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Review

Towards a Fair Scope of Protection for Plant Breeders' Rights in an Era of New Breeding Techniques: Proposals for a Modernization of the Essentially Derived Variety Concept

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Abstract: Plant breeders' rights (PBRs) are an important IP right, and as plant breeding has a crucial role to play in sustainability, it is vital that innovations in plant breeding receive the appropriate innovation incentives. The full breeders' exemption ensures that there is always free access to the plant variety protected by a PBR for developing new varieties. The price to pay for this exemption is that PBR holders cannot prevent third parties from taking advantage of their efforts and investments in developing a new variety. This invites free-riding, at the detriment of the PBR holder. The concept of "essentially derived varieties" (EDV), introduced in 1991, provided a "fix" for this problem. It allows PBR holders to extend, at least to some extent, the scope of protection of their PBR to those varieties which use all or most essential characteristics of the initial protection variety. Decades have passed, but no adequate interpretation of the complex EDV concept has been found. The advent of new breeding techniques (NBTs) has made the discussion about a fair scope of protection of PBRs all the more relevant. This necessitates a modernization of the EDV concept, if the PBR system is to remain relevant and continue to be an innovation-incentivizing mechanism. I argue that a broader scope for the EDV concept is essential and fair. Determining what essential derivation is will remain a difficult task also in the future. This is why I have additionally proposed a collaborative reward model, which will facilitate the functioning of the EDV system and is capable of providing more legal certainty in this area.

Keywords: plant breeding; plant breeders' rights; plant varieties; essentially derived varieties; scope of protection; fair protection; new breeding techniques; genome editing; collaborative reward model; sustainability

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1. Introduction

Intellectual property rights (IPRs) form now an inseparable part of plant breeding. The foundational concept underlying all IPRs is that, in return for the disclosure of the innovation, and the understanding that this will have been at the expense of (much) financial and/or intellectual effort, a time-limited exclusionary right is granted, allowing the IPR holder to exert some type of exclusionary and, where applicable, exclusive power over the subject matter protected by the IPR. Limiting ourselves to innovations in the area of plant breeding, IPRs will provide exclusionary/exclusive rights, preventing third parties from using the subject matter protected by the IPR to use or commercialize any plant product developed by using the IPR-protected plant product. The idea underlying IPR protection for technological innovations is that, in the absence of any form of IPR protection, people will have no incentive to innovate, as any third party/competitor would be perfectly capable of free-riding on the efforts of the one who discloses the fruit of his innovative effort [1–3]. This foundational rationale is also applicable to plant breeders' rights (PBRs), even though it must be admitted that the PBR system is quite different in

some respects compared to the other typical IPR-protecting technological innovations, i.e., patent rights.

Technological developments have seen exponential growth since the 1970s [4]. Whilst induced mutagenesis has already been known for some time, genetic modification of plants by inserting exogenous DNA into a plant, which started in earnest in the 1970s, has revolutionized plant breeding. This revolution has more recently been followed up by what may be an even more important (r)evolution, genome editing, amongst whichby means of CRISPR-Cas technology [4]. These new technologies are also called new breeding techniques (NBTs). Unsurprisingly, all these new technologies have become the subject of large portfolios of IPRs. The two most important intellectual property rights in this connection are patents and the plant variety rights system, also called PBRs.

The importance of plant breeding cannot be overestimated. The business space of plant breeding is fundamental and crucial in an era where sustainability is of paramount importance for the planet's future, and plant breeding plays and will continue to play a crucial role in this. It can also be imagined that plant breeding will, in the future, play an increasingly important role in the development of therapies. Indeed, we already have the use of cannabis for medicinal purposes. Taxol, derived from the taxus plant, is commonly used in cancer treatments, and it is expected that, in the future, more plants will be the source of medicinal therapies. It is therefore vital that innovation incentive mechanisms provide the best possible mechanism for stimulating innovation in plant breeding. This is why the present review is also very timely.

This review focuses on the lesser known of the two IPRs, i.e., the PBRs. Even though it may be less well known amongst the general public and even IPR lawyers, it is a very important IPR system with a view to stimulating innovation.

