical one:

1. argument: The existing EDV provision as described in article 14.5 of the Convention does not agree with the juridical base and the essence of the UPOV Plant breeder's rights system.

2. argument: The EDV provision complicates the mutation issue instead of simplifying it.

1. To explain the first argument AIPH wants to mention two important issues about the correct juridical base of EDV:

The first is: What is the exact meaning of the UPOV definition in UPOV Convention 1991 about the breeder (art. 1, iv UPOV 1991): "breeder means the person who bred or discovered and developed a variety".

One of the basic legal principles in the PVR system is that a person, who works out in his mind a thought that leads to a new variety, can apply for breeder's right. The system does not protect a physical plant, but the thought process leading to the development of a new variety. The eureka moment!

The legal system of intellectual property rights is to distinguish these property rights from physical properties. An intellectual property is the fruit of the processes of the mind. An abstract thought that can be protected by an intellectual property right, in our case a breeder's right. So the object of intellectual property is abstract. An abstract right you cannot feel, smell or hear. The object of IP is a creation of the mind, a product of the brain.

Ladies and gentlemen, the other important point is that: in civil law, to which Intellectual Property belongs, you have to unravel complex issues to come finally to a good and clear understanding. If the understanding is no good, the base of the legislation will be no good. You can compare this with building your house on the sand. To avoid this, it has to be clear what the object and what the subject of the law/legislation is. As said: the object of intellectual property is abstract.

If this is clear, it will be clear too that it is impossible to give another definition to 'breeder' than one who creates varieties. If such a new created variety meets the criteria of the plant breeder's rights system, the plant breeder's right will be granted to the breeder.

The concept of EDV does not differ from this abstract right. At most you could conclude that: what we forgot to formulate as a criteria to be granted for the breeder's right, yet we try to formulate that as an extra criteria called EDV. So in AIPH's opinion the problem should be solved at the right place and at the right moment in the UPOV system: so EDV should be solved under the conditions for the grant of the breeder's right (chapter III of the UPOV Convention 1991) and not under art. 14 UPOV Convention 1991, as EDV does not deal with the scope of the breeder's right.

2. The second argument of AIPH that essentially the EDV issue is not a juridical one is, as said, that the EDV provision makes the mutation issue complex instead of simplifying it. Before the enforcement of the UPOV Convention 1991, (in a nutshell) one relevant question had to be answered before there could be a ruling granted on a new PBR. "Is there a new variety or not?" Since the introduction of the EDV in 1991, there became a second question which had to be answered first. "Is this new variety essentially derived from another variety, yes or no?"

Unsolvable questions arise: one of the criteria for EDV is that the derived variety has to be independent and to be different from the initial variety. But what is an independent variety from a juridical point of view, as every variety biologically originates from other varieties?

Because of the fact that every new variety, like every living thing in nature, is born from parents, the only question here is: is the offspring different enough from his parents to grant it a new breeder's right. Governments and their controlling bodies should take their responsibilities seriously in setting out a logical, fair and consistent system in their decision-making process when they grant breeder's rights.

In addition to this it has been realised during recent decades, how difficult it is for controlling bodies to decide on the question as to whether there is a new variety or not. As mentioned earlier the introduction of an EDV exacerbates these problems.

It is clear, AIPH has fundamental problems with EDV.

In general we can see that when someone starts breeding with a new crop the progress you make with relatively small investments is initially enormous. But the more important the crop becomes, often through that same breeding work, the more investments the breeding requires and the less progress is made. If you bring that all under an EDV, this type of breeding might stop or at the very least, it will reduce healthy competition amongst breeders. Our fear is that in the final analysis the EDV provision will not stimulate breeding at all but in fact will encourage the opposite.

Nevertheless AIPH admits that since the introduction of it in the 1991 Convention the existence of the EDV provision is a fact. And in the course of time the practise teaches us that, for the most part, conflicts are solved between the breeder of the initial variety and the holder of the alleged EDV or the mutant finder.

However, AIPH pleads from the juridical point of view for another solution than the EDV provision in the UPOV Convention. We base our opinion on the arguments above.

We know it takes time to change Conventions and we know until this happens breeders and growers will have to deal with the EDV provision. Therefore AIPH gave in 2007 its recommendations or guidance concerning the existing EDV provision. See UPOV document CAJ-AG/07/2/4, Annex II, which you can find on the UPOV website.

Another solution could be in AIPH's opinion that UPOV should focus on the real important discussion, this being the distances between varieties and not on getting more and more complicated explanations of the articles of EDV in the UPOV Convention 91. The essence of the discussion should be: What is a variety, is there a new variety, yes or no? Who is a breeder and when can a breeder apply for a breeder's right?

If one can live with a certain bandwidth between varieties (which should be possible at least in ornamentals), the issue of EDV could be solved in a less complicated and more juridical clear way. Criteria for acceptance of and agreement on distances have to be made. UPOV should continue to formulate and describe the relevant characteristics for important varieties as was started before the introduction of the 1991 Convention, with the goal of helping to decide if the criteria for distinctness has been reached. So determination of what the characteristics are for the different varieties is needed. On the hand of these characteristics it has to be decided what an important characteristic is: disease resistance is more important for some varieties than for others, think of vegetables; for ornamentals the color of the flower is more important than the stand of the leaves; how important is the new characteristic for the commercial horticultural sector, how important is the new characteristic compares with other relevant characteristics?

AIPH is very willing to give contributions to the thoughts and discussions to help in coming to objective criteria for examining the distinction. After these questions are answered, the next set of questions arise regarding proof, evidence and enforcement of the right. These are essentially two different types of questions. The answers to these last set of questions have to be given as well, but not in PBR-law.

4. Resume and Conclusions

1. AIPH has fundamental problems with EDV from the juridical point of view and therefore pleads for a solution other than the EDV provision in the UPOV Convention. The provision does not agree with the juridical basis. The essence of the UPOV Plant breeder's rights system and based on our arguments herein, it follows that AIPH wishes to not regulate this issue by the EDV provision.

2. Regulations of any kind to solve the EDV issue should never block the breeder's exemption as the breeder's exemption is a very important possibility to improve the assortment of any crop. It is a basis for fair competition between breeders and opens the possibilities for new breeders.

3. AIPH is not in favour of rules that make the entrance to the market for new varieties more difficult or rules that strengthen the position of existing breeders against the position of new breeders. As stated, breeder's rights serve the general interest of society. This interest is stimulating breeding. The general interest of stimulating breeding and the interests of breeders (organised in associations or not) are not always equal.

Breeders have opposing interests and do not want new competitors.

4. AIPH has made clear that is not the goal of PVR to provide a monopoly position to existing breeders, nor to give certain breeders economic powers through cartels and to benefit some breeders above other breeders. On the contrary, current anti cartel rules, especially in the EU, are strongly enforced by the authorities with the aim of avoiding illegal competition and forbidding cartel agreements. The EDV provision in UPOV 1991 could easily create these scenarios.

5. The EDV provision is difficult to understand in the perspective of the essence of the intellectual property rights system. The provision discourages breeding activity, as it's difficult to imagine any commercial situation in which the holder of an breeder's right would honour someone else's EDV and give that person permission to exploit the EDV in the market. In fact, this could damage the holder of the first breeder's right.

6. AIPH considers it a disadvantage that questions of proof, which are caused by the EDV provision, are continuously mixed up with questions of principal law system.

7. AIPH is very willing to give contributions to the thoughts and discussions to help in coming to objective criteria for examining the distinction.

DISCUSSIONS ON SESSION I (TRANSCRIPTIONS)

Moderator: Mr. Peter Button, Vice Secretary-General, UPOV

SESSION I: TECHNICAL AND LEGAL ASPECTS OF ESSENTIALLY DERIVED VARIETIES AND THE POSSIBLE IMPACT ON BREEDING AND AGRICULTURE

Mr. Huib GHIJSEN, Netherlands

I have a question for Mr. Guiard. You mentioned that essential characteristics are not necessarily those used to establish distinctness. Do you have examples of such characteristics and if there are any other characteristics do they have to meet the UPOV requirements for characteristics?

Mr. Joël GUIARD (speaker)

Thank you for your question. I do not have a concrete example to mention, but I think that it is important for me to emphasize these differences because it is not mentioned anywhere that essential characteristics are the same as important characteristics for distinctness. There must be something different. Of course, the essential characteristics could be those used to establish distinctness, but it is possible, I think, that someone who wants to defend a case of essentially derived varieties can use characteristics such as, for example, the value of use of the variety, the content of some chemical substance, or the aptitude to flower before another variety, etc. More physiological characteristics of the variety which are not used for distinctness and I think one could also imagine, perhaps I may go too far, but one could imagine that among these essential characteristics one could also consider genotypic characteristics. As I said, I might be going too far. I think that it is in that spirit that it was said. So there is no limit a priori as to the characteristics that can be used. What is an essential characteristic? It could be many different things.

Mr. Richard BRAND, GEVES, France

As to the general remarks, I would like to change what was said this morning about mutations. Things like shortcut breeding or discouraging selection or plant breeding by mutation seems to be excessive. Plant breeders working on mutations have proven their effectiveness and bring important improvements to fruit-tree producers and plant growers. The mutant characteristic is not only visible regarding color; micro mutations would also need to be considered. So, yes, 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. Not just that, but there is plant breeding for continued improvements. That is my general comment. We need to find an equilibrium between the two systems to maintain plant breeders' rights.

Mr. Tjeerd OVERDIJK (speaker)

I have a question to Mr. Krieger. Mr. Krieger, it is always very interesting to hear your presentations with pleadings to broaden the concept of EDVs. Of course I have well studied the EDV position paper of CIOPORA which is already dating back to 2008, and in this position paper I thought to have clearly read that the EDV has also been introduced to fight plagiarism. This morning I seem to have heard you say something else and that the EDV has nothing to do with plagiarism and I also did not hear you refer to me-too-varieties which in the position paper are included. So my question is what happened in the meantime and what happens to the two varieties?

Mr. Edgar KRIEGER (speaker)

An excellent question and I appreciate that some people read our papers! In fact, in our EDV paper of 2008 we mentioned me-too-varieties and I considered me-too-varieties as a type of plagiarism and in fact the current EDV provisions do allow, if you interpret it in that way, for the inclusion of plagiarism. But it is not limited to that. We made a deeper legal analysis. It is not excluded to fight plagiarism. What we are opposing is that people limit it to the fight against plagiarism. This is not the case. The second thing is that of course, as with all things, our papers and ideas undergo an evolution so we made a deeper legal analysis and we found out that in fact fighting plagiarism is not a question of EDV, but rather a question of minimum distances. So the position evolved. I should say that it is not a final position. We have

discussed this in the board of CIOPORA in that direction and we will evolve our position and hopefully have an approved new position in April 2014 in Holland.

Mr. Thomas LEIDEREITER, Germany

I have a question for Ms. Hedwich Teunissen and thank her for the excellent presentation. This wonderful picture of the green and red flower which I loved, which seemed to be genetically almost identical, from the expert view you have, meaning the botanical, genetics expert, is it desirable to say it is an EDV or not? Would you say it should be protected by the initial variety or not?

Ms. Hedwich TEUNISSEN (speaker)

I already heard this question from a different person who had the same question as you. Well, I am a scientist and a molecular biologist so I see things from more the genetic point of view, so in this case we didn't see any molecular differences on DNA level, so I intend to follow the genetic conformity as the leading aspect in EDV discussion, so I would say this is an EDV from that view point.

Mr. François MEIENBERG, Association for Plant Breeding for the Benefit of Society (APBEBES)

I have a question related to the presentation by Ms. Nori Ignacio, where we have learnt that we have two innovation systems. The one from the informal seed sector and the one from the formal seed sector and that there is a lot of evidence that these interrelate, so that germplasm goes from the informal system to the formal system and vice versa. So my question is quite relevant as the UPOV system, including EDV rules, is expanding to more and more countries and developing countries where the informal system still plays a very important role. My question is to someone on the panel, have you any knowledge about assessments made of a possible impact of EDV rules on the informal seed system, especially the innovation in the informal system? Or, perhaps if you have no knowledge about this kind of research or studies, have you perhaps your own personal view – is it an issue or not?

Mr. Marcel BRUINS (speaker)

Thank you François– this is a good question. I think it is intrinsically linked to the seed sector to the seed system and I don't think we should take out EDV as an isolated item and assess its impact. What I do know is that a good set of regulations overseeing the entire seed sector does provide a lot of benefits to farmers and we have impact studies on that from different organizations and, of course, the plant breeders' rights regulations are part of that. In the same way if you compare the world map of countries that have a good set of regulations for seed certification, or seed testing, or for plant breeders' rights, and compare that with the hunger map as made by FAO, you see almost an inverted copy which means that those countries that do not have a good set of regulations have more hunger. I do not want to make the one-on-one comparison, but it is a clear indication that a certain set of regulations does help in decreasing hunger, in my view.

Mr. Joel GUIARD (speaker)

There is something that you must bear in mind – that the question of EDVs is only relevant if the initial variety is protected. If it is not protected, it has no impact whatsoever. Many varieties which are used both for conventional or informal selection – many of them are free to use. I think that this must be borne in mind too.

Mr. Faker GUERMAZI, Tunisia

My question is for Ms. Teunissen. If we have two varieties which are totally different from a phenotypic point of view, can one then speak about essentially derived varieties?

Ms. Hedwich TEUNISSEN (speaker)

I think this is a similar question to the one I had earlier and again, when you take this from the genetic conformity point of view, if you have done an extensive DNA analysis, also including relevant reference varieties and you find out that these varieties, although they are morphologically very different, have a very high or 100% genetic conformity, in my opinion, you should say that it is a strong indication that this is an EDV and then perhaps you can shift the burden of proof.

Mr. Peter BUTTON (moderator)

Just to clarify, you are suggesting it doesn't determine the outcome but it is a strong indicator that you should shift the burden of proof.

Mr. Bart KIEWIET, Netherlands

I have a question for Ms. Buma. Ms. Buma describes the breeder as someone with an "idea" about the variety he wants to create and once he has created that variety he is entitled to protection for that variety. So she said that the variety of the plant breeder's right is an abstract object. On the other hand she said that she is opposed, or rather the International Association of Horticultural Producers (AIPH) is opposed to the EDV concept and that means that, in her opinion, if a producer finds a mutation of a protected variety, he should be entitled to protection for that variety not as an EDV but, if I have understood her correctly, as an independent variety from the initial variety. But even if he would be entitled only to a title that is to be qualified as an EDV, my question is what is the intellectual efforts made by that producer to obtain that variety? In my opinion, it is only someone who has good eyes and observes in the field that one plant in thousands of plants or hundreds of plants is different from the other and then he says that this is a mutation. What is the intellectual effort made by that person to obtain that variety?

Ms. Mia BUMA (speaker)

Well I think it is clear that we have a fundamentally different approach to intellectual property. It is true that AIPH thinks that if there is a bright idea, there is a creation of the mind and intellectual property rights apply, no matter if it is in the field of patents or plant breeders' rights or models or whatever, then you could get an intellectual property right; you could become the owner of that. As I tried to explain, with the basic principle of the law system of intellectual property rights. You already mentioned immediately after my speech, but I think it is good to have a debate. We differ in opinions about this.

Mr. José Ignacio CUBERO, Spain

When dealing with DNA, genetic markers and looking for thresholds, I wonder when comparing populations such as the human beings and chimpanzees – what is the genetic difference and what is the threshold between human beings and chimpanzees?

Mr. Stephen SMITH (speaker)

So I think that is why we have to look at crop-specific answers to your question. Hopefully we will be able to have a much more informed debate and arrive at some solutions that help social welfare and benefit farmers. Just consider if, in fact, this room was occupied by chimpanzees, we would have a very different outcome. That is why it has to be crop-specific or genus-specific.

Mrs. Flora MPANJU, African Regional Intellectual Property Organization (ARIPO)

I am a patent examiner with ARIPO and before that I was a researcher in petroleum and we used to type the petroleum by using biomarkers. So it is no surprise to me. My question is, can you comment that whenever you are doing something, you don't have to do DUS testing, you have to do the biological markers if you want to know whether the variety is an EDV? So we should combine the two things, not only do DUS testing – what are your thoughts on this?

Mr. Gert WÜRTEMBERGER (speaker)

One should not forget that the UPOV system is based on phenotype and therefore I am astonished that most of the discussions and contributions reduced the whole problem to the genetic side. I try to emphasize that the differences in the phenotype are the starting point and, as I already mentioned in my contribution, Mr. Guiard seemed to confirm this, that 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.

Mr. Riad BAAZIA, Switzerland

I have a specific question to Mrs. Normita Ignacio about the empowerment of your organization or community, which means local communities in South East Asia. I do not know which kind of empowerment you are doing, maybe you're dealing with some countries or only small communities, which maybe could be linked with traditional knowledge and indigenous people.

Mr. Peter BUTTON (moderator)

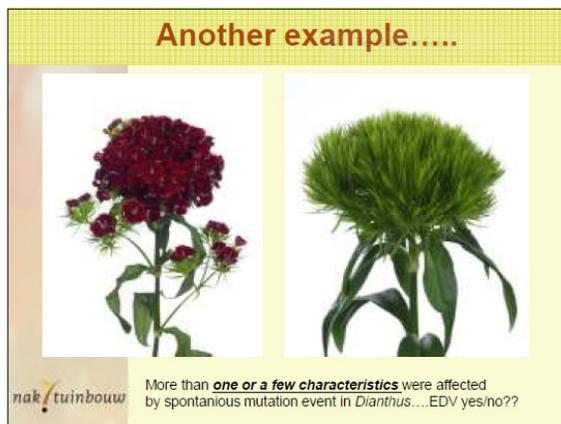
If I could ask you, Nori, to focus particularly on the subject of today in relation to farmer-breeders and perhaps if you could link that to essentially derived varieties in some way, that would be very useful.

Mrs. Normita IGNACIO (speaker)

I am not sure if I can do that, but I will try. We work specifically with farming communities and this involves indigenous communities. When we started our work with participatory plant breeding, we focussed mainly on prime irrigated areas, because that is where genetic erosion was very high. So after that, when we had proven that farmers could do this, we concentrated on building their capacity and providing the support that they need at the start of the project. They are able to produce their own seeds and their own varieties, according to their needs, the local conditions and preferences in the communities. After that we moved to other communities, indigenous communities as well. So it covers both prime irrigated areas and marginal areas and we work mainly with farmer-breeders in those communities.

Mr. Hidde KOENRAAD, Netherlands

Just getting back again to this picture in Ms. Teunissen presentation of the red and green flower head that she showed us. I understand from Mr. Würtenberger that the starting point for establishing an EDV is the phenotypical approach. I was wondering then the conclusion can only be, I assume, from your perspective, that the green flower would not be an EDV? Am I correct?



Mr. Gert WÜRTEBERGER (speaker)

In this case, it would be hard to argue that it is an EDV, if you proceed from the law as it is at the moment. I have to proceed from the law as I need to assume how the judges will see the concept and they will just look at the law. The documents, the records of the Diplomatic Conference, which led to the introduction of the EDV concept, do not reveal the extent to which an EDV might be beyond the examples you will find in the provisions in the UPOV Convention.

Mr. Edgar KRIEGER (speaker)

Maybe I can add one sentence. I have to object to this. There is one provision in the law and this is written down already in the UPOV Convention "except for the differences which result from the act of derivation" they should not be taken into account and we should not forget that. So if there are 10

differences and all of them result from the act of derivation, we should disregard them by checking if it is an EDV or not.

Mr. Sao CHESDA, Cambodia

The question is for Ms. Teunissen. Regarding the UPOV mission, for EDV we should have access to test guidelines, but we should select a specific species, especially cereal species for society, for food security.

Ms. Hedwich TEUNISSEN (speaker)

What I aimed to do in my talk was to give you a general approach that might be helpful as a sort of working model. But I think that if you want to come to EDV thresholds based on genetic conformity, which might be a nice tool to predict for EDV, it should be done on a crop by crop basis.

Mr. Peter BUTTON (moderator)

Thank you. I am afraid we have run out of time for questions in this session. It just remains for me to thank all the speakers from this morning for their presentations and for their contributions in answering your questions this afternoon.

SESSION II:
EXPERIENCE IN RELATION TO ESSENTIALLY DERIVED VARIETIES

EXPERIENCE ON ESSENTIALLY DERIVED VARIETIES IN AUSTRALIA

Mr. Doug Waterhouse, PBR Registrar, IP Australia

The notion of Essentially Derived Varieties (EDVs) was first introduced with the 1991 Act of the UPOV Convention (UPOV 91¹) in an effort to redress the balance of rights between plant breeders, where the second breeder used an existing PBR variety (the so called “initial” variety) to develop a “second variety” that was substantially the same as the initial variety. Circumstances where this was considered to occur may include where the second variety arose from a single spontaneous mutation; selection from within a variety; or through genetic manipulation by way of the insertion of say, one resistance gene.

The UPOV 91 definition of EDV is at [attachment 1](#). Suffice to say that the Convention text does not include operational detail and it is said by some to have an internal inconsistency between Article 14(5)(b) (i) and (iii), which makes the provision too difficult to use, as is.

Indeed over the last 22 years there has been almost no use of EDV in the public arena. One reason for the apparent lack of profile for EDV is that in most countries it is left to the first breeder to simply “declare” EDV over a second variety and then to prosecute the matter or an infringement in Court. Thus the national PVP² authority is usually not involved. However perhaps the major reason why EDV has not been pursued is industry’s general lack of certainty.

Development of Australia’s EDV provisions in conformity with UPOV 91

Australia was the first country to draft its PBR law in accordance with UPOV 91. The *Plant Breeder’s Rights Act 1994*³ (PBR Act) reflects the EDV wording of the Convention, though with three important elaborations ([attachment 2](#)).

The first elaboration defines “essential characteristics as heritable traits ... that contribute to the principal features, performance or value of the variety”.

The second elaboration avoids the tension between Article 14(b) (i) and (iii) by requiring that important differences (more than cosmetic) must be demonstrated if the second variety is **not** to be declared as an EDV.

- This explicitly “breaks the chain” of derivation whenever the second variety contains the expression of an important characteristic which differentiates it from the initial variety and the expression of that characteristic adds to the performance or value of the variety⁴. The consequence is that the “EDV chain” is potentially broken much earlier than otherwise may be the case.
 - The word “cosmetic” is interpreted in the context of the variety and the specific characteristic in question. For example, “colour of anthers” in some species (eg wheat) is not known to be important for value or performance. In other species (e.g. lily) anther colour does influence value and performance and therefore depending on the particular states of expression, differences may be considered important.

The third elaboration stipulates the government agency administering PBR, (IP Australia), is responsible for declarations of EDV (i.e. court action is not required in the first instance).

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.

¹ Also referred to in this paper as the Convention

² PVP (Plant Variety Protection), PVR (Plant Variety Rights) and PBR used almost interchangeably depending on jurisdiction.

³ *Plant Breeder’s Rights Act 1994* <http://www.comlaw.gov.au/Details/C2013C00153>

⁴ Additional supporting information is included in the *Plant Breeder’s Rights Bill 1994* Explanatory Memorandum (see [attachment 3](#))

- Membership of UPOV obliges Australia to meet minimum requirements but does not set upper limits, provided there is consistency with the minimum standards. These elaborations meet this test.

Review and confirmation of IP Australia as the EDV issuing Authority in the first instance

Australia's implementation of EDV was reviewed in 2007-2010 in the ACIP "Review of Enforcement of Plant Breeder's Rights (PBR)"⁵. Industry continued its strong support for IP Australia to administer EDV applications. While some changes were suggested (eg to remove the requirement that the second variety also be the subject of PBR⁶) there was a general sense that there was insufficient reason to warrant other substantive legislative change. There were general recommendations regarding greater education and awareness activities.

Administrative procedures

The PBR Act includes a number of provisions for the orderly administration of disputes arising from claims of EDV that may follow the granting of rights to a new variety, (PBR Act section 40).

The grantee of rights to the initial variety must provide the Registrar with a *prima facie* case that the second variety satisfies the definition of EDV and request the Registrar to declare the second variety essentially derived from the initial variety. A fee of AUD\$800 currently applies.

The onus is placed on the breeder of the second variety to rebut the claim. The reversal of the onus of proof is based on the fact that only the breeder of the second variety would be expected to have the knowledge of the breeding history of the second variety to rebut the claim. If the claim cannot be successfully rebutted, the Registrar will declare the second variety essentially derived.

- The PBR Act does not require publication of the detail of EDV decisions. However it is considered prudent to issue a public notice in the *Plant Varieties Journal* when an EDV is so declared in accordance with the spirit of UPOV 91 Article 30 (1)(iii).

Application may be made by either party to the *Administrative Appeals Tribunal* or to the *Federal Court of Australia* to review the Registrar's decision.

Rights to the EDV variety fall within the scope of rights to the initial variety. Thus, two persons may have rights to the second variety; and neither can exploit the rights without authorization from the other. The rights holders thus need to agree to conditions of commercialization.

Examples of Australia's experiences, using our "bright line" to assess EDV applications⁷

'Sir Walter' vs 'B12' (2005)

'Sir Walter' is a very popular variety of "soft leaf" Buffalo Grass⁸ (*Stenotaphrum*) in Australia with over 60 licensed growers/suppliers. It was granted PBR in March 1998.

The grantee of 'Sir Walter' claimed that 'B12' (the second variety) was EDV relevantly because in accordance with section 4(c) of the PBR Act

"The characteristics claimed as being different (greener internode colour and shorter internode length) are not important but only cosmetic. In fact the trait of longer leaf length would be considered a loss in quality not an improvement. It is worthy to note here that the selection procedure took place in only one season. Also the trials to substantiate the morphological differences took place only over one spring summer period. Given the plastic nature of Stenotaphrum to its environment, any trial should have covered at least two full growing seasons"

⁵ Australian Council for Intellectual Property (ACIP) "Review of Enforcement of Plant Breeder's Rights (PBR)" <http://www.acip.gov.au/reviews/all-reviews/review-enforcement-pbr/> last updated 06/07/2013

⁶ Currently this recommendation has not progressed.

⁷ Summaries of these examples focus on key turning points and are not a comprehensive dissertation of all matters argued.

⁸ Also known as St Augustine Grass. It is different from *Buchloe dactyloides* which is also known as Buffalo Grass in some jurisdictions.

and be carried out in different climatic zones to substantiate a true and consistent difference in a characteristic.”

The second breeder was invited to rebut the claim. The second breeder argued that the feature of shorter internode length is considered to be an “important (as distinct from cosmetic) feature” for a turfgrass variety such as ‘B12’ because it increases “thatch”. Increased thatch leads to wear tolerance (eg. the grass will tolerate more traffic). Several academic sources citing the importance of internode length in turfgrass breeding were referenced, including:

- Martin, Dennis. OSU Bermudagrass Breeding and Development Program Update May 23, 2002, Oklahoma State University, Stillwater, 2002 9
 - *“As with most improved turf type bermudagrasses, the excellent winter shoot survival, high shoot density and shorter internode length of this grass may make it more prone to thatching under intensive management, so scout for thatch regularly.”*
- Busey, P. 2003. “St. Augustinegrass”. Casler, M. D., and Duncan, R. R. (eds.) Biology, breeding, and genetics of turfgrasses. John Wiley & Sons, Inc, Hoboken, NJ, pp. 309-330 (reprinted on the internet)¹⁰
 - *“Cultivars with shorter internodes have higher wear tolerance (Busey, 1991, unpublished data).”*
- Karl Danneberger “Plant Anatomy” Turfgrass Management and Science, Ohio State University Department of Horticulture and Crop Science¹¹
 - *“Nodes are a key structure in turf recuperative ability from traffic-wear stress, environmental stress, and pests”.*
- Douglas E. Karcher, Michael D. Richardson, Joshua W. Landreth, and John H. McCalla, Jr. “Recovery of Bermudagrass Varieties from Divot Injury”, Applied Turfgrass Science, Plant Management Network, 2005¹².
 - *“Density in bermudagrass is dictated primarily by stolon and rhizome internode length. As internode length decreases, more crowns are produced per unit area and these result in more growing points for leaves.”*

The Registrar noted these academic sources and came to the view that shorter internodes was an “important (as distinct from cosmetic) feature” for a turfgrass variety such as ‘B12’ because it increases thatch.

The Registrar also considered data from two separate growing trials. The first data set was from the trial used in the examination of ‘B12’ for PBR registration. The second data set was from a separate trial commissioned by the grantee of ‘B12’ but under the supervision of a person accredited by the PBR Act to conduct such a trial for this species. Data indicated the average internode length (mm) in ‘B12’ was 50.4 with a standard deviation of 4.6 whilst in ‘Sir Walter’ it was 57.1 with a standard deviation of 4.8. The difference was statistically significant at the 99% probability level.

The Registrar concluded, on balance, that there was sufficient evidence that ‘B12’ had a shorter internode length and that this was an important (as distinct from cosmetic) feature which differentiates it from ‘Sir Walter’.

The application for EDV was dismissed on the basis that section 4(c) of the PBR Act had not been satisfied.

⁹ <http://home.okstate.edu/Okstate/dasnr/hort/hortlahome.nsf/toc/martin2> accessed 12.07.2005

¹⁰ <http://turfscience.com/staugustine/> accessed 12.07.2005

¹¹ <http://hcs.osu.edu/hcs570/handout1.html> accessed 12.07.2005

¹² <http://www.plantmanagementnetwork.org/pub/ats/research/2005/divot/> accessed 12.07.2005

Figure 1: Some morphological characteristics, including internode lengths, of 3 varieties of Buffalo Grass.



'Sir Walter' vs 'Kings Pride' (2007)

The grantee of 'Sir Walter' claimed that 'Kings Pride' (the second variety) was EDV relevantly because in accordance with section 4 of the PBR Act

'Kings Pride' is predominantly derived from 'Sir Walter'
[...]

'Kings Pride' does not exhibit any important (as distinct from cosmetic) features that differentiate it from 'Sir Walter'.

A genomic and morphological analysis provided in support of the claim failed to differentiate 'Kings Pride' from 'Sir Walter' in any of the primers used.

In rebutting the EDV claims, the breeder of 'Kings Pride' acknowledged that it was likely 'Kings Pride' and 'Sir Walter' shared a common genetic background.

However, they also asserted that 'Kings Pride' was not selected from an existing stand of 'Sir Walter'. Their own DNA analysis concluded the "maternal parent (of 'Kings Pride') is probably the same maternal parent as 'Sir Walter' and/or 'Shademaster'"¹³.

They also provided evidence that, on average, 'Kings Pride' had comparatively stronger plant vigor, longer internode length and longer stolon length than 'Sir Walter'.

The Registrar again noted academic sources citing the importance of stolon length in turfgrass breeding for density and thus thatch, including:

- Douglas E. Karcher, Michael D. Richardson, Joshua W. Landreth, and John H. McCalla, Jr. "Recovery of Bermudagrass Varieties from Divot Injury", Applied Turfgrass Science, Plant Management Network, 2005:14.
 - "Density in bermudagrass is dictated primarily by stolon and rhizome internode length."

The Registrar concluded, on balance, that there was sufficient evidence that 'Kings Pride' had a longer stolon length and that this was an important (as distinct from cosmetic) feature which differentiates it from 'Sir Walter'.

¹³ 'Shademaster' is another variety of Buffalo Grass registered in Australia and is the parent of 'Sir Walter'.

¹⁴ <http://www.plantmanagementnetwork.org/pub/ats/research/2005/divot/> accessed 12.07.2005

Accordingly the Registrar dismissed the application for EDV because the requirements of section 4(c) were not met. It was then not necessary to make a determination in relation to section 4(a) “predominantly derived”.

‘MC38’ vs MC51 (2012)

The grantee of ‘MC38’ (an apple variety) claimed that MC51 (the second variety) was EDV because:

“Variety MC51 was found growing in a uniform block of variety ‘MC38’ in our own orchard
[...]
It is a full tree sport of MC38 that has a full block red colour unlike the striped skin colour of MC38.”

The EDV application was first assessed against the administrative provisions outlined in section 40(1)(b) of the PBR Act (see attachment 2).

- The Registrar noted that the grantee of ‘MC38’ was by their own admission, also the “breeder” of MC51.

The EDV application was rejected for two reasons. First, the information provided did not indicate that “another person” was involved as is required by section 40(1)(b) of the PBR Act.

Second, there was no information or evidence of an Australian application for, or a grant of, PBR for MC51.

Comment

In broad context, it is noted that reference to “another person” in the PBR Act provides one possible administrative solution to avoid the potential mischief identified by Japan in their paper “The matters arising after the grant of a breeder’s rights in Japan” CAJ-AG/11/6/3, paragraph 30.

Attachment 1

Relevant Extract from the 1991 UPOV Convention

“Article 14

[...]

(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

[...]

(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.”

Relevant extracts from the *Plant Breeder's Rights Act 1994*

“Section 4 Definition of essentially derived varieties

A plant variety is taken to be an essentially derived variety of another plant variety if:

- (a) it is predominantly derived from that other plant variety; and
- (b) it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and
- (c) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.”

“Section 3 Definitions

[...]

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.”

“Section 40 Applications for declarations of essential derivation

- (1) If:
 - (a) a person is the grantee of PBR in a particular plant variety—(the initial variety); and
 - (b) another person is the grantee of, or has applied for, PBR in another plant variety (the second variety); and
 - (c) the grantee of PBR in the initial variety is satisfied that the second variety is, within the meaning of section 4, an essentially derived variety of the initial variety; and
 - (d) the initial variety has not itself been declared to be an essentially derived variety of another variety in which PBR has been granted;

the grantee of PBR in the initial variety may make written application to the Secretary for a declaration that the second variety is so derived.

[...]

Note: A decision under this section to declare, or not to declare, a plant variety essentially derived is reviewable by the AAT under section 77. “

(emphases added)

Relevant extract from the *Plant Breeder's Rights Bill 1994*

Explanatory Memorandum

Clause 4 – Definition of Essentially Derived Varieties

15. Describes an essentially derived variety as one which is genetically similar to the variety from which it is derived and differing only in cosmetic features, rather than in principal features or features of value.

COURT DECISIONS ON ESSENTIALLY DERIVED VARIETIES IN THE NETHERLANDS

Mr. Tjeerd F. W. Overdijk, Vondst Advocaten N.V., Netherlands

1. Introduction – the basics

Basically, Plant Variety Protection extends to acts in respect of the propagating material of the protected variety ("PV") (UPOV 14 Para 1). However, this is considered not enough and for this reason the UPOV Treaty (1991 Act) includes a number of provisions affording extended protection to varieties that are different from the PV ("non-PVs") (UPOV 14 Para 5):

- plant varieties whose production requires the repeated use of the PV (hybrids);
- plant varieties which are not clearly distinguishable from the PV (i.e. essentially the same as PV);
- varieties which are essentially derived from the PV.

In the UPOV EDV Seminar we will be focussing on the last extension which relates to EDVs.

Article 14 para 5 sub c UPOV 1991 lists some examples of ways along which EDVs may be obtained:

- natural or induced mutants;
- somaclonal variants;
- the selection of a variant individual from plants of the initial variety ("INV");
- Backcrossing; or
- transformation by genetic engineering.

The UPOV Treaty and national laws implementing the Treaty have been obviously heavily debated and duly considered. Yet, if we read the not uncomplicated text of the provision it leaves open a number of very important issues.

Art. 14 para 5 sub b UPOV 1991 defines when a variety qualifies as an EDV:

(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.

This paragraph is not the finest example of clear legal writing. It shows that the text has been heavily debated and that the wording is the result of a compromise.

In the Netherlands the EDV-provision has been implemented in the Seed and Planting Materials Act 2005 (Zaaizaad- en Plantgoedwet 2005).

Article 58 para 2 of this Act includes the following definition of an EDV:

2) For the application of the first subparagraph (a), a variety shall be deemed to be essentially derived from another variety in case the former variety

- (a) is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety,
- (b) on the basis of Article 49, 4th paragraph, is clearly distinguishable from the initial variety, and
- (c) conforms to the initial variety in the expression of the essential characteristics that results from the genotype or combination of genotypes of the initial variety, except for the differences which result from the act of derivation.

In the Dutch version the 'while retaining' part in paragraph 1 of the UPOV-definition has been left out in the Dutch Act, as it was considered an unnecessary and confusing duplication.

The third paragraph is kept closer to the UPOV-text than the comparable provision in the Community Plant Variety Regulation (CPVR), in which the 3rd paragraph reads that the former variety “essentially conforms” to the initial variety in the “expression of the characteristics” that results from the genotype or combination of genotypes of the initial variety. In the text of the Community Regulation the element ‘essential’ is placed in front of the word ‘conform’, instead of the word ‘characteristics’.

For all three sets of provisions (UPOV, EU, NL) typical questions to be answered when applying the EDV-provisions are:

- What is “derived”?
- When is a variety “predominantly” derived?
- When is there conformity in (the expression of) the essential characteristics? (for the CPVR: when is there ‘essential conformity’?);
- How do we know whether the expression of characteristics results from the genotype of the INV?

These are not simple questions as we are lacking clear guidance from the Treaty maker. In the states that have implemented the Treaty it is not much better.

2. Case law in the Netherlands

In the Netherlands we have so far had three disputes on EDVs that have reached the Courts and made it to a judgment:

- the Freesia case (2008);
- the Blancanieves case (2002, 2005, 2009);
- the Bambino case (2007 - 2010).

I happened to be involved as counsel for one of the parties in each of the three cases. It is always difficult (and maybe even ‘not done’) to discuss one’s own cases, but I can offer some justification in this case:

- several years have passed, so I have developed a good level of distance;
- I have acted for both defendants and plaintiffs, so I know both ends of the spectrum;
- there are no other judgments that could serve as examples of case law.

Obviously, there have been more disputes than the three mentioned before, but these have been settled before the courts rendered a decision.

At the time I became involved in the first EDV-dispute, in 2002, there was not an abundance of commentaries available to the practitioner and there was no case law at all. It gave me a sense of pioneering, which was thrilling (a nice challenge) and frustrating at the same time.

3. The Freesia case (Van Zanten v. Hofland) (2008)

In the Freesia the central characters were the variety Ricastor (INV) of Van Zanten and the variety Mercurius of Hofland (EDV).

The Freesia case was a fairly clear cut case, because the right holder for Ricastor had very convincing DNA Tests. For both varieties several samples had been collected from different locations. A comparison was made which included 25 other commercially available varieties.

The DNA test (AFLP and isolation with Qiagen DNeasy Mini Kit) showed no genetic difference.

The defendant raised some questions and had some criticism, but was unable to produce a counter test with different results.

Moreover the two varieties were very similar from a morphological point of view. The morphological differences were very small and only just enough for Mercurius to qualify as a new variety. The two varieties were identical in 38 out of 39 characteristics. Mercurius only had a slightly rougher stem. There was a difference in flower size, but this was a characteristic that was not listed in the DUS Guidelines.

Therefore this was a typical and very convincing case for an EDV. Hofland was ordered to cease all infringements of the PVR of Van Zanten and to no longer market its variety.

4. The Bambino case (Danziger v. Biological Industries) (2007 – 2010)

The second and third cases both were about Gypsophila's and in both cases Danziger was the plaintiff and its star variety Million Stars® was the INV.

In the third case Danziger sought an order to enjoin its competitor Biological Industries to further propagate and sell its new small flowered Gypsophila variety Bambino.

Danziger acted upon an extended version of the AFLP test done for the Blananieves case (dealt with hereafter), which showed a genetic similarity between the two varieties of approx. 0,91 (Jaccard Index). The parties battled heavily about the question whether this was enough for a finding of EDV. Danziger argued that 0,91 similarity on the Jaccard Index was unusually high.

The plaintiff had the advantage of having a very convincing expert in the court room. He suggested that the Bambino could be the result of some treatment with the help of radiation. This was in fact irrelevant, because it was purely hypothetical.

The court made reference to EDV guidelines for other crops to support that the threshold of 0.90 Jaccard was a good deciding line for dividing the burden of proof. This is in fact not a sound reasoning, because every crop should be viewed and judged upon its own specific characteristics.

The defendant argued: it cannot be EDV because I did not even use the plaintiff's variety in my breeding process. However, given the relatively high genetic similarity this was simply not convincing for the judge.

The parties argued a lot about morphological differences and similarities. The plaintiff claimed the differences were small; the defendant argued there were many. In this connection a problem for the defendant was that for a number of the differences it was not clear to what extent they were to be considered relevant for the purpose of a comparison because a number of differences related to characteristics that were not (yet) included in the relevant Examination Guidelines for Gypsophila.

Therefore the Provisions Judge came to the preliminary conclusion that the morphological differences were to be considered relatively small. On the basis of these findings the Provisions Judge gave a provisional injunction in 2007. Biological Industry appealed and the parties were also involved in principal proceedings on the merits. The appeal was still pending when the Hague Court of Appeal gave its ruling in the Blananieves case and thereafter, in 2010, the case was settled between the parties.

This case shows that it is sometimes possible to obtain an infringement order for a variety which shows more than just one or a few morphological differences with the INV, but at the same time, because the case was ended with an amicable settlement it is unclear what would have been the outcome if the case would have been litigated to the end.

5. The Blananieves case (2002 – 2009)

The oldest, longest and most prominent case (I think the first EDV-dispute in the world that reached the court) is the Blananieves case.

The relevant facts and claims of this dispute were as follows:

Plaintiff: Astée Flowers: breeder of of the Gypsophila varieties Blananieves and Summer Snow;
Defendant: Danziger: breeder of the Gypsophila variety Million Stars.

Danziger was spreading rumours in the market and was sending letters to growers that Blancanieves and Summer Snow would be EDVs of its variety Million Stars.
Plaintiff Astée sought an order from the court to enjoin Danziger from sending such warning letters and spreading information that Astée claimed to be wrong.