As a further delineation, this review focuses on PBRs in the context of NBTs. The reason that NBTs merit specific attention is that these techniques have not only revolutionized technological development, but they have also profound effects on the functioning of PBRs. As will be demonstrated in this review, whilst traditional breeding methods of crossing and selection often take many plant generations to arrive at the desired results, NBTs can achieve technological change at a much faster pace, which means that companies using such NBTs will be capable of entering the market with their newly developed products much sooner than would have been the case if traditional breeding methods were used. Moreover, NBTs are capable of achieving much more precise and predictable results. Whilst chemically induced mutagenesis is the least precise, and is more akin to a hoping that the chemical process will produce the/a desired result, and whilst the introduction of exogenous DNA via transgenesis equally lacks the precision to ensure that the desired effect is being achieved, one of the claimed major advantages of CRISPR-Cas is that the genetic modification in the plant genome by means of the genome editing complex is much more precise. This is important, as much of the PBR system seems to be looked at through the prism of technological development in a world of traditional breeding methods, whilst this is obviously disconnected from the reality of technological (r)evolution.

This review will focus on a specific contentious aspect of PBR protection, namely the concept of essentially derived varieties (EDVs) under the PBR system. In the first instance, this review will explain what PBRs are and why the system had been devised. In the second instance, it will be discussed what the EDV concept entails and how it works. Subsequently, it will be analyzed how essential derivation can be established and what the challenges are to implement such an EDV system. In the Discussion, it will be evaluated whether a narrow or broader scope should be provided to the EDV concept. In a further aspect, proposals are made for legislative change. This paper will moreover provide a reward model, which should lead to the more effective and fair implementation of the EDV concept, whilst respecting the foundational principle underlying the PBR system of access.

2. PBRs and EDVs: Concepts and Determination

2.1. Introductory Remarks

In this section of the paper, it will, in the first instance, be explained what PBRs, or plant variety rights, are, and how they are regulated by law. In a subsequent subsection, the central concept of EDVs will be explained, and it will be analyzed how a determination of essential derivation can be made. We will, at that occasion, clarify that such determination is often complex, which can at least partly be explained by the fact that such determination needs to marry both technical aspects with legal definitions.

PBR protection is a form of IPR protection which aims to provide protection for the development of new plant varieties. One of its main features is the protection and stimulation of innovation, something that it has in common with many other intellectual property rights, including the patent system. The PBR system is, in many respects, quite different, though, from the patent system, as will be seen throughout this review. At the international level, it is governed by the UPOV Convention, and in Europe, a community plant variety right system [5] has been created based on the UPOV Convention.

The PBR system and the UPOV Convention [6] take a special place in the IPR system. It is one of the older IP rights in modern times, and its foundational rationale, apart from providing some form of exclusive right to PBR holders, has also more equitable society features than some of the other traditional IPRs, such as patent rights. The first sentence of the preamble to the International Convention for the Protection of New Varieties of Plants, signed in Paris on 2 December 1961, reads ''Convinced of the importance attaching to the protection of new varieties of plants, not only for the development of agriculture in their territory, but also for safeguarding the interests of breeders […].''

According to some commentators, "in recognition of the fact that new varieties of plants are a powerful tool to enhance agricultural and overall economic development, the States party to the UPOV Convention wished to provide incentives for sustainable plant breeding. Their aim was to guarantee the moral and material rights of breeders in respect of their varieties, in accordance with clearly defined and internationally harmonized principles" [7] (p. 233). There was an additional 1972 Act, introducing a new financial contribution system, and a Revision in 1978, solidifying the position of UPOV as an international organization, endowing it with legal personality. The 1978 Revision also allowed the United States of America to maintain their dual-right system, i.e., both PBR and patent protection for new plant varieties. The 1991 Revision is the most relevant for the present review, as it introduced the EDV concept. It was also the revision that introduced the most important substantive law changes, taking into account lessons learned from using the UPOV system since the 1960s, whilst also recognizing important scientific developments, such as the more common use of DNA-based techniques [7].