Danziger had commissioned DNA tests on the basis of the AFLP-fingerprinting, which it claimed to prove a similarity at DNA-level between the varieties Million Stars® and Blancanieves of 0.944 Jaccard and 0.937 Jaccard. Danziger had no such test results for the variety Summer Snow. Danziger also claimed that Million Stars® on the one hand and Blancanieves and Summer Snow on the other showed a very high phenotypic similarity in essential characteristics and it also claimed that all the differences between the two varieties were no more than differences caused by act of derivation. It was known between the parties that the Blancanieves breeding process included an act of polyploidization and Danziger claimed that the phenotypical differences were all or primarily resulting from this act of polyploidization.

Astée Flowers, at some point during the proceedings, had made its own AFLP, which revealed a much smaller genetic similarity between Million Stars® and Blancanieves - 0.822 Jaccard;
The DUS test between the two varieties showed very substantial phenotypic differences: differences in 17 out of 21 of the characteristics mentioned in the UPOV DUS Guidelines.

In 2002 the Provisions Judge of the District Court in the Hague gave a provisional order which prohibited Danziger to make further claims that Blancanieves and Summer Snow would be EDVs of Dangypmini (P) Million Stars® (“Million Stars®”).
This court order was confirmed in a judgment in the main proceedings by the Hague District Court in 2005.
Danziger appealed against the judgment of the District Court, but lost the appeal in 2009.

The following elements are interesting to be highlighted in the decision of the Court of Appeal

The Court of Appeal says that there is a logical order of EDV assessment:

- 1) First we have to ask: is the alleged EDV distinct from the INV?
- 2) Secondly, we have to assess whether or not the alleged EDV is predominantly derived from the INV? (genetic conformity);
- 3) If so, we have to ask whether or not the derived variety is essentially similar to the INV in terms of expression of characteristics, resulting from the genotype or combination of genotypes of the INV (not taking into account differences resulting from the act of derivation)? (phenotypic conformity)

NOTE: these are all cumulative requirements!

With regard to the required level of genetic conformity the Court of Appeal considered that UPOV document IOM/6/2 provides important guidance for the interpretation of the EDV provision. It is clear that Article 14 para 5 sub (i) relates to the required level of genetic conformity. According to UPOV document IOM/6/2 “derived” means that genetic materials of the INV have been used in the creation of the later variety, which the Court of Appeal appears to support.

The establishment of genetic conformity is primarily a question of fact; Genetic conformity may be established using all available evidence;

The Court of Appeal also attaches great importance to a passage in UPOV document IOM/6/2 which says: “The examples of essential derivation given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few.” In this context the Court of Appeal also makes reference to a similar passage in the ISF Regulation for the arbitration of Disputes concerning Essential Derivation (“ISF RED”) which says:

“(…) the application shall contain phenotypic and molecular data of his variety compared to the PEDV [putative essentially derived variety; Court of Appeal] showing that the PEDV and the INV [initial variety;

Court of Appeal] are genetically and phenotypically very similar so that the PEDV differs from the INV by only one or a few simply inherited characteristics.”

Furthermore the Court of Appeal gives its interpretation of the wording:

“while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety”:

According to the Court of Appeal this implies that these are characteristics that are unique to the initial variety and that any characteristics typical of a certain group of varieties must be left out of consideration.

Assessment of genetic conformity

The decision of the Court of Appeal includes important observations in regard to the assessment of genetic conformity with the help of DNA fingerprinting.

With regard to the determination of genetic conformity between plant varieties by means of AFLP markers the Court of Appeal said that it is “open to objections”.

For a (reliable) determination of genetic conformity by means of DNA markers the most important conditions are:

- the use of multi-allelic markers; and
- a reliable sampling of the entire genome.

AFLP is a bi-allelic marker technology. This means that it includes a translational step in that it converts DNA variation in the chromosomes in a binary coding (1 and 0). As a result it is possible that genetic differences will be reduced to only one number, which may lead to loss of information on genetic variation.

In para 16 of the ruling the Court of Appeal remarks:

“because of their nature, AFLP markers cannot be regarded as multi-allelic markers. Moreover, it is unknown to what extent the markers used by Keygene represent the Gypsophila genome. AFLP markers occur in strong clusters in the genomes of many plant varieties. Therefore, a number of 230 to 260 markers provides insufficient certainty about the desired representative sampling of the Gypsophila genome.

Furthermore, dominant markers such as AFLP overestimate the real degree of identity between genotypes, since they do not reveal the possible underlying heterozygosis.

Although heterozygosis can be detected for certain population structures by means of Keygene’s technology, it does not become evident from its reports that this was used in the AFLP analysis at issue. 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.

Furthermore, the Keygene reports used by Danziger do not contain a calculation of a ‘standard error’ (‘bootstrap’ resampling of marker scores). Ploidy-level of reference varieties has been left out from the equation and influence of such omission is unknown.

Phenotypic similarity

The decision of the Court of Appeal also includes interesting observations on phenotypic similarity.

According to the Court of Appeal the alleged EDV and the initial 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.

The determination of distinctiveness focuses on the differences in essential characteristics, whereas the determination of derivation focuses on the similarities of essential characteristics in which the genome is expressed.

Essential to a variety are (is) those (that) unique (combination of) characteristics which determine the cultural and practical value and from which the variety derives its 'variability'. For ornamental crops the cultural and practical value is largely determined by the morphological characteristics.

In relation to the case at hand the Court of Appeal goes on to remark that the CPVO found 17 morphological differences with Million Stars during DUS tests for Blancanieves. 9 out of 17 of the different characteristics are related to plant architecture and flower morphology; these are specifically characteristics which are relevant for the cultural and practical value of a cut flower such as Gypsophila. Therefore the conclusion must be: Blancanieves differs from Million Stars more than only in one or a few inheritable characteristics and therefore cannot qualify as an EDV.

The Court of Appeal saw no reason to appoint an independent expert to perform a morphological comparison test.

6. Assessment of EDVs after the Blancanieves ruling?

The Blancanieves ruling poses the question whether AFLP is (still) suitable (as court evidence). The problem here is that AFLP is relatively reliable in terms of reproducibility, and it is quick and relatively cheap. Improvements to AFLP-work methods may help to obtain reliable sampling of genome and reliable results.

If for these reasons a plaintiff would wish to base an EDV-claim on a DNA fingerprint that has been produced with the AFLP method there are a number of elements that should be taken care of as a minimum (or checked by the defendant):

- Safeguards to obtain representative sample collection (plant material should be out of the control by the party commissioning a test);
- Guarantee of anonymity (testing agency should not know names of material to be tested);
- Determination of optimal reaction conditions;
- Assess representativeness of sampling of genome / distribution of markers;
- Separation of fragments & normalization;
- Careful analysis & reliable scoring;
- Use of multiple similarity matrices;
- Cluster verification and reliability & error checks.

7. Other views on what is 'predominant derivation'

The Blancanieves ruling has not been greeted with enthusiasm by the whole breeding community. There was unhappiness among those who favor a wide application of the EDV concept.

CIOPORA, the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants, has been striving for a much broader definition of EDVs than what has been accepted by the Hague Court of Appeal.

CIOPORA's position can be learned from its so-called EDV Position Paper that was published in 2008.

Highlights of the CIOPORA position:

- the EDV-concept is a true extension of the breeders' right and a temporary limitation of the breeder's exemption;

- the EDV-concept is of particular importance for two groups of varieties:
 - a) varieties which are solely based on the genome of the initial variety and where the genomic structure is highly conserved, e.g. spontaneous and induced mutants, GMO and apomicts; and
 - b) varieties resulting from crossing and selecting, including the initial variety, being predominantly derived from the initial variety and being destined for circumventing the exclusive right to exploit the initial variety (plagiarism or *me-too-varieties*).
- the words “predominantly derived” must be interpreted in such a way that:
 - it applies only in case the INV has been used in the process of developing the EDV;
 - a variety can only be predominantly derived from one variety, the INV;
 - it encompasses so-called *monoparentals*, i.e. varieties that are totally derived from the INV as well as varieties which must be regarded as me too varieties;
 - in respect of *me too varieties* the question whether or not there is predominant derivation has to be answered on the basis of the genome of the varieties in dispute and it is up to the breeders of the specific species to determine a threshold, above which predominant derivation must be deemed to exist. As long as no such thresholds exist, the courts have to decide on the basis of expert opinions.
- CIOPORA is in favor of a general genetic threshold for reversal of burden of proof for all ornamental crops (0,90 Jaccard) – because in the vast majority of cases this would present an acceptable borderline;
- Me too varieties are defined as “Varieties (...) destined for circumventing the exclusive right (...) (plagiarism or me-too-varieties)”: these retain all essential characteristics of INV and only show changes in insignificant characteristics and hence should be deemed “predominantly derived”;
- in the opinion of CIOPORA there exists no limit to the number of phenotypic differences between the INV and the so-called totally derived EDVs;
- Me too varieties must be considered EDVs if they retain all essential characteristics of the initial variety and only shows changes in insignificant characteristics, whereby “essential characteristics” shall mean the characteristics that are considered essential for the exploitation of the variety (in contrast to the usually longer list of botanical characteristics which may be relevant for the DUS examination).

Note: the broad view advocated by CIOPORA by definition brings crosses into the realm of EDVs. Given the one-or-very-few approach that transpires from the UPOV documents quoted in the Blancanieves judgment it is unclear whether this was indeed the goal of the makers of the UPOV 1991 Act.

ISF: advocates a crop by crop approach.

Reversal of burden of proof in case of strong similarity in genotype or phenotype.

Furthermore ISF has adopted a crop specific approach: conformity scales & thresholds in EDV protocols based on industry supported research.

As expressed in its Regulation for the Arbitration of Disputes concerning Essential Derivation (“ISF RED”) ISF supports the view that a variety that is accused of being essentially derived (“putative EDV” or “PEDV”) can only be held to be an EDV if it is genetically and phenotypically very similar to the INV “so that the PEDV differs from the INV by only one or very few simply inherited characteristics”.

UPOV has been well aware of the ongoing discussions about the scope of the EDV provisions. With a view to provide guidance to interested circles it has published Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (October, 2009). The Explanatory Notes mention that the Convention does not provide clarification of terms such as “predominantly derived” or “essential characteristics”. Yet, except for some non-committal remarks and some interesting remarks on so-called cascade issues, the UPOV Explanatory Notes do not offer much more clarity on the very important issues referred to before. This is rather disappointing, as it means that the breeders community at large is

left with a great deal of uncertainty about the correct application of the EDV-concept and there is a continued and substantial risk of disparity in the application by different national courts.

8. Conclusions

- So far, based on rulings obtained in the Netherlands and in view of the approach advocated by ISF, the prevailing view is that 'predominant derivation' is reserved for cases where the putative EDV is so similar to the INV that the two varieties differ from one another by only one or very few inherited characteristics.
- Further clarification is needed on the issue of whether the EDV-concept is aimed to bring crosses or other results from classical breeding within its reach (except repeated back-crossing).
- the breeding community at large would be helped with a clear definition of the term 'predominantly derived', and of what is meant by 'essential' in "essential characteristics".
- Another interesting open question is whether or not physical use of the INV is a condition for determination of EDV and/or whether the (re)use of genetic information could result in the creation of an EDV.
- These questions call for new or extended UPOV Explanatory Notes on EDVs.

COURT DECISION ON ESSENTIALLY DERIVED VARIETIES IN ISRAEL

Mr. Arnan Gabrieli, Seligsohn Gabrieli & Co., Israel

Introduction

1. The subject court decision was given by the Tel Aviv District Court, which is the court of first instance in matters concerning intellectual property. The Israeli Law of The Protection of Breeders' Rights Act 1973 (hereinafter: "the Act") introduced into Israeli law a new intellectual property right, i.e. the breeder's right. The Act follows the provisions of the International Convention in this respect.

2. It is interesting to note that to date, forty years after the coming into force of the Act, there are very few court cases in Israel which directly deal with substantive matters of breeders' rights and concerning essentially derived varieties, the case presented here is to date the only one.

3. In 1996, the Act was amended to reflect the amendments of the International Convention of 1991. Inter alia, the amendment enhanced the protection of the breeder's right by introducing the concept of essentially derived varieties.

The Act provides in this respect that the right of the breeder of the registered variety shall apply to an essentially derived variety.

The Act further provides that if the right holder of the original variety refuses to grant a license to utilise the EDV to the breeder thereof on reasonable terms, the Breeder's Right Council may grant a compulsory license under the terms and conditions to be fixed thereby.

The facts of the case

4. Danziger Dan Flower Farm (hereinafter: "the Plaintiff") is the owner of the breeder's right in a variety of gypsophylla, registered as Dangypmini, known commercially as "Million Stars" (hereinafter: "the Original Variety"). The Original Variety was registered in Israel in December of 1997 and became very successful worldwide.

5. The variety which was alleged to be an EDV of the Original Variety was registered in the European Union and is known by the name of Blancanieves (hereinafter: "the EDV"). An application to register the variety in Israel was filed in 2004. Originally the EDV was registered in the name of its breeder, Mr. Van der Kraan, who later assigned the right to the Netherlands company ASTEE (hereinafter: "the Defendant"). The EDV was marketed worldwide, inter alia in Israel, where it was also grown and propagated by an Israeli grower, under license from the Defendant.

When the EDV was discovered on the market by the Plaintiff, it was suspected by the Plaintiff that the Blancanieves was essentially derived from the Original Variety.

6. The Plaintiff sued the Defendant in the Tel Aviv District Court in February of 2003. The Plaintiff contended that the Blancanieves was essentially derived from the Original Variety and therefore the growing and propagation thereof in Israel constituted an infringement of the Plaintiff's rights in the Original Variety. The Plaintiff's contention was based first on genetic similarity analysis and on a close morphological similarity between the varieties.

7. The Defendant contended that the essentially derived variety protection is a very limited protection and should be granted only in very exceptional cases. It further contended that the Blancanieves was an original variety, independently bred by the Breeder and that the parents of the EDV were not the Original Variety, but rather certain other varieties. It further contended that the question whether the Blancanieves was an EDV should be decided by morphological criteria alone. The Defendant denied the existence of both the genetic and morphological similarity.

The evidence in the case

8. The Plaintiff supported its case by the following evidence:

Two genetic analyses were undertaken by the Dutch firm, Keygene, with a view to examining the DNA fingerprinting of the varieties by the AFLP method. The first showed a very strong genetic similarity between the Original Variety and the EDV. The second proved that the alleged parents of the EDV could not be its real parents.

The then Director of Keygene submitted an Expert Opinion to the Court, explaining the analyses undertaken, attaching DENOGRAMS. A further analysis of the DENOGRAMS was submitted in an Expert Opinion by a professor from the Weizmann Institute of Science.

The Plaintiff further submitted an Expert Opinion as to the morphological comparison between the two varieties made by an Israeli Professor of the Hebrew University of Jerusalem. This comparison showed a close morphological similarity between the varieties.

Finally, the Plaintiff submitted a Cytometric examination conducted by the "Plant Cytometry Services", showing that the EDV was tetraflorid, while the Original Variety was diflorid. Based on this evidence, the Plaintiff contended that the burden of proof was now shifted to the Defendant to prove that the Blancanieves was not an EDV.

9. The Defendant relied on a genetic analysis of the varieties conducted by the Dutch firm IdQ by the same AFLP method, under which there was no genetic similarity between the varieties and further submitted an affidavit by the original Breeder, in which he tried to explain the breeding process undertaken by him. In this affidavit, the Breeder said that he used in the breeding process Colchitsin, which material causes multiplication of the genetic material in the plant, which fact may explain the difference in the genetic material between the diflorid Original Variety and the tetraflorid EDV. In his cross-examination the Breeder admitted that at least one of the alleged parents of the EDV could not be and was not the real parent. Another Israeli professor gave an Expert Opinion to the Defendant, supporting the contention that the Blancanieves was not an EDV.

The issues in the trial

10. The Court had to decide the following issues:

(a) Whether the protection of an EDV under the Act should be construed as a very limited protection, so that an EDV should be a very exceptional case.

(b) Whether a genetic comparison is or is not relevant to the subject of derivation of varieties.

(c) If the answer to that question is positive, what kind of analysis is necessary in order to prove the existence of an EDV and whether those submitted to the Court are valid for the purpose.

Further, whether the evidence submitted by the parties proves or does not prove the legally necessary similarity in order to find that the Blancanieves was an EDV.

(d) If the answer to the question is negative, whether the morphological comparison between the varieties shown by the parties' evidence should lead the Court to a positive or negative conclusion in the case.

(e) A special legal issue: which of the parties bears the onus to prove that the Blancanieves is or is not an EDV.

The legal framework

11. As shown above, the definition of an essentially derived variety under the Act follows the definition in the International Convention. Needless to say, bar the very exceptional case where there is direct evidence of the fact that the breeder of the new variety bred it by using an original variety, it is very difficult to prove that a certain variety was essentially derived from another.

Taking the above fact into consideration, the Israeli legislature introduced into the Act a section which does not appear in the International Convention, nor to my knowledge in any other law concerning breeders' rights. This section (62A) provides that where the owner of an original variety shows to the Court either genetic conformity or morphological conformity between the Original Variety and the new variety, the burden of proof shifts to the Defendant and it is upon it to prove that the new variety is not an essentially derived variety. The purpose of this section is clear: it intends to facilitate the possibility of a breeder's right holder to enforce the protection granted to him by extending it to include an essentially derived variety.

12. Based on this Section, the Plaintiff contended that in view of the evidence submitted thereby, the Defendant should bear the onus to prove that the Blancanieves was not an EDV.

The Court's rulings

13. Following a long trial, during which all experts were cross-examined and the parties summed up their cases in writing, the Court rendered its decision, in which it found that the Blancanieves was an EDV of the Original Variety, issued a permanent injunction against the utilisation of the EDV and fixed a date for conducting the second phase of the trial concerning the damages to which the Plaintiff may be entitled.

14. Coming to this conclusion, the Court decided the issues enumerated above.

(a) The Court rejected the Defendant's contention that the protection granted under the EDV provision should be construed as limited to rare exceptional cases, where the difference between the varieties is in only one morphological quality.

(b) In interpreting Section 62A of the Act, the Court accepted the Plaintiff's contention as to the shifting of the burden of proof.

(c) The provisions of Section 62A clearly express the legislature's intention that genetic characteristics of the varieties are very relevant to deciding the issue of EDV.

(d) The Court found that the DNA fingerprinting or AFLP method is scientifically recognized and valid.

(e) The Plaintiff proved to the Court's satisfaction a genetic conformity between the varieties and the burden of proof should be shifted to the defendant.

(f) The defendant did not succeed in proving that Blancanieves is not an EDV. The alleged parents of the EDV could not be the real parents and the Court did not find sufficient and coherent evidence to show that the Blancanieves was derived independently of the Original Variety.

EXPERIENCE ON ESSENTIALLY DERIVED VARIETIES IN JAPAN

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1. Provisions of EDV in the “PVP and Seed Act”

Japan’s “PVP and Seed Act,” which complies with the UPOV Convention, provides definition of the Essentially Derived Variety (EDV). The Article 20, which specifies “The effects of the Breeder’s Right,” describes the definition of the EDV as being comprised of two factors.

The first factor describes the idea of the EDV as “varieties which are bred by changing of the expressions of the characteristics of the registered variety while retaining the expressions of its essential characteristics.”

The second factor defines methods by which EDVs are produced. Specifically, four methods are defined in the Ordinance of MAFF, Article 15: selection of mutant, backcrossing, transformation by genetic engineering, and cell fusion (asymmetrical fusion only).

2. Japan’s experience and a guidance book

Since it is very difficult to define EDV strictly by words, we have published a guidance book named “Guidance of PVP and Seed Act” in April 2009, in order to provide basic notions of the EDV.

The book explains that whether a variety is an EDV of another registered variety is primarily an issue between breeders concerned, and is eventually judged by the courts. There has been no lawsuit to the court so far in Japan. In the presentation, an example of a Japanese breeding company which sought advice from MAFF on the notion of EDV will be introduced.

The guidance book also provides some examples of plant varieties which may be considered as EDVs. Those include plant varieties which have characteristics of enhancement of disease resistance, difference in flower color, and change in growth habit compared to the original varieties.

We would like to learn about the knowledge and experiences of member countries in relation to EDV in order to improve our guidance on this issue to breeders.

SESSION III:
**POSSIBLE ROLE OF FUTURE UPOV GUIDANCE
ON ESSENTIALLY DERIVED VARIETIES**

THE ROLE OF “SOFT LAW”/GUIDANCE IN DIFFERENT JURISDICTIONS

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This paper details the potential of ‘soft law’ to promulgate instruments about the conception of ‘essentially derived varieties’ introduced by the *International Convention for the Protection of New Varieties of Plants* in 1991 (UPOV 1991). After addressing the forms of ‘soft law’ possible under the UPOV 1991 the paper provides a case study example of adopting the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation* under the United Nations *Convention on Biological Diversity* (CBD) as a ‘soft law’ means of addressing the uncertain and contentious access and benefit-sharing obligations. The paper concludes with some key learnings for adopting ‘soft law’ instruments.