2.2. What Are PBRs and Why Do We Have the System?

A plant variety has been defined in Article 1(vi) of the UPOV Convention [6]:

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

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

A basic example can illustrate the definition. A "Golden Delicious" apple is (1) a plant grouping within a single botanical taxon of the lowest known rank, being a grouping of apples. (2) It is defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, which means that it has certain phenotypical characteristics, which can relate to both morphological and physiological traits of the variety. (3)

It is distinguished from any other plant grouping by the expression of at least one of the said characteristics, which are the specific characteristics of "Golden Delicious" apples, i.e., golden color and a mild sweet flavor, amongst other things. (4) The variety must also be capable of being propagated unchanged, which means that the specific characteristics of the variety must remain present after propagation (be it that slight variations will be inevitable when propagating plants). For instance, if a certain white rose would, after propagation, turn red, it would not fulfil this requirement and could not be labeled a plant variety.

In order to obtain PBR protection, a variety must fulfill the following requirements. According to Article 5(1) UPOV Convention, the plant variety for which protection is sought must be:

"(i) new,
(ii) distinct,
(iii) uniform and
(iv) stable." [6,8]

The abovementioned four requirements, the so-called DUS criteria, which need to be fulfilled in order to attain PBR protection, are further defined in UPOV 1991 as follows.

Novelty: Article 6 UPOV Convention:

> "The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety
>
> (i). in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and
>
> (ii). in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date." [6,8]

Distinctness: Article 7 UPOV Convention:

> "The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be." [6,8]

Uniformity, Article 8 UPOV Convention:

> "The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics." [6,8]

Stability, Article 9 UPOV Convention:

> "The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle." [6,8]

The PBR system suits the needs and demands of breeders. The most important of these are the need to obtain some form of exclusive rights for innovation in the breeding and development of new plant varieties. Second, and quite importantly, it also guarantees access to third parties to use protected varieties with a view to developing new varieties. This guaranteed access, in the form of a full breeders' exemption, is unique to the PBR system, and does not exist to the same extent in any other IPR system. This concept will be further explained in this paper.

The system is relatively low-cost, at least when compared to the rather expensive patent system, which is another point of attraction for a business where margins can be quite small.

The scope of protection is relatively narrow, i.e., protection is limited to the specific variety that will be commercialized. In this sense, it is rather different from patent protection, which commonly has a wider scope of protection. One other important design feature of the PBR system relating to scope of protection is that it is not easy for plant variety right holders to enforce their rights against competitors. Enforcement is limited to activities with the propagating material of the protected variety (Art. 14(1) UPOV 1991, typically covering production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, and stocking for any of the aforementioned purposes) and, in some very limited cases, also to harvested material. Propagating material is the common term, used in the UPOV Convention as well as in many national plant variety protection laws, to specify those parts of plants that are used (or at least could be used) for the production of the protected variety, such as grafts, cuttings, bulbs, layers, rhizomes, and seeds [9] (pp. 130–131). The term "harvested material" refers to all products of the harvest. Dependent on the variety in question, it includes fruit, vegetables, mushrooms, flowers, cereals, fodder, and fibers [9] (pp. 130–131).

Moreover, these rights are all subject to the full breeders' exemption (Art. 15 UPOV 1991 Convention), according to which it is not necessary to obtain consent from the PBR holder for a third party to use the protected variety with a view to developing and marketing a new variety (Art 15(1)(iii) UPOV 1991). The full breeders' exemption is unique to the PBR system and is in no other IPR available. This obviously also limits, to a major extent, the enforceability of the PBR.

PBR protection is a very important form of IPR protection for breeders. However, some of the concepts in the PBR system have led to debate, and modernization of the PBR system is needed, also in light of recent technological developments, such as NBTs. One area of debate relates to the interpretation of the concept of what is an essentially derived variety (EDV). This concept influences the scope of the exclusive right of the PBR, which makes it especially important, as the scope of protection of an IPR influences the extent to which the PBR holder can exercise his/her rights against third parties. As we have seen, the full breeders' exemption limits enforcement against free-riding by competitors to a major extent. A very clear but also fair scope of protection is necessary to come to an efficient and effective protection for the PBR holder. In the next section, the EDV concept is explained.

2.3. Essentially Derived Varieties: What and Why?

It is useful to start first by explaining why the EDV concept has been introduced. The concept of EDV has expanded the scope of protection of the PBR holder. As noted, prior to the UPOV 1991 Convention, PBR holders could not enforce their PBRs against third parties who used the protected variety to develop a new variety and market that new variety. This was because the full breeders' exemption allows, in principle, for using the protected variety for further breeding and marketing that newly developed variety without the consent of the PBR holder of the variety that has been used to create the new variety. The rationale for the full breeders' exemption is the fundamental principle of access. Plant breeding is an incremental and iterative process. Plant breeders use and build upon the work of previous plant breeders and rely on existing plant varieties for the initial source of genetic variation [10] (p. 205), which requires access.