1. Introduction

The *International Convention for the Protection of New Varieties of Plants* in 1991 (UPOV 1991) introduced the concept of ‘essentially derived varieties’ (EDVs) as an expansion of the scope of breeder’s rights¹. The UPOV 1991 text deems a plant variety as an EDV according to a threshold standard and then provides possible examples, albeit key terms, such as ‘predominantly derived’ and ‘essential characteristics’, remain uncertain². At the Diplomatic Conference on the adoption of the EDV provision the conference resolved:

The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requests 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 varieties³.

Over time the Council of UPOV has sought to clarify the meaning of EDVs issuing an explanatory note in 2009⁴. More recently UPOV’s Administrative and Legal Committee (CAJ) and Administrative and Legal Committee Advisory Group (CAJ-AG) have again been considering the scope of EDVs preparing a revised version of the explanatory note⁵. Despite ongoing discussions the participants have been unable to settle on common understandings about key elements of the expressed UPOV 1991-expressed EDV standard⁶. Further, as the UPOV 1991 obligations are implemented through domestic laws then it is the

¹ *International Convention for the Protection of New Varieties of Plants* (of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991), Article 14(5).

² See International Convention for the Protection of New Varieties of Plants, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention* (2009) UPOV/EXN/EDV/1, [3].

³ 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) p 349. See also Administrative and Legal Committee Advisory Group, Report, Seventh Session (2012) CAJ-AG/12/7/3, [10]-[21].

⁴ See Council, Report, Forty-Third Ordinary Session (2009) C/43/17, [23(f)]; UPOV/EXN/EDV/1, above n 2. Noting that after the Diplomatic Conference the Administrative and Legal Committee ceased considering the matter in 1993 and only re-engaged in 2002: see Administrative and Legal Committee, Report, Forty-Sixth Session (2003) CAJ/46/8 Rev, [50]; Administrative and Legal Committee, Report, Thirty-Second Session (1993) CAJ/32/10, [29].

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

⁶ See CAJ-AG/12/7/3, above n 3; Administrative and Legal Committee Advisory Group, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision)*, Sixth Session (2011) CAJ-AG/11/6/3; Administrative and Legal

courts of Contracting Parties that will ultimately determine the meanings. So far, however, the courts have had difficulty applying the UPOV 1991 standards⁷ and the 'available court decisions [are] contradictory and not helpful'⁸. Perhaps 'if there was clear guidance the courts would have less need for interpretation'⁹. This paper considers the kinds of 'soft law' instruments that might be made under the auspices of the UPOV 1991 that could be useful to plant breeders, courts and others as authoritative sources for interpreting and applying the UPOV 1991 EDV standards.

The paper is structured as follows: Part 2 outlines the obligations imposed on Contracting Parties to UPOV 1991 highlighting that UPOV 1991 is implemented through domestic laws for granting and protecting breeders' rights; Part 3 sets out a conception of 'soft law' in distinction to 'hard law'; Part 4 outlines the UPOV 1991 obligations to identify the sources and scope of powers available to promulgate 'soft law' instruments; Part 5 sets out a case study of the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation* (Bonn Guidelines) under the United Nations *Convention on Biological Diversity* (CBD) to illustrate the elegance of 'soft law' in dealing with a deeply contested and intractable issue; and Part 6 sets out some conclusions including the key learnings from the Bonn Guidelines experience that might be adopted in promulgating 'soft law' instruments. These conclusions are that 'soft law' instruments are eminently possible under UPOV 1991 and that such instruments could be useful to plant breeders, courts and others as authoritative sources for interpreting and applying the UPOV 1991 EDV standards.

2. UPOV 1991 obligations

The basic obligation of a UPOV 1991 Contracting Party is that 'Each Contracting Party shall grant and protect breeders' rights'¹⁰. The agreement then imposes requirements on Members, providing:

Each Contracting Party shall adopt all measures necessary for the implementation of this Convention; in particular, it shall:

- (i) Provide for appropriate legal remedies for the effective enforcement of breeders' rights;
- (ii) Maintain an authority entrusted with the task of granting breeders' rights or entrust the said task to an authority maintained by another Contracting Party;
- (iii) Ensure that the public is informed through the regular publication of information concerning:
 - Applications for and grants of breeders' rights; and
 - Proposed and approved denominations.¹¹

These measure effectively require each Contracting Party to establish laws within its jurisdiction to administer the granting of plant breeder's rights consistent with UPOV requirement for a plant breeder's right where the variety is 'new', 'distinct', 'uniform' and 'stable', and a means of enforcing a plant breeder's right once granted. This has been achieved through legislation of a plant breeder's right¹², governmental agencies to assess and grant a plant breeder's right and a court system to enforce infringements of plant breeder's rights. For example, the Australian Parliament has adopted the *Plant Breeder's Rights Act 1994* (Cth) that is administered by the governmental agency IP Australia¹³, and infringement of the plant breeder's rights is resolved through the courts¹⁴. Importantly, as a consequence of UPOV 1991's form, implementing the obligations depends on Contracting Parties interpreting UPOV 1991 and reducing the requirements to legislation in the context of their domestic legal systems. It is then these domestic standards that are administered by the governmental agency and subject to scrutiny by the courts of the Contracting Party.

Committee Advisory Group, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision)*, Fifth Session (2010) CAJ- AG/10/5/3.

⁷ See Bart van Wezenbeek, 'What is the Essence of "Essentially Derived"?' (2010) 196 *Managing Intellectual Property* 150; Jay Sanderson, 'Essential Derivation, Law and the Limits of Science' in Matthew Rimmer (ed.), *Patent Law and Biological Inventions* (Federation Press, 2006) pp 46-48.

⁸ CAJ-AG/12/7/7, above n 5, [27].

⁹ CAJ-AG/12/7/7, above n 5, [30].

¹⁰ International Convention for the Protection of New Varieties of Plants, Article 2.

¹¹ International Convention for the Protection of New Varieties of Plants, Article 30(1).

¹² For a listing of Contracting Party legislation see <http://www.upov.int/upovlex/en> (UPOV Lex).

¹³ See Department of Industry, Innovation, Science, Research and Tertiary Education, *Annual Report 2011-2012*.

(Department of Industry, Innovation, Science, Research and Tertiary Education, 2012) pp 226-229.

¹⁴ *Plant Breeder's Rights Act 1994* (Cth) ss 3 ('Court') and 56.

According to UPOV 1991 the Contracting Parties are 'members of the Union'¹⁵. The organs of the Union are the 'Council' and the 'Office of the Union'¹⁶. And the 'tasks of the Council' include the very broad power to 'in general, take all necessary decisions to ensure the efficient functioning of the Union'¹⁷. Decisions addressing the 'tasks of the Council' require a 'simple majority of the votes cast' by members¹⁸. To change UPOV 1991 there would need to be a formal conference of Contracting Parties¹⁹ and a majority of 'three-fourths of the votes cast'²⁰. An alternative and perhaps easier means of seeking change would be to adopt various 'soft laws' to establish norms. These are considered next.

3. What is 'soft law' (and 'hard law')?

There remains some confusion and disagreement about exactly what is 'soft law', how it might operate and how it might contrast with 'hard law'²¹. Perhaps the most useful understanding for 'soft law' is in distinction to 'hard law'. For present purposes 'hard law' might be conceived as formally legally binding laws (being precise laws that impose obligations and that are interpreted and implemented by a third party), and become 'soft law' if the laws 'are weakened along one of the dimensions of obligation, precision, and delegation'²²:

Obligation means that states or other actors are bound by a rule or commitment or by a set of rules or commitments. Specifically, it means that they are legally bound by a rule or commitment in the sense that their behavior thereunder is subject to scrutiny under the general rules, procedures, and discourse of international law, and often of domestic law as well. *Precision* means that rules unambiguously define the conduct they require, authorize, or proscribe. *Delegation* means that third parties have been granted authority to implement, interpret, and apply the rules; to resolve disputes; and (possibly) to make further rules²³.

According to this understanding, 'soft law' is something less than formally legally binding 'hard law' along a continuum of relatively less binding²⁴. The consequence of 'soft law' is therefore to characterize the degree to which an instrument is precise, the degree of the binding legal obligation, and the degree of delegation of interpretation and implementation. With these flexibilities 'soft law' has advantages:

... soft law is sometimes designed as a way station to harder legalization, but often it is preferable on its own terms. Soft law offers many of the advantages of hard law, avoids some of the costs of hard law, and has certain independent advantages of its own. Importantly, because one or more of the elements of legalization can be relaxed, softer legalization is often easier to achieve than hard legalization. This is especially true when the actors are states that are jealous of their autonomy and when the issues at hand challenge state sovereignty. Soft legalization also provides certain benefits not available under hard legalization. It offers more effective ways to deal with uncertainty, especially when it initiates processes that allow actors to learn about the impact of agreements over time. In addition, soft law facilitates compromise, and thus mutually beneficial cooperation, between actors with different interests and values, different time horizons and discount rates, and different degrees of power (footnotes omitted)²⁵.

¹⁵ International Convention for the Protection of New Varieties of Plants, Article 23.

¹⁶ International Convention for the Protection of New Varieties of Plants, Article 25.

¹⁷ International Convention for the Protection of New Varieties of Plants, Article 26(5)(x).

¹⁸ International Convention for the Protection of New Varieties of Plants, Article 26(7).

¹⁹ International Convention for the Protection of New Varieties of Plants, Article 38(1).

²⁰ International Convention for the Protection of New Varieties of Plants, Articles 26(7) and 38(2).

²¹ There is a huge literature about 'soft law' from various positivist, normative, political economy, and so on, perspectives, and so on. Useful overviews include Jaye Ellis, 'Shades of Grey: Soft Law and the Validity of Public International Law' (2012) 25 *Leiden Journal of International Law* 313; Andrew Guzman and Timothy Meyer, 'International Soft Law' (2010) 2 *Journal of Legal Analysis* 1; Hartmut Hillgenberg, 'A Fresh Look at Soft Law' [1999] *European Journal of International Law* 499; Alan Boyle, 'Some Reflections on the Relationship of Treaties and Soft Law' (1999) 48 *International and Comparative Law Quarterly* 901; and so on.

²² Kenneth Abbott and Duncan Snidal, 'Hard and Soft Law in International Governance' (2000) 54 *International Organizations* 421 at 421-422. See also Martha Finnemore and Stephen Toope, 'Alternatives to "Legalization": Richer Views of Law and Politics' (2001) 55 *International Organizations* 743 (critiquing Abbott and Snidal). This is not the only way to conceive 'soft law' albeit this is the preferred approach of this author.

²³ Kenneth Abbott, Robert Keohane, Andrew Moravcsik, Anne-Marie Slaughter and Duncan Snidal, 'The Concept of Legalization' (2000) 54 *International Organizations* 401 at 401.

²⁴ See Gregory Shaffer and Mark Pollack, 'Hard vs Soft Law: Alternatives, Compliments, and Antagonists in International Governance' (2010) 94 *Minnesota Law Review* 706 at 712-717 and the references therein.

²⁵ Abbott and Snidal, above n 22 at 423.

UPOV 1991 might be considered to be 'hard law' in the sense that it is an agreement that imposes an obligation on Contracting Parties to 'grant and protect breeders' rights'²⁶, with some precision defines the threshold criteria of breeders' rights²⁷, and then delegates authority for implementing and enforcing the law to governmental agencies and the legal system of the Contracting Party²⁸. In this scheme, and according to the previous definitions, 'soft law' is all the laws (actions and instruments) that weaken along one of the dimensions of obligation, precision and delegation. Providing some kind of definition about EDVs that is not itself a part of the text of UPOV 1991 is a weakening of the 'hard law' of UPOV 1991. The next issue to consider is the form of 'soft law'.

4. Forms of 'soft law'

UPOV 1991 provides for both a 'Council' and an 'Office of the Union'²⁹. The Council has a range of tasks including the broadly framed power to 'in general, take all necessary decisions to ensure the efficient functioning of the Union'³⁰. The Office of the Union is then to 'carry out all the duties and tasks entrusted to it by the Council'³¹. The Council assisted by the Office of the Union has already promulgated some 'soft law' in the form of 'Explanatory Notes'³², 'Guidance'³³, 'Guidelines'³⁴, 'Rules'³⁵, 'Mechanisms'³⁶, 'Lists'³⁷, 'Statistics'³⁸, 'Reports'³⁹, 'Press Releases'⁴⁰, 'Experience and Cooperation' reports⁴¹, "Assistance" webpage⁴², and so on. Each of these instruments provides some measure of interpretation or direction (even if only obliquely) about the ways that the UPOV 1991's obligations might be addressed by Contracting Parties. A notable illustration of the place of this 'soft law' is the clear statement in each of the 'Explanatory Notes'⁴³:

The purpose of these Explanatory Notes is to provide guidance on ... [the subject matter of the Explanatory Note] under the 1991 Act of the International Convention for the Protection of New Varieties of Plants.

The only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself, and these Explanatory Notes must not be interpreted in a way that is inconsistent with the relevant Act for the member of the Union concerned⁴⁴.

²⁶ International Convention for the Protection of New Varieties of Plants, Article 2.

²⁷ International Convention for the Protection of New Varieties of Plants, Articles 5-19.

²⁸ International Convention for the Protection of New Varieties of Plants, Article 30.

²⁹ International Convention for the Protection of New Varieties of Plants, Article 30.

³⁰ International Convention for the Protection of New Varieties of Plants, Article 26(5)(x).

³¹ International Convention for the Protection of New Varieties of Plants, Article 27(1).

³² See Council, Report, Forty-Sixth Ordinary Session (2013) C/46/19, [21]; Council, Report, Forty-Fourth Ordinary Session (2010) C/44/17, [21] and [22]; C/43/17, above n 4, [20], [23] and [27]; and so on.

³³ See C/46/19, above n 32, [19]; Council, Report, Forty-Fifth Ordinary Session (2012) C/45/18, [19] and [23]; C/43/17, above n 4, [15], [17], [21], [22] and [25]; and so on.

³⁴ See C/45/18, above n 33, [16]; C/44/17, above n 32, [17] and [34]; and so on.

³⁵ See C/46/19, above n 32, [25] and [28]; C/44/17, above n 32, [24]; and so on.

³⁶ See C/46/19, above n 32, [30]; and so on.

³⁷ See C/46/19, above n 32, [44]; C/44/17, above n 32, [20]; C/43/17, above n 4, [18]; and so on.

³⁸ See C/46/19, above n 32, [44]; and so on.

³⁹ See C/46/19, above n 32; C/45/18, above n 33; C/43/17, above n 4; and so on.

⁴⁰ See C/46/19, above n 32, [50]; C/45/18, above n 33, [41]; C/44/17, above n 32, [49]; and so on.

⁴¹ See C/44/17, above n 32, [16]; and so on.

⁴² See C/45/18, above n 33, [8].

⁴³ See C/44/17, above n 32, [21] and [22]; C/43/17, above n 4, [23].

⁴⁴ International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Conditions and Limitations Concerning the Breeder's Authorization in Respect of Propagating Material under the UPOV Convention (2010) UPOV/EXN/CAL/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on the Definition of Variety under the 1991 Act of the UPOV Convention (2010) UPOV/EXN/VAR/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Cancellation of the Breeder's Right under the UPOV Convention (2009) UPOV/EXN/CAN/1, [1]; UPOV/EXN/EDV/1, above n 2, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on the Enforcement of Breeders' Rights under the UPOV Convention (2009) UPOV/EXN/ENF/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Genera and Species to be Protected under the 1991 Act of the UPOV Convention (2009) UPOV/EXN/GEN/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on National Treatment under the 1991 Act of the UPOV Convention (2009) UPOV/EXN/NAT/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Novelty under the UPOV Convention (2009) UPOV/EXN/NOV/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Nullity of the Breeder's Right under the UPOV Convention (2009)

In short, the Council and the Office of the Union have sufficient power to promulgate 'soft law' instruments and they have a record of such actions. The next question to address is how 'soft law' might address EDVs? Perhaps the best approach here is to detail as a case study about the adoption of the Bonn Guidelines and their dealings with intellectual property under the CBD. This is addressed next.

5. Case study – Bonn Guidelines

The CBD was concluded at the United Nations Conference on Environment and Development in 1992⁴⁵. One of the CBD's objectives was the fair and equitable sharing of the benefits from using genetic resources⁴⁶, 'including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding'⁴⁷. This benefit-sharing objective marked a fundamental shift in binding international measures to conserve biodiversity⁴⁸. First by recognising the sovereign right of countries over their genetic resources⁴⁹. Second, by linking access to those resources with the outcomes of scientific research and commercial uses, and access to technology on more favourable and non-commercial terms, including the products and technologies of the private sector derived from those genetic resources⁵⁰. And third, by introducing intellectual property⁵¹ into the economic and policy debates about conserving genetic resources that might benefit future technological, economic and social development⁵².

The problem was that the CBD itself did not provide much guidance about how access and benefit sharing might be operationalized by Contracting Parties. While there was almost universal consensus that the predominantly poor countries with the majority of the Earth's useful biological diversity (the South) should benefit from the exploitation of that diversity by the predominantly rich and technologically advanced countries (the North), the content of the benefits to be shared and the issue of access to and transfer of technology protected by intellectual property to exploit those genetic resources remained contentious⁵³. The outcome in the final CBD text was just agreeable diplomatic language effecting a compromise and a postponement of the issues to the implementation stages, such as 'that patents and other intellectual property rights may have an influence on the implementation of this [CBD]' with an obligation to 'cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'⁵⁴. And it was this process navigating intellectual property during the implementation stages that illustrates an approach to

UPOV/EXN/NUL/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on the Right of Priority under the UPOV Convention (2009) UPOV/EXN/PRI/1, [1]; International Convention for the Protection of New Varieties of Plants, Explanatory Notes on Provisional Protection under the UPOV Convention (2009) UPOV/EXN/PRP/1, [1].

⁴⁵ For an overview of the Conference and its various outcomes see Michael Grubb, Matthias Koch, Kay Thomson, Abby Munson and Francis Sullivan, *Earth Summit Agreements: A Guide and Assessment* (Earthscan Publications Ltd, 1993).

⁴⁶ The term 'genetic resource' is broadly defined to mean 'genetic material of actual or potential value' and 'genetic materials' means 'any material of plant, animal, microbial or other origin containing functional units of heredity': *Convention on Biological Diversity, Art 2*. In practice, however, the CBD definition has difficulties with respect to leaving out biochemicals, leaving out *ex-situ* holdings acquired before 29 December 1993, including human genetic materials and applying only to some marine resources: see Conference of the Parties to the Convention on Biological Diversity, *Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information* (1995) UNEP/CBD/COP/2/13, pp 15-18.

⁴⁷ Convention on Biological Diversity, Art 1.

⁴⁸ An earlier non-binding arrangement adopted in the *International Undertaking on Plant Genetic Resources for Food and Agriculture* (Food and Agriculture Organisation of the United Nations, *Report of the Conference of FAO, Twenty-second Session* (1983) C 1983, [285] (Resolution 8/83)) applied the 'common heritage' principles to certain agricultural plant genetic resources that was later amended to recognise farmers rights and the legitimacy of intellectual property over elite plant varieties (Food and Agriculture Organisation of the United Nations, *Report of the Conference of FAO, Twenty-fifth Session* (1989) C 1989, [108] (Resolutions 4/89 and 5/89)), and later amended to recognise 'that nations have sovereign rights over their plant genetic resources' (Food and Agriculture Organisation of the United Nations, *Report of the Conference of FAO, Twenty-sixth Session* (1991) C 1991, [104] (Resolution 3/91)).

⁴⁹ Convention on Biological Diversity, Art 15(1).

⁵⁰ Convention on Biological Diversity, Arts 15, 16 and 19.

⁵¹ For the purposes of this article 'intellectual property' is a term used generally to mean copyright, patent, plant breeder's rights, know how, trade secrets/confidential information and geographic indicators; for an overview of intellectual property applied to genetic resources see Graham Duffield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan, 2004) pp 25-41.

⁵² *Convention on Biological Diversity*, Preamble and Arts 3, 10, 11, 15, 16, 19 and 22.

⁵³ For a summary of those contemporary competing South and North views see Alexander Gillespie, 'Common Property, Private Property and Equity: Clash of Values and the Quest to Preserve Biodiversity' (1995) 12 *Environmental and Planning Law Journal* 388 at 389-392 and the references therein.

⁵⁴ Convention on Biological Diversity, Art 16(5).

'soft law' that was able to engage with the particular technical issues in detail, effect acceptable compromises and deliver an agreement that was practical for the parties involved according to their particular needs and circumstances.

The CBD as 'hard law' provides for an Amendment, a Protocol or an Annex ('restricted to procedural, scientific, technical and administrative matters')⁵⁵ that binds all the Contracting Parties following a two-thirds majority vote of the Contracting Parties present at a meeting (after attempting and failing consensus) and then ratification, acceptance or approval by at least two thirds of the Contracting Parties to the CBD⁵⁶. An Amendment, a Protocol or an Annex about access and benefit sharing that mandated how intellectual property was to be addressed was not a viable option at the time. A 'soft law' alternative for resolving the contentions was the Bonn Guidelines.