The full breeders' exemption is unique in IP rights. To take the example of the other IP right that protects technological innovation, patent law, it is not allowed to use the patented protected to develop a new product, without having obtained a license from the patent holder for this use. There is a limited research exemption in most patent law systems, but this is, in general, quite narrowly defined and will only cover acts done on the

patented subject matter for the purposes of research, i.e., where one uses the patented subject matter to do research on that patented subject matter. It will, in any event, never cover the use of a patented product with a view to develop a new, possibly competing product. More recently, in Europe, some countries have introduced a limited breeders' exemption, in most cases inspired by the limited breeders' exemption introduced in the so-called UPC system (Art 27(c) Agreement on a Unified Patent Court), according to which "The rights conferred by a patent shall not extend to any of the following: […] (c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties." This Agreement has not yet entered into force, it must be emphasized [11]. The limited breeders' exemption allows third parties (and hence also competitors) to use a patented plant for the development of a new plant (variety), but any commercialization of such a new plant (variety) would still require the consent and hence license of the patent holder [12]. The limited breeders' exemption in patent law guarantees access to plant material whilst at the same time safeguarding the legitimate interests of the patent holder.

In the absence of an EDV concept, and in light of the full breeders' exemption, initial PBR holders would see competitors using their innovative effort and investment to develop and market varieties that largely use the genotype of the initial PBR. This implies that competitors developing and commercializing mutations based on the protected variety can do so without restrictions, effectively eating away at the profits of the plant variety right holder. This, in turn, may have rather negative consequences in terms of the preparedness of breeders to go through the laborious process of filing for PBR protection in the first place. This was seen as unfair, as it invites free-riding, and was deemed contrary to the innovation incentive idea underlying the PBR system. Indeed, most IP rights start from the underlying rationale that, in the absence of any kind of enforceable right, market players will have no incentive to invest in innovative activities [1–3].

The full breeders' exemption and its consequences is the conundrum with which breeders have to live. Because access is a cornerstone of the PBR system, doing away with the full breeders' exemption was never deemed an option. However, not doing anything else was also deemed not an option, as it could have made the PBR system ineffective and, even worse, uninteresting for users. Something needed to be done to protect the legitimate expectations and rights of the plant variety right holders.

There were a number of paths that could have been followed. One path could have been to replace the full breeders' exemption with a limited one, as we now know in the patent acts of some countries. A limited breeders' exemption would guarantee access, but consent would be required to commercialize any variety whose development would have required access to a PBR protected variety. The advantage of such a solution is its transparency and clarity. The major disadvantage of the limited breeders' exemption is that it covers all PBR-protected varieties for any use, and is hence not only limited to EDVs. Such a solution might look too akin to some of the stronger exclusive rights known under the patent system, and it could be understood that this was maybe not the most desirable path to follow.

Another option was to introduce a system where access was guaranteed, but where the commercialization of a variety that has been developed by using most or all characteristics of a PBR-protected variety would require consent. This would provide a narrower scope of protection than the more blanket-style scope under the limited breeders' exemption. For better or for worse, such a system was introduced in the form of the EDV system.

The rationale was hence to extend the scope of protection of the PBR holder so as to allow him/her to enforce his/her rights and protect his/her investment in the innovative activity of developing new varieties. Indeed, a new variety—for instance, a new mutation—can relatively quickly create a new market, become a best-seller, and consequently eat away any profits that might have otherwise gone to the original PBR holder. The "quickly" is relative, but nevertheless important, as, depending on the type of variety, it

may take 1–2 years in a greenhouse to prove stability, followed by 3 years of environmental field trials to gather agronomic data and a further year to receive variety approval (the latter likely more applicable to crops than at least some ornamentals). There will additionally be some time required to achieve adoption in the market for the new variety, which will equally be dependent on the type of variety, i.e., ornamentals or crop, and even within these, there could be differences in lead time to adoption.