Following the signing of the CBD, the first Conference of the Parties (COP) adopted a medium-term 'Access to Genetic Resources' programme of work that included two subjects, the compiling of information and documents about access to genetic resources and the sharing of its benefits (Article 15), and about access to and transfer of technology in exchange for that access (Article 16)⁵⁷. Significantly, the consideration of intellectual property was placed under the 'Access to Genetic Resources' programme rather than the 'Issues Relating to Technology' programme, thereby linking intellectual property considerations to the transfer of technologies that made use of the accessed genetic resources⁵⁸. The effect of this decision was to focus the role of intellectual property in the arrangements for access to genetic resources (thus linking Articles 15 and 16(5)), rather than the broader debate about restricting intellectual property in making technology available to developing countries as a possible means of alleviating poverty (as set out in Articles 16(1) and (2))⁵⁹. In effect this decision framed the consideration of intellectual property as one of the many matters to be addressed in negotiating access rather than as a barrier to technology transfer.

At the second COP the 'Access to Genetic Resources' programme was considered⁶⁰, with the COP deciding to compile the views on possible options for developing national legislative, administrative or policy measures to implement Article 15⁶¹. The second COP also sought to analyse the impact of intellectual property on the conservation and sustainable use of biological diversity and the equitable sharing of benefits from their use 'in order to gain a better understanding of the implications of Article 16(5)', including 'inviting Governments and other relevant stakeholders to submit case studies that address the role of intellectual property in the technology transfer process, in particular the role of intellectual property rights in the transfer of biotechnology'⁶². The third COP continued this work deciding to seek further information about existing mechanisms both addressing access to genetic resources and sharing the benefits⁶³. The third COP also sought to extend co-operation with other institutions dealing with intellectual property, notably the World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO)⁶⁴.

⁵⁵ Convention on Biological Diversity, Art 30(1).

⁵⁶ Convention on Biological Diversity, Arts 29 and 30(2)(a).

⁵⁷ Conference of the Parties to the Convention on Biological Diversity, *Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity* (1995) UNEP/CBD/COP/1/17, p 62.

⁵⁸ See UNEP/CBD/COP/1/17, above n 57, p 62. See also Conference of the Parties to the Convention on Biological Diversity, *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity* (1995) UNEP/CBD/COP/2/19, p 28.

⁵⁹ See Conference of the Parties to the Convention on Biological Diversity, *Intellectual Property Rights and Transfer of Technologies which Make Use of Genetic Resources* (1995) UNEP/CBD/COP/2/17, p 2. See further Conference of the Parties to the Convention on Biological Diversity, *Report of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity* (1997) UNEP/CBD/COP/3/38, pp 97-98; Conference of the Parties to the Convention on Biological Diversity, *Promoting and Facilitating Access to, and Transfer and Development of Technology* (1996) UNEP/CBD/COP/3/21.

⁶⁰ See UNEP/CBD/COP/2/19, above n 58, pp 26-28.

⁶¹ UNEP/CBD/COP/2/19, above n 58, p 64.

⁶² UNEP/CBD/COP/2/19, above n 58, p 65.

⁶³ UNEP/CBD/COP/3/38, above n 59, pp 95-97.

⁶⁴ UNEP/CBD/COP/3/38, above n 59, pp 98-101. See also Conference of the Parties to the Convention on Biological Diversity, *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use (A Preliminary Study)* (1996) UNEP/CBD/COP/3/22.

After considering the various materials before the meeting⁶⁵, the fourth COP decided to convene a Panel of Experts on Access to and Benefit-Sharing (the Panel):

to draw upon all relevant sources, including legislative, policy and administrative measures, best practices and case studies on access to genetic resources and benefit-sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements⁶⁶.

The focus was to be on legislative, administrative and policy measures for prior informed consent, references to the country of origin in relevant publications and patent applications, mutually agreed terms including on benefit-sharing and intellectual property and technology transfer, and incentive measures to encourage the conclusion of 'contractual partnerships'⁶⁷.

The subsequent report of the Panel reached a broad consensus about the 'principles that should govern access and benefit-sharing arrangements' and 'a common understanding of the key concepts such as prior informed consent, mutually agreed terms, and fair and equitable benefit-sharing', together with 'important information and capacity-building needs associated with access and benefit-sharing arrangements'⁶⁸. The key recommendation of the Panel was the need to develop guidelines about prior informed consent and mutually agreed terms⁶⁹.

At this early stage the Panel considered intellectual property might provide an incentive to comply with the CBD's prior informed consent requirements by a requirement to provide evidence of satisfactory consent on applying for intellectual property (presumably this was addressed to patents and plant breeder's rights that require formal registration)⁷⁰.

Significantly, the Panel considered the COP needed to explore intellectual property issues 'in greater depth' recognising that intellectual property was a component of other domestic and international legal instruments⁷¹. However, in dealing with intellectual property, the Panel concluded:

The Panel acknowledged that intellectual property rights may have an influence on the implementation of access and benefit-sharing arrangements and may have a role in providing incentives for users to seek prior informed consent. The Panel was not able to come to any conclusions about these issues, and therefore suggests that the [COP] consider these matters further⁷².

Usefully the Panel identified a number of issues that required further study, including that intellectual property application procedures require that the applicant submit evidence of prior informed consent, the place of intellectual property in traditional knowledge related to genetic resources, the guiding parameters for contractual arrangements⁷³, application of the formal intellectual property threshold standards and the

⁶⁵ See Conference of the Parties to the Convention on Biological Diversity, *Measures to Promote and Advance the Distribution of Benefits from Biotechnology in Accordance with Article 19* (1998) UNEP/CBD/COP/4/21; Conference of the Parties to the Convention on Biological Diversity, *Addressing the Fair and Equitable Sharing of the Benefits Arising out of Genetic Resources: Options for Assistance to Developing Country Parties to the Convention on Biological Diversity* (1998) UNEP/CBD/COP/4/22; Conference of the Parties to the Convention on Biological Diversity, *Review of National, Regional and Sectoral Measures and Guidelines for the Implementation of Article 15* (1998) UNEP/CBD/COP/4/23; Regional Meetings on Biological Diversity, *Report of the Latin American and the Caribbean Regional Preparatory Meeting* (1998) UNEP/CBD/RC LAC/3/2.

⁶⁶ Conference of the Parties to the Convention on Biological Diversity, *Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (1998) UNEP/CBD/COP/4/27, p 109.

⁶⁷ UNEP/CBD/COP/4/27, above n 66, p 110.

⁶⁸ Conference of the Parties to the Convention on Biological Diversity, *Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (1998) UNEP/CBD/COP/5/23, pp 24-25.

⁶⁹ Conference of the Parties to the Convention on Biological Diversity, *Report of the Panel of Experts on Access and Benefit-sharing* (1999) UNEP/CBD/COP/5/8. See also UNEP/CBD/COP/5/23, above n 68, pp 24 and 54-55.

⁷⁰ See UNEP/CBD/COP/5/8, above n 69, p 23.

⁷¹ See UNEP/CBD/COP/5/8, above n 69, p 24.

⁷² UNEP/CBD/COP/5/8, above n 69, p 27.

⁷³ Meaning '(a) Regulating the use of resources in order to take into account ethical concerns; (b) Making provision to ensure the continued customary use of genetic resources and related knowledge; (c) Provision for the exploitation and use of intellectual property rights include joint research, obligation to work any right on inventions obtained or provide licenses; (d) Taking into account the possibility of joint ownership of intellectual property rights': UNEP/CBD/COP/5/8, above n 69, p 25.

resulting scope, and an assessment of the effect of intellectual property as an incentive to conservation and benefit-sharing⁷⁴.

In parallel with the Panel's work, the fourth COP convened an Inter-Sessional Meeting on the Operations of the Convention (ISOC) as 'a preparatory discussion' on access to genetic resources⁷⁵. The ISOC began assessing the relationship between intellectual property and the relevant provisions of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* and the CBD⁷⁶, *ex situ* collections made before 29 December 1993⁷⁷, and a number of other matters that the Panel should consider⁷⁸ without formally making any firm conclusions about the place of intellectual property in access and benefit-sharing arrangements.

The fifth COP took note of the Panel's report⁷⁹ and the ISOC report⁸⁰, and then decided, in dealing with access to genetic resources, to establish an Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing with the mandate to develop guidelines and other approaches to access and benefit sharing⁸¹. The outcome of this decision was the Ad Hoc Open-Ended Working Group's report that recommended the adoption of the *Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation*⁸², although key terms remained to be defined, including 'access to genetic resources', 'benefit-sharing', 'commercialisation', 'derivatives', 'provider', 'user', 'stakeholder', 'ex situ collection' and 'voluntary nature'⁸³. The key objective of the guidelines was 'to assist Parties in developing an overall access and benefit-sharing strategy and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits'⁸⁴. In addressing the role of intellectual property in implementing access and benefit-sharing arrangements the Ad Hoc Open-Ended Working Group recommended that the COP 'invite' countries to disclose the country of origin of genetic resources in applications for intellectual property 'as a possible contribution to tracking compliance' with the obligations under the CBD of prior informed consent and the mutually agreed terms to access genetic resources⁸⁵. Further information gathering about intellectual property and access and benefit sharing was also recommended and a role envisioned for WIPO in developing model intellectual property clauses for negotiation of mutually agreed terms in contractual agreements⁸⁶.

As 'merely the first step on a long and complex process to secure access and benefit-sharing'⁸⁷ under the CBD, the sixth COP adopted the Bonn Guidelines⁸⁸ as voluntary guidelines that apply to *all* genetic resources covered by the CBD (except human genetic resources)⁸⁹, in a manner that is 'coherent and mutually supportive of the work of relevant international agreements and institutions'⁹⁰ and 'without prejudice' to the *International Treaty on Plant Genetic Resources for Food and Agriculture*⁹¹. The sixth COP 'invited' countries 'to use the Guidelines when developing and drafting

⁷⁴ UNEP/CBD/COP/5/8, above n 69, pp 23-26.

⁷⁵ UNEP/CBD/COP/4/27, above n 66, p 132.

⁷⁶ Conference of the Parties to the Convention on Biological Diversity, *Report of the Inter-Sessional Meeting on the Operations of the Convention* (1999) UNEP/CBD/COP/5/4, pp 30-31.

⁷⁷ UNEP/CBD/COP/5/4, above n 76, pp 31-32.

⁷⁸ UNEP/CBD/COP/5/4, above n 76, pp 28-30.

⁷⁹ UNEP/CBD/COP/5/23, above n 68, p 25. See also Conference of the Parties to the Convention on Biological Diversity, *Access to Genetic Resources* (2000) UNEP/CBD/COP/5/21.

⁸⁰ UNEP/CBD/COP/5/23, above n 68, p 21.

⁸¹ UNEP/CBD/COP/5/23, above n 68, pp 197-198.

⁸² Conference of the Parties to the Convention on Biological Diversity, *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing* (2001) UNEP/CBD/COP/6/6, p 14.

⁸³ UNEP/CBD/COP/6/6, above n 82, pp 14 and 15.

⁸⁴ UNEP/CBD/COP/6/6, above n 82, p 16.

⁸⁵ UNEP/CBD/COP/6/6, above n 82, p 36.

⁸⁶ UNEP/CBD/COP/6/6, above n 82, pp 36-38.

⁸⁷ Conference of the Parties to the Convention on Biological Diversity, *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (2002) UNEP/CBD/COP/6/20, p 19.

⁸⁸ UNEP/CBD/COP/6/20, above n 87, pp 60-62 and 253-269 (Bonn Guidelines).

⁸⁹ UNEP/CBD/COP/6/20, above n 87, pp 60-62 and 253-269 (Bonn Guidelines), cl 9.

⁹⁰ UNEP/CBD/COP/6/20, above n 87, pp 60-62 and 253-269 (Bonn Guidelines), cl 10.

⁹¹ UNEP/CBD/COP/6/20, above n 87, pp 60-62 and 253-269 (Bonn Guidelines), cl 10.

legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing⁹².

The form of the Bonn Guidelines was primarily as a practical guide:

to assist Parties in developing an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits⁹³.

The outcome of the Bonn Guidelines has been to operationalize the CBD's access and benefit-sharing provisions turning opaque diplomatic language in the text of the CBD into workable and practical principles and processes, albeit not part of the binding text of the CBD:

The Guidelines have two main aims:

1. To guide countries as providers in setting up their own national legislative, administrative or policy measures for access and benefit-sharing, such as recommending the elements that should make up a prior informed consent (PIC) procedure.
2. To assist providers and users in the negotiation of mutually agreed terms (MAT), by providing examples of what elements should be included in these agreements⁹⁴.

With broad participation and involvement among stakeholders there was also broad support for the Bonn Guidelines, and a formal basis for the subsequent elaboration and negotiation of a binding international regime on access to genetic resources and benefit-sharing in the form of a Protocol – the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (Nagoya Protocol)⁹⁵.

6. Conclusions

UPOV 1991 provides the Council with very broad powers including 'in general, take all necessary decisions to ensure the efficient functioning of the Union'⁹⁶. Under this power the Council has promulgated a range of instruments about the meanings and processes under UPOV 1991 including instruments in the form of 'Explanatory Notes', 'Guidance', 'Guidelines', 'Rules', 'Mechanisms', 'Lists', 'Statistics', 'Reports', 'Press Releases', 'Experience and Cooperation' reports, "Assistance" webpage, and so on. These are classical 'soft law' instruments because they encourage Contracting Parties to implement UPOV 1991 in particular ways while not altering the binding obligations set out in the formal text of UPOV 1991. This suggests that an instrument promulgated by the Council to elaborate the EDV provisions in UPOV 1991 is a 'soft law' approach to finding useful directions to Contracting Parties implementing UPOV 1991.

The case study of the CBD's Bonn Guidelines illustrates the elegance of 'soft law' in dealing with a deeply contested and intractable issue of intellectual property in access and benefit-sharing arrangements. While the Bonn Guidelines do not commit Contracting Parties to particular intellectual property standards they have provided guidance about how intellectual property might be taken into account in implementing the CBD's objective. Most importantly, however, the Bonn Guidelines were a major step in canvassing the potential for agreements about access and benefit sharing and formed the basis for future negotiation of the Nagoya Protocol. The key learnings in developing the Bonn Guidelines were:

⁹² UNEP/CBD/COP/6/20, above n 87, p 253.

⁹³ UNEP/CBD/COP/6/20, above n 87, pp 60-62 and 253-269 (Bonn Guidelines), cl 12.

⁹⁴ Secretariat of the Convention on Biological Diversity, *The Bonn Guidelines*, Factsheet (Secretariat of the Convention on Biological Diversity, 2011) p 3 available at <<http://www.cbd.int/abs/infokit/revised/print/factsheet-bonn-en.pdf>> (accessed 12 August 2013).

⁹⁵ Conference of the Parties to the Convention on Biological Diversity, *Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (2010) UNEP/CBD/COP/10/27, [103] and pp 83-107 (Nagoya Protocol).

⁹⁶ International Convention for the Protection of New Varieties of Plants, Article 26(5)(x).

1. Frame the issue from the perspective as one of the many issues that need to be resolved rather than as a barrier issue that requires participants to definitively determine their positions on any particular issue.
2. Harness the existing bureaucratic machinery that has existing reporting deadlines to drive and regularly benchmark progress.
3. Actively collect materials from all stakeholders likely to be affected and interested in the problems and solutions.
4. Establish different groupings (working parties, expert panels, and the like) to address particular contentious issues and actively seek out experts to provide information, directions and solutions.
5. Prepare the formal outcomes and recommendations in a way that does not finally decide issues where there remain differences, such as key terms, key processes and key conclusions.
6. Make the final outputs broadly informative, flexible and as part of an evolving process rather than an end of discussions and developments.

As the analysis in this paper shows, 'soft law' is eminently possible under UPOV 1991 and the Council has sufficient powers and the machinery to promulgate appropriate 'soft law' instruments that could be useful to plant breeders, courts and others as authoritative sources for interpreting and applying the UPOV 1991 EDV standards.

Attachment 1: An extract from the Bonn Guidelines demonstrating the introductory general provisions and the provisions detailing dealings with intellectual property. Notably the guidelines are presented as assistance emphasizing their 'Voluntary nature', 'Ease of use', 'Practicality', 'Acceptability', 'Complementarity', 'Evolutionary approach', 'Flexibility', and 'Transparency'.

BONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING OUT OF THEIR UTILIZATION

I. GENERAL PROVISIONS A.

Key features

1. These Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.
2. Nothing in these Guidelines shall be construed as changing the rights and obligations of Parties under the *Convention on Biological Diversity*.
3. Nothing in these Guidelines is intended to substitute for relevant national legislation.
4. Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources.
5. Nothing in these Guidelines, including the use of terms such as 'provider', 'user', and 'stakeholder', should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the Convention.
6. Nothing in these Guidelines should be interpreted as affecting the rights and obligations relating to genetic resources arising out of the mutually agreed terms under which the resources were obtained from the country of origin.
7. The present Guidelines are voluntary and were prepared with a view to ensuring their:
 - (a) *Voluntary nature*: they are intended to guide both users and providers of genetic resources on a voluntary basis;
 - (b) *Ease of use*: to maximize their utility and to accommodate a range of applications, the Guidelines are simple;
 - (c) *Practicality*: the elements contained in the guidelines are practical and are aimed at reducing transaction costs;
 - (d) *Acceptability*: the Guidelines are intended to gain the support of users and providers;
 - (e) *Complementarity*: the Guidelines and other international instruments are mutually supportive;

- (f) *Evolutionary approach*: the Guidelines are intended to be reviewed and accordingly revised and improved as experience is gained in access and benefit-sharing;
- (g) *Flexibility*: to be useful across a range of sectors, users and national circumstances and jurisdictions, guidelines should be flexible;
- (h) *Transparency*: they are intended to promote transparency in the negotiation and implementation of access and benefit-sharing arrangements ...

Appendix I

SUGGESTED ELEMENTS FOR MATERIAL TRANSFER AGREEMENTS

Material transfer agreements may contain wording on the following elements ...

B. Access and benefit-sharing provisions

1. Description of genetic resources covered by the material transfer agreements, including accompanying information ...
4. Whether intellectual property rights may be sought and if so under what conditions ...

Appendix II

MONETARY AND NON- MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to ...
 - (i) Joint ownership of relevant intellectual property rights.

POSSIBLE ROLE OF FUTURE UPOV GUIDANCE IN CASES BEFORE THE COURTS

Mr. Gordon Humphreys, Member of the Second Board of Appeal, Office for the Harmonization in the Internal Market (OHIM)

Introduction

The International Convention for the Protection of New Varieties of Plants ('UPOV') is more than half a century old and has 71 Contracting Parties. The Office for Harmonization in the Internal Market (Trade Marks and Designs) ('OHIM') is not quite 20 years old and provides trade mark and design registration protection for the whole of the 28 Member States of the EU by one application. UPOV and OHIM are undeniably very different, yet they face some common challenges.

This paper focuses on the treatment of OHIM guidelines by the Court of Justice and General Court of the EU ('the Courts'). It starts by looking at (I) the specific context of OHIM and the historical need for guidelines at OHIM, before considering (II) trends and developments in the treatment of OHIM guidelines by the Courts, (III) the current elaboration process of OHIM guidelines and, finally, drawing (IV) conclusions on how UPOV guidance may be received by the Courts in the light of the OHIM experience.

I.-The specific context of OHIM and the need for guidelines

OHIM is a specialist agency of the EU. It is the largest EU agency to have been set up in the wake of the Maastricht Treaty and has, amongst other tasks, a primary mandate to examine and register Community trade marks ('CTMs') and Community designs ('RCDs') from its seat in Alicante, Spain. Examination of trade mark applications is made *ex officio* in so-called *ex parte* cases. This means that OHIM examiners check to see whether applications fulfil the formal and substantive requirements needed to achieve registration (e.g. that the signs applied for are able to function as trademarks and do not contravene public policy considerations). Where that check reveals difficulties, examiners must notify objections to the applicant and, having received comments in return, issue reasoned decisions. The proceedings are *ex parte* because there is only one party to the proceedings before OHIM.

Examiners also have to issue decisions in *inter partes* cases. These arise where a CTM application, or an existing CTM registration, comes into conflict with an earlier CTM or national mark (from an EU Member State). These cases are called *inter partes* because there are two parties to the proceedings.

Ex parte and *inter partes* examination also exists in relation to RCDs, although *ex parte* examination is far less onerous and therefore gives rise to a considerably smaller number of decisions than *inter partes* cases.

Both *ex parte* and *inter partes* decisions, whether on CTMs or RCDs, are appealable to the Boards of Appeal ('the Boards'). The Boards of Appeal are part of OHIM but are independent in their decision-taking. The Boards' decisions are, in turn, able to be appealed to the General Court of the EU ('the GC') in Luxembourg. GC judgments may, on a point of law, also be appealed to the Court of Justice of the EU ('the ECJ'). The ECJ is, therefore, the court of final instance of the EU in CTM and RCD matters. However, the EU Courts in Luxembourg also hear cases involving other areas of industrial and intellectual property such as copyright, plant and vegetable variety matters, etc. In addition, the ECJ receives preliminary references from national Member State courts on *inter alia* trade mark and design cases.