The advent of new breeding technologies (NBTs) such as molecular technologies, genetic engineering, and genome editing technologies has only made this shift more relevant. In the earlier days of plant breeding, it was a rather time-consuming process, and this long period of time provided, in effect, some lead time advantage to the breeder of the original variety (or, as it is called in UPOV speech, the "initial variety" (IV)), as any competitor would also have to go through the same lengthy process to bring his/her new competing variety to the market (which requires some form of regulatory approval). This lead time advantage has started to disappear with the NBTs, which are capable of introducing mutations in a much faster way than was conceivable in the past. This speedier process has as a consequence that these new mutations can enter the market, and hence compete with the IV (which is PBR-protected), much faster than was ever imaginable with traditional breeding methods. For example, a color mutation inserted via NBTs in flowers could have a very important effect on the market position of the variety from which the color mutation was made, potentially destroying the entire market for the "out of fashion" color flower. The flower with the new color would clearly be distinct from the "older" color variety, and could hence obtain a PBR in its own right. However, it would have been predominantly derived from the "older" color flower variety, which has obtained also a PBR. In the absence of a concept such as the EDV concept, it would not be possible for the PBR holder for the "older" color variety to exercise his/her rights against the new color variety. Introducing a feature in the PBR system allowing the right holder to enforce his rights vis-à-vis third-party developers using the protected variety was an obvious means to provide a more effective form of PBR protection.

Under the new EDV provision, if the normal protection requirements (novelty, distinctness, uniformity, and stability) are fulfilled, the breeder of an EDV is granted a PBR and may thus assert all rights resulting from variety protection against any third party. Use of the protected variety, called the initial variety (IV), for purposes of breeding an EDV, is also allowed without the consent of the PBR holder for the IV. However, the marketing of the EDV requires the authorization of the breeder of the IV from which it was essentially derived. The result is that the breeder who desires to exploit commercially an EDV requires the permission of the owner of the IV such that this owner can reap some of the reward for his "efforts" to create the IV, upon which the subsequent creation was dependent.

An EDV has been defined in Art. 14(5) UPOV 1991:

"Art. 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,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected 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."

There are hence three fundamental conditions that must be fulfilled to qualify as an EDV. The first one is that the EDV is predominantly derived from the IV. Second, the EDV is clearly distinguishable from the IV. Third, the EDV conforms to the IV in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. All these conditions must be cumulatively fulfilled.

The UPOV 1991 Convention provides a couple of examples of breeding techniques that may result in EDV designation, in particular:

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.

2.4. When Is There Essential Derivation?

An important question is how to determine whether a new plant variety is essentially derived or not. The problem is that no clear definitions have been provided for the above-mentioned three criteria to qualify as an EDV. The UPOV Convention merely refers to the aforementioned examples, but further guidance is absent. There is a general consensus, not only in the literature [10,13,14] but also amongst users of the system [15,16], that the provision is very complex.

Fundamentally, essential derivation is determined by conformity (which is the same as "similarity" in common parlance) to the initial variety and predominant derivation from the IV. It is of course given that the EDV is distinct from the IV.

The main issue is to distinguish between cases where a new variety is derived from the IV, but does not trigger the EDV concept, and cases where it is essentially derived from the initial variety, and which triggers the EDV rule. During the negotiations for the UPOV 1991 Convention, it was already made clear that this was always going to be a rather difficult task: "from a technical point of view it was rather difficult to decide what was an essentially derived variety and what was not" [17] (point 1119, p. 346). The Japanese delegation pleaded for the development of guidelines, as it "felt that it was very important to have criteria common to all member States on the distinction between essentially derived and other varieties" [17]. The Diplomatic Conference adopted a resolution to that effect [18] (p. 122 and p. 349).

Conformity

How, then, is conformity to the IV determined? Article 14(5) UPOV states that:

"(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." Essential characteristics refers in this context to "important" or "relevant" characteristics of the variety.

The wording "conforms to the initial variety in the expression of the essential characteristics" seems to suggest that the differences cannot be substantial. Moreover, we know that it must be distinctive from the initial variety, as this is also a requirement of the EDV concept. However, more specific guidance is absent in the text of the UPOV Convention.