With some 800 people working at OHIM, drawn from the 28 Member States of the EU (as well as seconded national experts from Norway, Switzerland and other non-Member States), examiners are drawn from a wide range of legal cultures and traditions. The work load is heavy and OHIM is committed to ISO quality and time standards. Internal streamlining is essential at the level of OHIM examiners, if efficiency, consistency in decision making and legal certainty are to be achieved. Guidelines are a powerful tool for achieving this goal. However, they are only binding on examiners and, to preserve the principle of independence of decision-making, in no way obligate the Boards of Appeal.

OHIM opened its doors for business on 1 April 1996. For some two years prior to that date, preparations were made within OHIM for dealing with the expected deluge of CTM applications. In those early days, many of the examiners were recruited from national industrial property offices, and others came from

private practice. Even in an EU-15 context, the legal traditions were diverse. Many were convinced that their national way of doing things was the only correct and rational way forward. Differences of opinion inevitably arose and precious time was lost in contrasting opinions. Guidelines were drafted to help users of the OHIM know what to do and what to expect and also to enable examiners to do their job as efficiently as possible.

Inevitably it was impossible to conceive of every imaginable scenario but senior examiners and OHIM management, under the guiding hand of Mr Alexander von Mühlendahl (one of the founding fathers of the CTM), drew up a set of instructions for the cases most likely to be frequently encountered. The guidelines blended together various legal traditions and also created some *sui generis* ones. They did this at a time when no Court judgments on the CTM existed.

Inevitably cases before the Courts soon followed the commencement of operations at OHIM. The Court of First Instance (the former name of the General Court) and the Court of Justice consisted of judges who were highly experienced on competition law and in interpreting the EC Treaty but who had considerably less experience in trade mark matters. In the first cases, 'Baby Dry'¹, 'Trustedlink'², 'Chef/Cheff'³, etc. the OHIM agents defending the Office's decisions before the Court dedicated a sizeable chunk of their written pleadings to a sort of 'mini lecture' on EU trade mark law and the practice of the Office. Just how well received that was by the Court is hard to know for certain. No express mention of it was made in the judgments but the informal feedback was that this approach was helpful, even though it was rumoured that many of the judges in the Court of First Instance at that time favoured the creation of a separate court at EU level to deal with trade mark matters (an idea taken up by the Treaty of Nice but yet to be implemented).

II.-Trends and developments in the treatment of OHIM guidelines by the Courts

In the early days of the OHIM, submissions before the examiners and the Boards as well as pleadings before the Courts were full of references to decisions and judgments at national level. Understandably, neither the Court nor the Office wished to align itself to a particular national approach. One way of achieving this objective was for the Court consistently to rule that national decisions and judgments were not binding (see, for example, 'Electronica'⁴, 'VITALITE'⁵).

The next step was to hold that the Office (including the Boards) was not bound by their own previous decisions. The Boards were convinced that their decision-making independence required them to be free from the obligation to follow OHIM guidelines (see, for example, 'Loose cannon/Canon'⁶). However, the Boards did not – generally-speaking - dismiss the guidelines out of hand.

For example, in the 'Loose cannon/Canon' decision⁷ they were referred to as 'reasonable and logical'⁸ in the context of whether to suspend a case or not. In the event, the Board opined that the particular facts of the case warranted an approach that diverged from the guidelines.

In a number of cases, the Board has drawn attention to the fact that the guidelines are only general instructions and are not of a legislative nature; they are not exhaustive and are constantly evolving as a result of acquired experience (see 'COYOTE UGLY/COYOTE UGLY'⁹). In addition, the Boards have stated on numerous occasions that the legality of decisions must be assessed solely on the basis of the Community trade mark regulation and not on the basis of previous decision-making practice of the Boards, the national offices, the Opposition Division or even the Opposition Guidelines (see, for example,

¹ Judgment of 8 July 1999, T-163/98.

² Judgment of 26 October 2000, T-345/99.

³ Judgment of 13 June 2002, T-232/00.

⁴ Judgment of 5 December 2000, T-32/00, para. 46.

⁵ Judgment of 31 January 2001, T-24/00, para. 36.

⁶ Decision of the Second Board of Appeal of 7 November 2006 - R 1205/2005-2, paras. 12-16.

⁷ Cited above.

⁸ Para. 16 of the decision.

⁹ Decision of the Second Board of Appeal of 26 April 2011 - R 1212/2010-2 and R 1213/2010-2, para. 28.

'Biosphere/SFERA *et al.*'¹⁰). That approach has been echoed in cases involving procedural points, as well as *ex parte* and *inter partes* issues.

Nevertheless, when the guidelines accord with the result that the Board is seeking to achieve in a particular case, it is not unknown for the Board to refer to them to offer additional support for its ruling. Thus, in 'JIMI HENDRIX/EXPERIENCE HENDRIX II'¹¹, the Board cited with approval the definitions of 'nature' and 'purpose' of goods to be compared in an *inter partes* context as set out in the Opposition Guidelines. A similar approach to the guidelines was taken on the procedural point of the need for a request for proof of genuine use of a mark to be 'clear and precise', in 'FRANKI/FRANKI'¹².

Given the varying approaches of the Boards to OHIM guidelines, it is hardly surprising that the Courts have largely mirrored these stances. In this regard, it should be borne in mind that the OHIM decisions that are appealed to the GC are those of the Boards of Appeal. Only some 10% of Board decisions are appealed to the GC and, of these, over 80% are generally confirmed. What the Boards say is taken seriously by the GC.

The starting point for the GC and the ECJ is that Community trade mark law must be assessed solely on the basis of the Community trade mark regulations, as interpreted by the Community judicature, and not on the basis of a previous practice of the Office (see, for example, 'Lokthread'¹³, and 'Standbeutel'¹⁴).

In procedural matters, it might be thought that Courts would be somewhat less deferential to OHIM's specialist knowledge and experience. Both the ECJ and the GC have a wealth of experience in applying rules of procedure and considerable case law has been established in the area. The right to be heard, the principle of legality, and so forth are universal truths that transcend specific fields of law.

In this context, the GC has held that 'th[e] guidelines are merely a set of rules setting out the line of conducts which OHIM proposes to adopt' ('Carlo Roncato'¹⁵). The ECJ has echoed that sentiment in 'Standbeutel'¹⁶, by stating that the legality of decisions must be assessed solely on the basis of the Regulations.

That trend has been confirmed recently by the ECJ, in 'Leno Merken'¹⁷, where the ECJ was called upon to consider the value of a Joint Statement in Council minutes in relation to interpreting a provision of the Community trade mark Regulation (on the geographic extent of use of a CTM). Although the OHIM guidelines referred to that Joint Statement and followed the approach it advocated (by considering use in one Member State to be sufficient), the Court considered that unless the Joint Statement was referred to in the secondary legislation, it could not be used for interpreting the particular provision. Moreover, the Court 'noted that the OHIM Guidelines are not binding legal acts for the purposes of interpreting provisions of European Union law'.

However, it has happened that occasionally, when the GC has found that the OHIM guidelines support a particular stance it has adopted in a judgment, even on procedural matters, it has been willing to refer to them – albeit almost as an afterthought. For instance, in 'VR'¹⁸ ruling on a claim for restitution of rights (*restitutio in integrum*), the GC approved the interpretation of the phrase 'all due care in the circumstances' given in the OHIM guidelines.

Similar occasional positive comments are to be found in certain judgments dealing with *ex parte* matters. For example, in 'Musical notation'¹⁹, the ECJ held that a sound mark could constitute a sign of which a trade mark could consist and that 'this interpretation [wa]s supported ...[*inter alia*] by the Examination Guidelines of the OHIM'. Again the reference to the guidelines seems to be tagged on to a list of other supporting texts.

¹⁰ Decision of the First Board of Appeal of 14 September 2009 – R 1637/2008-1, para. 32.

¹¹ Decision of the Fourth Board of Appeal of 16 November 2009 – R 1730/2008-4, para 28.

¹² Decision of the Fourth Board of Appeal of 21 October 2009 – R R-975/2006-4, para. 20.

¹³ Judgment of 12 June 2007 T-339/05, para. 56.

¹⁴ Judgment of 12 January 2006, C-173/04, para. 48.

¹⁵ Judgment of 7 July 2010, T-124/09, para. 20.

¹⁶ Cited above, at para. 48.

¹⁷ Preliminary ruling of 19 December 2012 – C-149/11, paras. 45-48.

¹⁸ Judgment of 19 September 2012, T-267/11, para 20.

¹⁹ Judgment of 27 November 2003, C-283/01, para. 28.

In *inter partes* judgments, the same generally negative approach to OHIM guidelines is to be found (see, for example, in 'Budweiser'²⁰). In the field of *inter partes* cases involving pharmaceuticals, the GC has also held that any marketing authorization granted by the European Medicine Agency (including those granted pursuant to its guidelines on the acceptability of names for human medicinal products), has no bearing on the likelihood of confusion (see 'Travatan'²¹).

At first sight, one may have thought that OHIM guidelines, if not followed by the Boards, give rise to an infringement of legitimate expectations. The protection of legitimate expectations will, in principle, be extended to any individual in a situation where the EU authorities, in particular by giving him precise assurances, have caused him to entertain legitimate expectations (see, in particular, in 'Innova Privat-Akademie v Commission'²², and the case-law cited). However, the GC has refrained from finding that there is an infringement of legitimate expectations in cases that have come before it from OHIM. For example, the Court has held that the plea was not raised before the Boards and could not be raised for the first time before the GC (see 'BIOMATE'²³) or that the expectations in fact arose from the appellant's own unilateral act ('BIOMATE'²⁴). In 'My baby'²⁵, the GC did not rule out the theoretical possibility of the guidelines creating legitimate expectations. In that case the appellant argued *inter alia* that the OHIM guidelines had led it to believe that the documents it produced to prove the existence of its earlier rights would be sufficient. However, the Court found that the arguments it raised in support of that contention were 'irrelevant for the purpose of demonstrating that the contested decision infringe[d] the principle of protection of legitimate expectations' ('My baby'²⁶).

The conclusion that one may draw from the Court's approach to pleas of legitimate expectations is that they will be extremely difficult to uphold. There is a reticence to find that it is actually the guidelines that have somehow induced the appellant into an erroneous course of action.

However, one must avoid being overly sceptical about the value of guidelines in a judicial context, even in *inter partes* matters. The Guidelines of the Standing Committee on the Law of Trade Marks of WIPO on well-known trade marks, adopted in September 1999, have been applied by OHIM and the UK courts as well as being incorporated into the legislation of the Ukraine and the Baltic States²⁷. This demonstrates that guidelines on matters affecting *inter partes* proceedings (such as the well-known character of the earlier mark) can be taken seriously when they emanate from international experts.

Although OHIM is a supra-national organization, its decisions are reviewed by the GC and the ECJ. That review is thorough and far reaching, especially since the Courts now consider they have the necessary know how in trade mark and design matters. This may be a fundamental difference as compared to vegetable and plant variety matters that have come before the GC and where the Court has been less willing to make a full substantive review of the case. This may be a factor that plays to the advantage of UPOV when its guidelines are considered by the courts. The subject matter is highly technical and outside the expertise of most judges.

III.- Current elaboration process of OHIM guidelines

In the context of trademarks and designs at EU level, the OHIM has sought to reinforce the credibility of its guidelines by completely overhauling them. First, it has created so-called knowledge circles, composed of the leading experts within the Office on particular areas of trademarks and designs. Second, it has invited members of the Boards of Appeal to sit as observers in those knowledge circles. Board members are encouraged to contribute ideas, offer constructive criticism and generally assist in whatever way they can. Third, leading decisions of the Boards as well as judgments of the GC and ECJ have been distilled into basic principles that can easily be understood and applied by examiners and users of the system alike. Fourth, draft guidelines are circulated to national offices and commented on

²⁰ Judgment of 25 March 2009, T-191/07, paras. 48-49.

²¹ Judgment of 22 September 2005, T-130/03, 'Travatan', para. 79.

²² Judgment of 19 March 2003, T-273/01, para. 26.

²³ Judgment of 30 June 2004, T-107/02, para. 80.

²⁴ Para. 87 of the judgment.

²⁵ Judgment of 27 June 2012, T-523/10, para 82.

²⁶ Para. 86 of the judgment.

²⁷ See <http://www.camtrademarks.com/index.php?q=node/93>

with a view to trying to harmonize OHIM practice with that of the Member States. Finally, user groups – both owners and legal practitioners – are invited to make comments and observations.

Periodic meetings, both formal and informal, are also arranged between OHIM and the judges in the GC and ECJ to discuss points of common interest. It is to be hoped that by bringing the Boards into the guideline drafting process, working towards convergence of national practices and systematically incorporating EU case law into the guidelines, these documents will increase in importance and provide a point of reference not only for OHIM and its users but also for the Courts.

IV. - Conclusions on how UPOV guidance may be received by the Courts in the light of the OHIM experience

In general terms, the Courts are not well disposed to referring to OHIM guidelines. In part, this is understandable because OHIM is an inferior instance in the EU decision-making hierarchy and also because OHIM's Boards have set the example of diverging from the guidelines on numerous occasions. On the other hand, OHIM guidelines have sometimes been used by the Boards and by the Courts as an additional reason for reaching a particular finding in a case.

Unlike OHIM guidelines, those of UPOV will not have a predetermined order in a judicial hierarchy. Although their value is more of an unknown quantity, it is hard to imagine that it will be any less than that of OHIM's guidelines before the Courts. Therefore, a worst case scenario would be that UPOV's guidelines are only referred to by the courts as an additional reasoning for reaching a finding.

However, such a pessimistic view is unlikely to be the future. OHIM's guidelines only deal with matters pertaining to the register of trademarks and designs and do not touch upon infringement of rights. This is likely to be a fundamental difference as compared to courts called upon to interpret UPOV guidelines. More importantly, the technical nature of UPOV may well create a situation in which judges, who feel uncomfortable about cases involving subject-matter in which they have little or no expertise, will take more note of the UPOV guidelines than the EU judges take of those of OHIM. The example of the WIPO guidelines on well-known marks is an encouraging sign that when international experts give their recommendations on a subject, there is more willingness from judges, decision-makers and national or regional IP offices to listen. This should give hope to UPOV.

OHIM's efforts to reinforce the credibility of its guidelines, by inviting contributions from a broad spectrum of stakeholders in the system (Boards, national offices, user groups, etc.), is an interesting initiative. Whether it yields the desired results remains to be seen. However, it may be a useful strategy to follow in ensuring the maximum effectiveness of any future guidelines.

POSSIBLE ROLE OF ARBITRATION, MEDIATION AND EXPERT DETERMINATION

Mr. Erik Wilbers, Director, Arbitration and Mediation Center of the World Intellectual Property Organization (WIPO)

WIPO Alternative Dispute Resolution (ADR) Procedures for the Resolution of Essentially Derived Varieties (EDV)-Related Disputes: An Informal Exploration

The number of intellectual property (IP) and related commercial disputes has increased with the growth of international commerce. Although such disputes can be brought before national courts, litigation is not always well equipped to take account of the particularities of this type of dispute because the issues are often complex and require specialized expertise. ADR procedures, including arbitration and mediation, can be particularly advantageous to resolve IP disputes out of court, especially contractual disputes involving parties from different jurisdictions. The following looks at different ADR procedures that are available, and reflects on their potential use in the context of EDV-related disputes.

Mediation

In a mediation procedure, a neutral intermediary, the mediator, helps the parties to reach a mutually satisfactory settlement of their dispute. Any settlement is recorded in an enforceable contract. The mediator cannot impose a decision. Experience shows that intellectual property litigation often ends in settlement. Mediation is an efficient and cost-effective way of achieving that result while preserving, and at times even enhancing, the relationship of the parties. If a settlement cannot be reached, mediation can be followed by available court or agreed arbitration options.

Arbitration

Arbitration is a consensual procedure in which the parties submit their dispute to one or more chosen arbitrators, for a binding and final decision (award) based on the parties' respective rights and obligations and enforceable under the applicable arbitration law. As a private alternative, arbitration normally forecloses court options.

Expert Determination

Expert determination is a procedure in which the parties submit a specific matter (e.g. technical question) to one or more experts who make a determination on the matter, which can be binding unless the parties have agreed otherwise.

Advantages of Mediation, Arbitration, Expert Determination

ADR procedures may offer the following advantages for IP and related commercial disputes:

- *A single procedure.* Parties can use ADR to settle in a single forum disputes involving several jurisdictions, avoiding the expense and complexity of multi-jurisdictional litigation, and the risk of inconsistent results.
- *Party autonomy.* As opposed to court litigation, ADR allows parties to exercise greater control over the way their dispute is resolved because of its private nature. The parties themselves can select the most suitable neutral for their dispute, specialized in the subject matter in dispute. Additionally, the parties may choose the place and language of the proceedings and the applicable law.
- *Expertise.* The parties can appoint arbitrators, mediators or experts with specific proficiency in the relevant legal, technical or business area. It is of greatest importance to achieve high-quality solutions in IP disputes where judges may often not have the relevant expertise in the pertinent area.
- *Neutrality.* ADR can be neutral to the law, language and institutional culture of the parties, preventing any home court advantage that one of the parties may enjoy in court-based litigation.
- *Cost and time efficiency.* Economically viable and speedy dispute resolution is essential in IP and related commercial disputes. ADR methods allow parties to save significant costs that the

parties would otherwise undergo in multi-jurisdictional court proceedings. In this regard, ADR mechanisms provide for short timelines which the parties can further adapt. Specific fast-track methods exist to provide for even faster solutions, such as “expedited arbitration”.

- *Confidentiality.* ADR proceedings and their results are confidential, allowing the parties to focus on the merits of the dispute without concern about its public impact. This may also be of particular relevance where commercial reputations and trade secrets are involved.
- *Preserving long-term relationships.* By using ADR mechanisms, in particular mediation, parties may preserve their business relationships as business interests can be taken into consideration and viable long-term solutions can be adopted in a less confrontational forum.
- *Finality and international enforceability of arbitral awards.* When the parties refer their disputes to arbitration, they benefit from the finality of arbitration awards. Arbitral awards are normally final and binding and not subject to appeal, unlike court decisions. In addition, the United Nations Convention for the Recognition and Enforcement of Foreign Arbitral Awards of 1958 generally provides for the recognition of arbitral awards on a par with domestic court judgments without review on the merits which greatly facilitates the enforcement of awards across borders.

WIPO Arbitration and Mediation Center (WIPO Center)

With offices in Geneva, Switzerland and in Singapore, the WIPO Center is a neutral, international and non-profit dispute resolution provider specialized in IP and related commercial disputes. The WIPO Center offers ADR options, such as mediation and arbitration, to enable private parties to efficiently settle their domestic or cross-border disputes, without the need of court litigation. 16% of arbitration and mediation cases filed with the WIPO Center relate to life sciences, most of them in a multi-jurisdictional context.

Use of WIPO ADR in Disputes involving EDVs

The standard [WIPO Mediation](#), (Expedited) Arbitration, and Expert Determination Rules are generally appropriate for all commercial disputes, and additionally feature provisions addressing specific needs in intellectual property disputes, namely provisions on confidentiality, evidence, experiments, site visits, agreed primers and models, and trade secrets. Also, WIPO Expedited Arbitration provides a reduced time frame and fee structure in cases that are less complex and modest in dispute value.

At the same time, specific areas of intellectual property transactions may benefit from tailored adaptations to the standard WIPO ADR framework, for example in relation to rules, fees and clauses. Such adaptations promote efficiency gains through ADR processes that reflect legal and business standards and needs of the area. The WIPO Center, drawing upon its experience under the standard WIPO Rules, as well as the WIPO-initiated Uniform Domain Name Dispute Resolution Policy (UDRP) and related policies, focuses significant resources on designing and establishing such adapted ADR procedures. In this effort, the WIPO Center collaborates with intellectual property owners and users, their representative organizations and associations, as well as with other interested private or public entities and external experts.

Parties involved in disputes in the area of EDVs could benefit from availability of such tailored ADR procedure. In the interest of time and cost efficiency, such voluntary mechanism could take the form of an expedited arbitration procedure, preceded by, if parties so wish, settlement attempts through mediation. A specific procedural timeframe could be developed, together with a schedule of fixed case-appropriate fees. The procedure could be developed to specifically address a range of particularities related to EDV-related disputes, such as their often international character, and resulting need to establish jurisdiction and achieve enforceability of the arbitral award; and the need for specialized expertise in the procedure which could be supported through the availability of a WIPO list of EDV-specialized neutrals and experts. In terms of substance, cases might benefit from the availability of general UPOV guidance. Also, it could be worth considering encouraging party agreement that would permit publishing anonymized summaries of the award on issues of substance.

Upon request, the WIPO Center remains available to continue dialogue with UPOV and its stakeholders to further explore parties’ interests and needs relating to EDV-related dispute resolution, and the reflection of these in a tailored ADR procedure.

WIPO Arbitration and Mediation Center, November 2013 <http://www.wipo.int/amc/en>

DISCUSSIONS ON SESSIONS II AND III (TRANSCRIPTIONS)

Moderator: *Mr. Martin Ekvad, Vice Chair of the Administrative and Legal Committee*

SESSION II: EXPERIENCE IN RELATION TO ESSENTIALLY DERIVED VARIETIES

SESSION III: POSSIBLE ROLE OF FUTURE UPOV GUIDANCE ON ESSENTIALLY DERIVED VARIETIES

Mrs. Flora MPANJU, ARIPO

My question is to Mr. Lawson. Naturally, we can use guidelines to solve the problem, but imagine that in the CBD that there were the Bonn Guidelines, but as they are not binding they didn't work. Now there is the Nagoya Protocol, but it has created a lot of problems. They say in Africa that they do not want to buy it. So how do you think that this type of guidance is going to work in UPOV? Because they cause a problem – they are just guidelines, but are not binding on anyone. Even in the African context, the examiner cannot just refuse the application because they are simply guidelines. So how are you going to solve this problem?

Mr. Charles LAWSON (speaker)

I certainly understand that you say that they are guidelines and are not enforceable, but as we saw with the OHIM guidelines, they do have some kind of effect on decision makers. So they may not be formerly binding but they certainly provide information. And when you are looking for a consistent approach they certainly take into account the diversity of views of stakeholders and they provide decision makers with some kind of basis for making consistent decisions.

Mr. Riad BAAZIA, Switzerland

Nowadays the Bonn guidelines are contested they have been adopted and there are many interesting instruments, the Nagoya Protocol and others. But you mentioned the CBD, do you think that it could be useful, because WIPO nowadays has a kind of agreement, but we are talking about traditional knowledge, but you said that it could be useful for this issue or do you have another suggestion?

Mr. Charles LAWSON (speaker)

I think that the benefit of guidelines is that they provide a grounding for consensus. As you see with the Bonn Guidelines and the Nagoya Protocol, they cannot address all the issues and take into account every perspective, so there are always going to be disagreements, but they provide a basis for some kind of consensus. I think that if you look around the world, the Bonn Guidelines did provide the basis for a number of jurisdictions to develop their own internal laws. So yes, there may not have been a final resolution in the way that a hard law was, but they were a step in the direction of providing some kind of guidance. Now, as to how they might be useful for EDVs; they can address some of the sorts of problems we have seen today – disagreements about the definition of words and can provide some insight into that. They will likely provide some insight into the range of techniques or the range of technologies that are going to provide some insight into how, over time, EDVs will be resolved. It is a way of bringing the different stakeholders together to reach consensus. Whether you get consensus is another matter though.

Mr. Huib GHIJSEN, Netherlands

I have a question for Mr. Doug Waterhouse. I understand the definition of essential characteristics and the procedure before the Office has a very important role. I wonder, what is the position of the DNA markers in this procedure? We had an interesting dispute this morning on whether to base the decision on phenotypic characteristics or genetic characteristics and that is one of the issues that we have to solve. So I am curious on how that is dealt with in Australia.

Mr. Doug WATERHOUSE (speaker)

The Australian Law follows UPOV Article 14 and has three additional elaborations. It doesn't ignore the UPOV requirements and one of those requirements is that the variety needs to be predominantly derived

and perhaps DNA information could be used to satisfy that requirement. It is not necessary to use DNA in relation to the essential characteristics, as I think I have explained.

Mr. José Ignacio CUBERO, Spain

Through the first part of the afternoon, and throughout the Seminar, we have heard about essential characteristics, but I think that nobody has defined them nor given an example. I feel that it is essential to define the essential characteristics – someone has mentioned that – and even to list them because, if not, I think the tendency will be towards using more and more molecular markers and I think that UPOV was created to defend plant breeders' rights and not molecular markers' rights.

Mr. Tjeerd OVERDIJK (speaker)

One thing that can be said about morphological characteristics, I think, is more or less the same as has been said with respect to genotypic characteristics or data: you have to decide on a crop by crop basis, or at least on the basis of the various types of crops that there are, what the essential characteristics could be in each case. For example, for vegetable crops, the essential characteristics can be quite different than for ornamental crops. That is one general comment that I could make. On the other hand, in ornamental crops, we have the DUS protocols, which list all the characteristics against which varieties can be tested and which can, apparently, be important. In the 'Blancanieves' case, which I spoke about in my contribution, the Court said that in an ornamental variety like the Gypsophila varieties which were in that case, related specifically to the cultural and commercial values of those varieties. So there it was a bit less broad than all the DUS characteristics, but in any event many characteristics of the plant's appearance are important for those who buy them. I am certainly not the only one who is going to comment here, I think.

Mr. Doug WATERHOUSE (speaker)

Australia has defined what essential characteristics are, and it does that by talking about the role of that characteristic in determining the performance or value of the variety without determining the particular morphological element that we are talking about. We have taken a broader approach than trying to identify whether it is a particular morphological element and we have looked at it in a more generic way, looking at performance and value.

Mr. Gert WÜRTEMBERGER (speaker)

My question follows up your answer and the question leading to these answers. My question is particularly addressed to Mr. Waterhouse and Mr. Overdijk. Mr. Waterhouse, you mentioned that among the three elaborations on EDVs, the essential characteristics play an important role and you mentioned that those characteristics which are essential contribute to principle features, performance or value. Where is the starting point for these characteristics? You somehow have to define where you start from. The EDV concept is an exception to the general breeder's concept and if you try to cover it by the breeder's right of the initial variety, and the initial variety is protected among certain criteria, then these criteria, I could imagine, should be the starting point because then the question arising where you end up with non-protected features of the presumed EDV concept. You seem to then extend the protection of a protected variety to an endless range of additional characteristics.

Mr. Doug WATERHOUSE (speaker)

It is a long and complicated question, but let me attempt to answer two elements. The first is that, in the Australian system, we define what is not an EDV, what breaks the connection of EDV. That is by way of one or more characteristics that contribute to the value or performance of the variety. The second element to your question, I think, is: does that open the door to the second varieties having an endless list of new and important characteristics? I agree that it does open that door and that in fact, we believe, is in our national interest to have these new varieties that add performance, that add value. We want to find a way to implement EDV so that we get access to those varieties. So we do not limit the characteristics to just those that are already described in the first variety. If the second variety has an additional characteristic that adds value, then that is the one where we start. In fact, then we go back to industry to ask industry whether or not they believe it to be an important characteristic so, in that way, I can be more protected in my decisions, because we are being advised by industry what is and what is not important.

Mr. Huib GHIJSEN, Netherlands

If you allow me, I would like to elaborate on this issue because it is a key issue of the whole EDV system and I think the former question was raised that if you add additional characteristics whether you open the door for a broader protection. For instance, we all know that the characteristic yield is a very important characteristic in many crops, but quite difficult to establish and to measure and quite expensive. If you take an EDV and it is clear that it has a better yield, you have to test the two varieties for yield because the initial variety also has a good yield. Furthermore, I have looked into all the UPOV texts and guidelines and also in the 1961 Convention and there they already talk about essential characteristics, later on it talks of relevant characteristics or important characteristics. I think that one of the failures of the EDV definition is that there is not a good definition of what is meant by the essential characteristics that play an essential role in the whole system. So I think that we first need a good guideline on what exactly we mean by essential characteristics.

Mr. Joël GUIARD (speaker)

I should like to add a point on this – we should always bear in mind that in the UPOV Convention it is clearly established that in order to establish distinctness before delivering the right, there are no questions of value. In EDV, it is by definition completely different from all protected varieties within the UPOV protocol. 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. I think that Mr. Waterhouse was very clear, because he refers to new characteristics which did not exist, be they the length of stamens or the distance between leaf nodes, which had been studied at the scientific level, but had not been taken into account in defining the initial variety. I think that this approach may allow us, perhaps not in all cases, to partially respond at least to whether a variety is essentially derived or not.

Mr. Stephen SMITH (speaker)

Would members of the panel agree with the mission statement of UPOV, that it is 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 and how does this play into deciding how to work and determine EDVs?

Mr. Doug WATERHOUSE (speaker)

The question is leading, obviously! We necessarily agree that we support the UPOV mission statement. We all attach ourselves to that completely. The elements though are “an effective system of protection” and that the consequence of that is “for the benefit of society”. I think that one of the metrics of that, it is not the only one, but one of them 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. Whether that be by investment, by attracting new people in, by supporting existing breeders, they are the sort of factors that we need to balance and that, I think, takes us all the way back to the start which was that 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. That is a very long answer to my question. We have heard from the breeders today that, in fact, they have some very different approaches to EDV; what is EDV what is not. Perhaps that is to do with the technologies that they handle. But as a policy person, what are the breeders doing to get together to give us a unified shortlist of things we can address, that we can hear with just one voice, because we need to have that clarity. So my question to you, the breeders; what are you doing?

Mr. Stephen SMITH (speaker)

Well, we are working hard on a crop by crop basis to try and come to some guidelines that can give some clarity, so that we can spend more time in breeding and less time in Courts! But there are many crops to work on.

Mr. Alessandro BERTI, Switzerland

A short question for Mr. Wilbers. I would just like to know whether arbitration decisions are appealable and, if so, what are the main grounds for appeal.

Mr. Erik WILBERS (speaker)

In principle, no, they are not appealable in the conventional sense that we know from the Courts. If you don't like the outcome in the Courts, you think it is in your interest to appeal, you think you have a better chance at the next level, you appeal in the Courts. In arbitration, there are very limited grounds of trying to overturn or to change the outcome of the arbitration, the award. Those limited grounds are recognized by arbitral law and by treaty across all of our jurisdictions and there are some very limited circumstances if one party can prove that the arbitrator was bribed or there has been a breach of natural justice. If you can prove that, as a party, you were denied a full opportunity to present your case, for example, you requested a hearing for a very good reason to present certain witnesses and you were denied that opportunity without a reasonable explanation for that. In that sort of very narrow situation, you can have a so-called appeal to try and overturn the result. But the standard situation in arbitration is that it ends with the arbitral award. You can always look at these things in two ways, but certainly this is one of the reasons why corporate counsel prefer arbitration, precisely because they prefer to have early certainty about a dispute as opposed to uncertainty for a longer time. It is a balancing act, but in principle, arbitration gives you earlier certainty.

Mr. Marcel BRUINS (speaker)

I have another question for Mr. Wilbers. For the information of the audience, there is already a system available for dispute settlement in EDVs at the International Seed Federation (ISF) and we are working with the World Intellectual Property Organization (WIPO) to find a good solution on how to investigate the best resolution for the needs in that respect. In analogy with your own findings, our surveys also indicate that arbitration is indeed cheaper and faster. I would like to ask you if you could elaborate a little bit on how you could pull away the parties from court cases and bring them into arbitration. Because what we are seeing up to now is that the seed companies are resorting only to court cases to settle their EDV disputes and not so much to arbitration.

Mr. Erik WILBERS (speaker)

I do believe, and I am saying this very generally and not just in respect to EDV context, in principle Alternative Dispute Resolution (ADR) arbitration, mediation, whatever it is, should not try to become popular just by making the courts look bad. That is a definitely negative proposal – it might be true, but that still doesn't add much positive value and I think that this is where, when you try to design systems, the challenge lies and I think that your question goes to that. You can try to design something, but you need parties to buy into that, especially the ones with the deeper pockets, the ones that trust the courts more or think that they can outspend the other side. It is a combination of factors, first of all you will not be able to convince everybody; some parties will just naturally take cases to the courts although they know that the courts are more expensive and are going to be taking more time. There are many court cases where you can wonder why they did ever go to court, in light of the way that those cases settled. If you look at the statistics of court litigation, including intellectual property, if you look at the United States of America statistics, everyone is afraid of the cost of patent litigation in the United States of America, but the reality is that more than 90% of cases settle before the judge has actually decided the case, and yet this goes on. So Parties do find, either for reasons of habit or they find some other reason to use that system. Sometimes it is good to step aside and question that a little bit, is this the right track? The court systems are nationally based; obviously, there is not that much harmonization (I am generalizing here) and enforceability of foreign judgments is questionable in many cases, if you don't have a treaty. The courts, just like in a sense the national obtaining of IP rights, is a throwback to the times when things were organized by jurisdiction. Ever since we are internationalizing our commerce whereas when there is a dispute we still run to a national court. It is understandable, but it may pay off to try to change that. Maybe the way to do that is not to convince the individual players in this who have their own reasons, but indeed to look at the design, to give incentives and, if I may come back just very briefly to the example of domain name that was very briefly mentioned. This is the situation whereby trademark owners, thousands of them from around the world, file cases, instead of going to the courts, into a special Alternative Dispute Resolution (ADR) system in order to not have to spend too much time and money getting back their trademark identity on-line. It is a very successful system by many standards. One

incentive why they are actually doing this is because they have not given up their rights to go to court. This sounds like a paradox – how can a system work if you do not shut down the option of going to court, but that is just one design element that was created precisely to give the people the comfort of choice. Now I am not saying that that particular dual option is necessarily one way forward for EDV, but I am giving this an example of what you can try to give people incentives to go forward. The final thing I want to say probably sounds too philosophical now, because it is the end of the day, is that to create the right solution you need to understand the problem very clearly, and maybe still, although I was asked to venture just some Alternative Dispute Resolution (ADR) thoughts about this topic, still probably the best way to get to the best options is to drill down deeper into the disputes. We have a meeting taking place on Monday where 100 domain name panelists are coming to Geneva, these are the type of people that we appoint in these cases, and what we will do with them on Monday is that we have a full day where we talk about the precedents of the past years and the precedents going forward. This is non-binding, soft law, these panelists are appointed to individual cases, but we try to bring them together in a way that information is shared, almost in the same way as you are doing today, except on an institutionalized basis. Just a few thoughts.

Mr. Martin EKVAD (moderator)

Thank you, Mr. Wilbers, for adding a philosophical touch to our meeting. I should like to thank you all for the active participation in the discussions and to thank all the speakers and the panel for the work you have done this afternoon.

CLOSING REMARKS

Ms. Kitisri Sukhapinda, President of the Council of UPOV

Session 1: Technical and legal aspects of essentially derived varieties and the possible impact on breeding and agriculture

- The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requested the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines, for the adoption by the Council, on essentially derived varieties.
- Key elements of the guidelines on EDV were considered at 1992 Meeting with International Organizations (IOM/6/2) – and provide a good starting point for future work.
- Currently, 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.
- Two possible starting points:
 - predominant derivation (genetic conformity)
 - essential characteristics (phenotype)
- Need to consider impact on breeders, including farmer-breeders, farmers, growers and society as a whole.

Session 2: Experience in relation to essentially derived varieties

- Australian PBR law provides a workable “bright line” on EDV
- Japan: certain examples which may be considered as EDVs are provided, but it is finally a matter for the courts to decide
- Court case experience in the Netherlands:
 - for a variety to be qualified an EDV the differences with the Initial Variety should not be more than one or very few inheritable characteristics (both in terms of genetics and phenotype)
- Court case experience in Israel:
 - if there exists a genetic or a morphological conformity between the two varieties, the assumption is that the defendant actually used the original variety to produce the EDV: this is only prima facie evidence, by which the burden of proof is shifted to the defendant, who now has to explain the suspicious conformity
 - Breeders need clear guidance

Session 3: Possible role of future UPOV guidance on essentially derived varieties

- “Soft law” may be an option, e.g. Guidelines.
- Guidelines that embrace a broad spectrum of stakeholders and interests may be more credible and persuasive for the Courts.
- The international standing of UPOV may help in the use of guidelines by Courts.
- Alternative Dispute Resolution (ADR) mechanisms - Mediation, Arbitration and/or Expert Determination - could be useful tools for EDV
- ISF and WIPO provide ADR options
- Publication of an anonymized summary of ADR outcomes could offer guidance and could lead to harmonization

SPEAKER BIOGRAPHIES

SPEAKER BIOGRAPHIES



MARCEL BRUINS

Marcel Bruins has served as Secretary General of the International Seed Federation (ISF) since 2007. Before taking on this position he was Manager Plant Variety Protection with Seminis Vegetable Seeds, which he joined in 1998 and where he also worked on patents and trademarks. During this period he was a member and chairman of committees in the European Seed Association, the Dutch Seed Association and the ISF. After studies in plant breeding and plant pathology, research at Plant Research International and completing his PhD, Marcel worked as Manager IP Rights at a large public research institute and as a License Broker for agricultural and biotech inventions at Rotterdam Innovation Center for Inventions.



MIA BUMA

Mia Buma, owner of Mia Buma Advies, worked as a company lawyer for the Association of Dutch Flower Auctions (VBN) from 1993 to 2008. In this function, assignments in her portfolio fell under the wide scope of Dutch law. In addition, Mia got more and more involved in plant variety rights and its relation with other intellectual property rights. Another specialism is arbitration law. With regard to PVR, Mia is internationally active as Secretary of the Committee for Novelty Protection for the International Association of Horticultural Producers (AIPH). In this capacity she keeps abreast of all new developments within UPOV and represents AIPH, which has the observer status, in UPOV. In spring 2008 Mia started her own consultancy bureau, Mia Buma Advies, and she is working now freelance for (among others) the Dutch flower auctioneer FloraHolland, the Dutch Association of Wholesale Trade in Horticultural Products (VGB) and AIPH.

Highlights in her career include:

- (1986) Course in international law and international relations, University of Vienna, Austria
- (1987) Law Degree at the University of Leiden, the Netherlands
- (1987) Master's program, Introduction to the English Legal System, University of Exeter, England.
- (1988) Work experience with the legal firm Bowling & Co., Solicitors, London, England.
- (1989-1993) Lawyer for the Dutch Ministry of Agriculture, Conservation and Fisheries, in the Department of Legal Affairs.
- (1996) Qualified as Mediator
- (2002) Member of the Board of the 'Koninklijke Maatschap de Wilheminaolder' (a large private agricultural farm in Zeeland (NL) of 2000 hectares)
- (2005-2008) Member of the Board of the Dutch Company Lawyers Association



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Mr. Peter Button was appointed Vice Secretary-General of UPOV on December 1, 2010, having previously held the role of Technical Director at UPOV since 2000.

Mr. Button, a national of the United Kingdom, holds a B.Sc. Honors degree in Biological Sciences. From 1981 to 1987 he worked for Twyford Seeds Ltd., a plant breeding company in the United Kingdom, on the development of new cereal varieties. Between 1987 and 1994 he was the General Manager of Twygen Ltd., a company which developed micropropagation systems for the commercial production of seed potatoes and soft fruit stocks and continued as General Manager, following the change of ownership, of GenTech Propagation Ltd. in 1994. In 1996, Mr. Button joined the British Society of Plant Breeders as Technical Liaison Manager, where his responsibilities included the operation of officially licensed variety trials. In 1998, he became Technical Liaison Officer for the United Kingdom Ministry of Agriculture, Fisheries and Food (Plant Variety and Seeds Division), where he was responsible for the operation of the tests and trials associated with the United Kingdom Plant Breeders' Rights and National List schemes and Seed Certification in England and Wales and was the United Kingdom representative in the UPOV Technical Committee.



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The Plant Sciences Unit clusters within the Institute for Agricultural and Fisheries Research (ILVO) all the plant-derived research and is composed of 4 different research domains (www.ilvo.vlaanderen.be). The Plant sciences unit has infrastructure and equipment for performing breeding and selection programs, applied biotechnology and eco-physiological research. In 2011 a new research greenhouse was taken into use housing a new eco-physiological lab, separate growth rooms and custom infrastructure with sufficient steerable separate compartments. In 2012 is further invested in the creation of growth rooms including LED lighting. Recently investments in a complete new infrastructure of 3 movable rain-shelters was done.

The Plant sciences unit has very close contacts within the horticultural and agricultural sector for various research projects. This guarantees project results easily are transferred to interested companies. The ILVO Plant Sciences Unit aims to raise knowledge for rational approaches to plant breeding.

The research domain Plant-Applied Genetics & Breeding (GV) owns an extensive knowledge and competence in plant research in the area of plant breeding, in vitro techniques, biotic and abiotic stress resistance. The research is concentrated on fodder crops like forage grasses and clovers, vegetables, chicory and green manure crops on the one hand and ornamental plants as azalea, roses, woody ornamental trees, Begonia, Araceae and chrysanthemum on the other hand. Plant-GV has an extensive and well-characterized gene bank of azalea and related Rhododendron species. Also an extensive collection of Begonia is available. Plant-GV has a long-lasting expertise in the use of DNA markers for protection of cultivars (cultivar identification, plant variety protection, fraud) and for the support of resistance breeding.

Different marker techniques (AFLP, microsatellites, STS, SNP) were developed in various crops (mainly grasses, clovers and pot azalea, rose). Data acquisition and analysis methods were developed for those applications. Expertise is present for expression analysis using RT-qPCR and the translation from model crops for the isolation of candidate genes. Recently also NextGen sequencing for transcriptome analysis has started in azalea and ryegrasses that allows to isolate faster and easier candidate genes. Plant-GV also collaborates in the recent Rose Genome Sequencing Initiative (<http://rosegenome.org/>) for sequencing the rose genome.

Jan De Riek is specialist in molecular genetics and marker assisted breeding; leads national and EU projects for molecular breeding of ornamental and agricultural crops e.g. coordinator of the EU-Marie Curie **ForESTFlowers** project (FP7-People-2010-IRSES 269204) 'Expressed sequences (EST) as tags

for functional genes for genetic characterization of flowering woody ornamental shrubs from an oriental origin' and FP5 project **GENEROSE** (QLRT-2001-01278), partner in FP7-REGPOT-2009-1-245751 **PROFICIENCY**. Several regional projects with the Flemish agency for Innovation by Science and Technology (IWT) for the ornamental industry (a.o. impact of polyploidy in roses on (a)biotic stress resistance).

CIOPORA Board member since 2008 (International community of breeders of asexually reproduced ornamental and fruit varieties). CIOPORA is an international non-governmental organization, representing the interests of breeders of asexually reproduced ornamental and fruit varieties worldwide. Top priority of CIOPORA is the constant development of systems of protection which both, international state organizations and single states, have provided for the protection of the intellectual property concerning ornamental and fruit plants.



MARTIN EKVAD

Martin Ekvad has been President of the Community Plant Variety Office “CPVO” since 2011. Before taking up this post, he worked as CPVO Head of Legal Affairs and, before that, as a lawyer (Advokat) in the law firm Linklaters, in Brussels and in the law firm Magnusson Wahlin Advokatbyrå, in Stockholm. Prior to working in private practice, Mr. Ekvad worked at a civil court for two years. Mr. Ekvad has a law degree from the University of Lund, Sweden and a LL.M. from King’s College in London.



Name: Arnan Gabrieli (Founding Partner)

Phone: 972-3-5661446

Email: mail@sgl.co.il

Fields of Practice:
Intellectual Property Law in Israel

Overview:

Arnan Gabrieli, one of the leading experts in intellectual property law in Israel, is a founding partner and the Senior Partner of our firm. Arnan's practice includes advising and litigating in all causes of intellectual property law.

During his four decades of practice, he has gained vast experience in all the IP fields.

In his litigation practice, Arnan was party to most of the significant intellectual property cases argued before the Israeli courts including numerous major patent cases argued before Israeli courts and the Registrar of Patents. He represented clients in trademark and copyright infringement cases, as well as passing-off, trade dress and trade secret cases, in which many significant precedents were set.

Arnan's practice includes providing legal opinions regarding the patentability and/or infringement of inventions, the availability of trademarks, the prosecution of trademark and design applications and the protection of copyright and goodwill. He also deals extensively with the prosecution of trademark and design applications.

Arnan Gabrieli was a member of legislative committees which drafted the most important Israeli IP laws and has represented our clients before the legislative authorities.

Qualifications:

Lecturer, College of Management, Faculty of Law (1994 to present)
Editor-in-Chief of "Hapraklit", Israel Bar Quarterly Review (1980-1987)
Lecturer, Tel Aviv University, Faculty of Law (1972 to present)

Education:

Hebrew University, Jerusalem
Faculty of Law, M.Jur.

Admitted to Practice:

Israel. 1960.



JOEL GUIARD

Joel GUIARD, 63 years old, is an agronomist specialized in genetic and plant breeding working in GEVES, the French examination office for testing new varieties. He has been involved in the implementation of regulations on varieties and seeds for more than 30 years. He has a long experience in National listing and Plant Breeder's Right domains with active participation in European Commission, UPOV and CPVO bodies.

He was part of the Diplomatic conference for the revision of the UPOV convention in 1991 where he chaired the working group producing the definition of the variety. At UPOV level, he chaired TWA and BMT technical working groups and two times the Technical Committee.



GORDON HUMPHREYS

Gordon Humphreys holds an LL.B from the University of Buckingham (UK), an LL.M from the University of Wales, Cardiff, and a master's degree in economic law from the University of Liège (Belgium). He qualified as a barrister of England and Wales and was admitted to the Brussels Bar as an *avocat* in 1994. Following a period in private practice in Luxembourg, he joined the Legal Department of the OHIM in 1997, acting in several of the earliest Community Trade Mark cases before the (then) Court of First Instance. He was Head of the Register Service from 2002-2005 before taking up his present duties as a member of the OHIM Boards of Appeal since December 2005, handling both trade mark and design cases. He has published a number of articles on trade marks and designs in leading IP journals and is a regular speaker at conferences. He is also qualified as a mediator with the Chartered Institute of Arbitrators and is a member of the OHIM Mediation Unit.



EDGAR KRIEGER

is German, born 1965, married and father of three boys.

His professional education and career is that of a lawyer, he also holds a diploma in business administration.

He worked for 5 years in an international law firm and is specialized in Intellectual Property Law – and here especially Plant Breeders' Rights, in which he also wrote his doctorate thesis. As a lawyer he advised mainly agricultural breeders, inter alia in questions of farm saved seed, including several hundreds of court cases up to the European Court of Justice.

In January 2004, Dr. Krieger took over the position as Secretary General of CIOPORA. In this position he shapes the position of breeders of asexually reproduced ornamental and fruit varieties in regard to IP protection and advises governments worldwide on the requirements of effective protection for these varieties.

Dr. Krieger is member of

- the IP Committee of the International Chamber of Commerce (ICC),
- the Special Committee on Biotechnology (Q 114) of the International Association for the Protection of Intellectual Property (AIPPI),
- the Expert Committee for the Protection of New Varieties of Plants of the German Association for the Protection of Intellectual Property (GRUR) and
- the Legal Experts Group of the Community Plant Variety Office (CPVO).

Dr. Krieger is author of several articles on Intellectual Property Protection for plant innovations, and sought-after speaker on conferences and seminars on that matter worldwide.



RAIMUNDO LAVIGNOLLE

Director
Plant Variety Register Direction
NATIONAL INSTITUTE ON SEEDS
Argentina

e-mail address : rlavignolle@inase.gov.ar

Born in 1962 in Morón, Argentina.

Married, three children.

I am an agronomic engineer and have postgraduate studies in intellectual property rights and new technologies. I started my career as assistant of the seed testing laboratory of Northup King Seeds Argentina in 1983, running seed quality tests, mainly germination and vigor tests; whilst studying at the University of Buenos Aires. In 1990 entered as a staff of the Central Laboratory of Seed Testing, of the National Institute of Seeds (INASE), Argentina. At the end of that year, I moved to become an examiner of applications for national list and plant breeder's rights of the Plant Variety Register of the INASE. In 1993, I became the director of the Plant Variety Register, responsible for the National Catalogue of Plant Varieties: i.e. the national list of varieties as well as for the granting of plant breeder's rights in Argentina. Since 1994, I represented Argentina at UPOV meetings, in particular at the Technical Committee and Council of UPOV. In 1998, I took up a position as Senior Program Officer of the International Union for the Protection New Varieties of Plants (UPOV) and, in 2000, I was promoted to Senior Counsellor. I was responsible for the programs for cooperation and assistance in the development of plant breeder's rights systems in conformity with the UPOV Convention for countries in Latin-America, the Caribbean and Africa; the establishment and running of UPOV distance learning courses; coordination of the sessions of the Technical Working Party for Agricultural Crops (TWA), the Technical Working Party for Automation and Computer Programs (TWC) as well as Spanish linguistic issues related to technical areas. In 2010 I was promoted to Director. In 2012 I came back to Argentina. Since January 2012 I am Plant Variety Director of the National Institute of Seeds (INASE) again. I am responsible for National List and Plant Breeder's Rights in Argentina and the coordination of 7 Technical Committees: (cereals, maize-sorghum, oil crops, cotton, forage crops, variety denomination and biotechnology). I also represent Argentina at UPOV meetings.



CHARLES LAWSON

Charles Lawson is an Associate Professor in the Griffith Law School, Griffith University. He studied science and law at the Australian National University and holds a Bachelor of Science with Honours in biochemistry and genetics and a Bachelor of Laws. He also holds a Doctor of Philosophy from the ANU's Research School of Biological Sciences in molecular biology and biochemistry and a Master of Laws from Queensland University of Technology for research into patenting and competition. Before joining the university sector he worked as a lawyer in both the private and public sectors. His research focus is on patents and public administration law.



NORMITA G. IGNACIO

Executive Director

Southeast Asia Regional Initiatives for Community Empowerment

Normita G. Ignacio has a career in rural development that spans more than two decades. Particular to her work as a development professional, she has vast experience in charting and organizing programs in agriculture, food security and organizational capacity building. She is responsible for successful development programs in countries in the Southeast Asian region. In these programs, she has demonstrated technical and organizational expertise in sustainable agriculture and has skillfully displayed acumen in integrating multi-stakeholders participation, community education and systems management into programs she has undertaken. Her vast experience in design, development, implementation, monitoring and evaluation of educational initiatives, as well as facilitation of training, workshops and conferences, has gained her a renown as a development professional in both national and international circles.

Before joining Southeast Asia Regional Initiatives for Community Empowerment (SEARICE) in 2003 as Program Coordinator, she had a string of assignments at the International Institute of Rural Reconstruction (Philippines) in various capacities. While there, she developed the bio-intensive gardening (BIG) system together with communities for adaptation to different agro-ecological conditions as a strategy for household food security and nutrition. This was adapted in many developing countries of Asia, Africa and Latin America.

As Regenerative Agriculture Specialist, also at the IIRR, she developed and implemented projects related to sustainable agriculture (SA) to include agroforestry and upland management, integrated farming system, community-based plant genetic resource conservation, and alternative pest management going through the full cycle of project management (from project conceptualization, designing, strategy formulation, planning, implementation, financial management, monitoring and evaluation). A major achievement as project manager was the formation of a grassroots organization called Family Food Production Foundation Incorporated (FFPFI). This organization became a recipient of *Bayaning Filipino* (Filipino Heroes) Award and the group remained a regional top performer in land distribution under the land reform program of the Philippine government.

She developed sustainable agriculture as an integrated subprogram within the bigger rural development program of IIRR as Regenerative Agriculture Subprogram Coordinator. One of the major accomplishments in this area was the widespread implementation of the postharvest project throughout Vietnam with expansion in Cambodia, with recognition by the government of Vietnam through an award conferred by the President of Vietnam for the project's contributions to poverty alleviation in the country.

Nori, as she is popularly known, facilitated sessions in various IIRR international courses, such as Participatory Monitoring and Evaluation, Integrated Conservation and Development, Community-Managed Health as a Training Specialist. She managed a five-year capacity building program on Sustainable Agriculture Training of Trainers involving 12 partner organizations in the Philippines, Thailand, Indonesia, Cambodia, Laos, Vietnam, Nepal, India, Bangladesh, and Sri Lanka. In a

consultative capacity, her work has also seen her successfully undertaking capacity-building activities and evaluating programs in Zambia, Kenya and Guatemala.

Nori earned her Bachelor of Science, Major in Agriculture at the University of the Philippines at Los Baños, Laguna, Philippines in 1983, wherein she was awarded a University Scholarship Grant. In 2000, she earned her Masters Degree in Development Management (MDM) at the Asian Institute of Management, Makati City, Philippines under an Asian Development Bank Scholarship.

She is credited with publications and research initiatives covering various interests in the fields of agriculture, biodiversity, food security and conservation.



TJEERD OVERDIJK

Tjeerd Overdijk began work as a private practice lawyer in 1984 and gradually focused his practice entirely on intellectual property law. He is one of the founding partners of the law firm Vondst Advocaten in Amsterdam, the Netherlands, a specialized law firm fully dedicated to intellectual property law and information technology law. He has a longstanding experience in litigating a wide variety of I.P. cases, both at first instance and appellate levels, including opposition proceedings before the Benelux Office for I.P., the Boards of Appeal of OHIM and the CPVO, and the Court of Justice of the EU. A substantial part of litigated cases involve infringement and invalidity disputes in relation plant variety rights, and disputes on licensing agreements involving such rights. He has been involved in a number of PVR infringement cases involving EDVs. Tjeerd Overdijk is an active member of various professional and sector associations, including AIPPI, Plantum NL, CIOPORA and ESA.



STEPHEN C. SMITH

Dr. J. Stephen c. Smith
Research fellow
Germplasm security coordinator
Research and product development
Pioneer hi-bred international, inc.
Dupont agriculture and nutrition

Dr. Smith (B.Sc. University of London), M.Sc. (Conservation of Plant Genetic Resources) and Ph.D. (Evolution of Maize), University of Birmingham (England). Research Fellow at Pioneer Hi-Bred International, employed by Pioneer since 1980. Research interests include genetic diversity, issues related to germplasm access and benefit sharing, use of morphological and molecular data for variety identification, demonstrating the importance of sustainable use of genetic diversity to improve agricultural productivity, pedigree analysis of crop varieties and intellectual property protection (IPP). Responsibilities include managing a technical support group that provides data required to obtain patents and Plant Variety Protection (PVP) and to undertake research to demonstrate the important role of plant genetic resources and IPP in plant breeding and agriculture. Dr. Smith serves on intellectual property committees of the American Seed Trade Association (ASTA), the International Seed Federation (ISF) as Chair, and the Biotechnology Industry Organisation (BIO). He is a Fellow of the Crop Science Society of America and received the 2005 ASTA Chairman's Distinguished Service Award for service to the industry in the field of intellectual property protection. Dr. Smith chaired the C8 (genetic resources) Division and the Sperling lectureship committee of the Crop Science Society of America. He is a member of the Editorial Board of the journal *Plant Genetic Resources, Characterization and Utilization*. Dr. Smith has served as a Board member of Bioversity International (previously the International Plant Genetic Resources Institute) of the Consultative Group on International Agricultural Research (CGIAR), and currently serves as Board member of the National Council of Commercial Plant Breeders. He has served on a review panel of the CGIAR Generation Challenge Program. He is a member of the advisory council of the Bioethics Program and Iowa State University, and a member of the CropLife International germplasm access and benefit sharing committee. In 2011, Dr. Smith was appointed to a 4 year term on the US National Genetic Resources Advisory Council. He recently represented industry through the International Chamber of Commerce at a technical expert meeting of the Convention on Biological Diversity. He chairs the Pioneer DuPont Genetic Resources Issues Team, a group that was instrumental in securing a \$1m contribution to the Global Crop Diversity Trust. He has published around 100 peer reviewed scientific papers including on genetic resources and intellectual property protection.



KITISRI SUKHAPINDA

Kitisri Sukhapinda, Ph.D., J.D.
Patent Attorney
Office of Policy and International Affairs
United States Patent and Trademark Office
U.S. Department of Commerce

Kitisri Sukhapinda serves as an attorney advisor in the Office of Policy and International Affairs, United States Patent & Trademark Office (USPTO). Kitisri plays a key role in formulating plant related intellectual property policy. She leads the United States Delegation to the Council of the International Union for the Protection of New Varieties of Plants (UPOV), and currently holds the position of the President of the UPOV Council.

Kitisri has a wide range of experiences in both law and science, and in both public and private sectors. Before joining the USPTO, Kitisri worked in a law firm advising clients on patent-related matters. Prior to becoming an attorney, Kitisri was a senior scientist at a Fortune 500 company. Her roles included leading research programs in plant biotechnology, and coordinating collaborative research projects with universities. Kitisri was named a co-inventor of five U.S. patents.

Kitisri received a bachelor's degree in Crop Science from North Carolina State University, master's and doctorate degrees in Plant Breeding from Iowa State University, and a law degree from Indiana University, United States.



HEDWICH TEUNISSEN

Hedwich Teunissen, female, molecular biologist, graduated from the department of Plant Breeding, Wageningen University (NL) in 1996. She did her PhD in the group of Phytopathology, Swammerdam Institute for Life Sciences, University of Amsterdam (NL), working on the molecular (gene-for-gene) interaction between *Fusarium oxysporum* f. sp. *lycopersici* and tomato. Plant-fungal interactions were further exploited during a post-doc study at the Max-Planck-Institute for Terrestrial Microbiology in Marburg, Germany in the group of Prof. Regine Kahmann where she worked on the transmission of the pheromone signal in *Ustilago maydis*, causing smut disease in maize. Since 2004 she is employed at Naktuinbouw, (Netherlands Inspection Service for Horticulture), as molecular biologist. In this function she established a laboratory facility for the molecular identification of plants and also plant pathogens using DNA fingerprinting techniques. Plant variety identification using molecular markers is successfully applied to support DUS testing, to manage reference collections and to investigate suspected infringements of Plant Breeders' Rights as well as EDV. Furthermore, she closely follows the fast developments of new DNA technologies. In cooperation with academia the latest DNA technologies are implemented into the Naktuinbouw laboratory to facilitate the genetic conformity studies. In addition to applied research, she is representing Naktuinbouw in international organisations like the 'Variety Committee' of ISTA and the working group for Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) of UPOV.



DOUG WATERHOUSE

Doug is a graduate in botany and forestry from the Australian National University where he specialised in quantitative genetics. Working initially with the Research School of Biological Sciences, he worked on the forerunner to “Global Warming” before moving to the CSIRO Division of Wildlife and Ecology.

In 1978 Doug moved to the Department of Agriculture as part of the Lucerne Breeding Team and released the widely acclaimed series of varieties starting with ‘Nova’, ‘Aurora’ and ‘Aquarius’. In the 1990s he turned his attention to conservation issues and joined the then Department of Conservation and Land Management to direct their programs related to revegetation and salinity control including work on developing more than 100 native and introduced species for land and water reclamation.

After a stint as Senior Examiner, Doug has, for the last 11 years, been Chief of the Australian Plant Breeder’s Rights scheme and the Chairman of the Plant Breeder’s Rights Advisory Committee. He has been a regular delegate in UPOV sessions since 1996, a member of the Editorial Committee, Chairperson of the session on Plant Variety Protection at the Second World Seed Conference and, from 2006 until 2009.



ERIK WILBERS

Erik Wilbers, of The Netherlands, is the Director of the Arbitration and Mediation Center of the World Intellectual Property Organization (WIPO). Based in Geneva, Switzerland, with offices also in Singapore, the WIPO Arbitration and Mediation Center is an international non-profit provider of services for the out-of-court resolution of commercial disputes arising out of technology and intellectual property transactions.

Following studies in the United States and the Netherlands, Erik was a research fellow at the Max Planck Institute for Intellectual Property Law. Before joining the WIPO Center in 1996, he practiced with the law firm of Clifford Chance, was on the legal staff of the Iran-United States Claims Tribunal, and headed a division of the Compensation Commission of the United Nations Security Council.

The WIPO Center creates and operates policies and facilities that aim to enhance the effectiveness of intellectual property dispute resolution. So far, parties from around the world have used these services in over 350 cases in a wide range of subjects and values. The WIPO Center furthermore has administered over 27,000 Internet domain name cases.



GERT WÜRTEMBERGER

Dr. jur
Rechtsanwalt

Professional Career

- Legal Studies at the University of Munich and the London School of Economics (1975 – 1980)
- Internships, inter alia, at the Indo-German Chamber of Commerce, Mumbai and at the Law firm Matsuo + Kossugi, Tokyo (1980 – 1983)
- Lawyer at the law firm Wuesthoff & Wuesthoff; Partner at Wuesthoff & Wuesthoff as of 1989 (1984 – 2012)
- Scholarship for Legal Studies Kings College, London (1985)
- Doctorate at the University of Marburg, Dissertation on the Subject “Die Priorität im Sortenschutzrecht” [Priority Rights in Plant Variety Law] (1993)
- Managing Partner at Wuesthoff & Wuesthoff (2007 – 2011)
- Member of the Editorial Board of the British Journal *Intellectual Property Law & Practice*, Oxford University Press (since 2005)
- Chairman of the GRUR Expert Committee for the Protection of Plant Varieties (since 2007)
- Chairman of the Southern German Arbitration Tribunal for Seed and Plant Variety Rights Disputes (since 2010)
- International Co-ordinator of the Revista Eletrônica do IBPI – Instituto Brasileiro de Propriedade Intelectual (since 2010)
- Co-founder and partner of the law firm WürtenbergerKunze (since November 2012)

LIST OF PARTICIPANTS

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LISTA DE PARTICIPANTES

(dans l'ordre alphabétique des noms
in the alphabetical order of the surnames
in alphabetischer Reihenfolge der Namen
por orden alfabético de los apellidos)

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prepared by the Office of the Union
vom Verbandsbüro erstellt
preparada por la Oficina de la Unión*

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Mr. Maikal AVESKAMP	Senior Breeder, Limgroup BV, Netherlands
Mr. Johannes BAARS	Researcher Mushrooms, Wageningen University and Research Centre (WUR), Netherlands
Mr. Riad BAAZIA	Consultant, Switzerland
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Ms. Ronalee BIASCA	Director of Africa-Asia Agricultural Enterprise Pro Bono Program, Switzerland
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Mr. Michael GOHN	Probstdorfer Saatzucht, Austria
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