Traditionally, conformity is based on close phenotypic resemblance, on small differences in some inherited traits, or on a strong genetic similarity [19]. Determining what is an essentially derived variety is hence a rather difficult challenge, as it involves multiple characteristics, both phenotypic and/or genotypic similarity. Over the years, especially the

International Seed Federation (ISF) has put considerable effort into establishing quantifiable scientific approaches to determining whether a variety is an EDV (discussed in more detail further below in this review).

Predominant derivation

What, then, is predominant derivation? According to CIOPORA, "Predominant derivation is given if material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety, has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists" [15].

It requires the demonstration of the use of the IV in the development of the EDV. It has, in this connection, also been said that the requirement of predominant derivation is a question of genetic origin: "The question of genetic origin is simply an issue of determining the pedigree of the putative EDV and that its genealogy can be traced to the alleged initial variety" [13] (p. 509).

Predominant derivation can be established in different ways, such as through the evaluation of heterosis of the cross between putative EDV and IV (expected to be negligible in the case of essential derivation), by phenotypic markers (more recently, molecular markers in some species), or pedigree notes [19] (p. 526). The use of molecular markers is now a common approach. There are multiple techniques available here. One of them, which has been used in the case law, assesses relationships based on so-called amplified fragment length polymorphisms (AFLPs). Amplified fragment length polymorphism polymerase chain reaction (AFLP-PCR) is a relatively cheap, easy, fast, and reliable method to generate hundreds of informative genetic markers. This allows one to determine genetic diversity, and hence also genetic origin [20–23].

ISF's view on predominant derivation can be found in its "ISF View on Intellectual Property": "ISF is of the opinion that, for the purpose of EDV assessment, 'predominant derivation' may result from:

(i). The use of plant material of an initial variety for transformation by genetic engineering, selection or back-crossing followed by selection in the breeding process,

or

(ii). The use of molecular marker data, of an initial variety for the purpose of selection of genotypes very close to the genotype of the initial variety, or in the case of hybrids for the purpose of selection of genotypes very close to the genotype of its parental line(s) or of the initial hybrid itself" [16].

This also gives more insight into how conformity may be determined. Molecular markers [24], phenotypic traits, genetic similarity, etc., can all be used to establish conformity and hence also predominant derivation. The scientific and quantifiable approach will seek to estimate genetic conformity based on all of the aforementioned factors, and if this conformity exceeds a certain "generally accepted threshold", there is a prima facie case for essential derivation. The holder of the now putatively essentially derived variety must then prove that he has not used the initial variety in line with the aforementioned thresholds, by, for instance, submitting breeding records [10] (p. 218) [25].

This approach has led to the development of a number of quantitative tests to determine the degree of similarity, and with this also the threshold for such similarity beyond which predominant derivation and, by consequence, essential derivation can be decided [26]. The ISF has done this exercise for a variety of crops, such as ryegrass [27], maize [28], oilseed rape [29], cotton [30], lettuce [31], and mushrooms [32]. It has further developed threshold criteria in its arbitration system [33].

2.5. Challenges in Determining Essential Derivation

The quantitative and statistical analyses touched upon above are not without their problems: "The 'new' variety is highly genetically similar, because of the explicit use of the protected variety in the breeding process, but simultaneously just enough phenotypic

difference was introduced to allow the 'new' variety to pass the UPOV distinctness test, which would make the 'new' variety eligible for breeders' rights. […] The most controversial of these requirements concerns the estimation of the degree of conformity between initial and potentially derived variety. Dispute exists around empirical and statistical questions regarding the optimal traits and test statistic to be used" [34] (p. 36).

The challenge and problem with all these scientific approaches are that one tries to quantify a fundamentally legal question: how different does a plant variety need to be in order (not) to be considered essentially derived? This is not unique to the PBR system. Other IPR systems have equally quantitative and qualitative analyses to make. For instance, in copyright, to determine infringement, some form of quantitative copying will need to be identified, even though qualitative criteria are also used. In patent law, when seeking to determine whether there is infringement by equivalence, some quantitative factors are inevitably taken into account as well, but again, qualitative factors will also be relevant.

A quantitative approach might not always provide the desired (or indeed desirable) answer. Sanderson correctly points out that "a plant species may have a narrow genetic base and therefore have inherently high genetic similarities" [10] (p. 220). He refers in this connection to cotton (Gossypium), whose genetic diversity is small compared to other plants [35]. In these situations, it is very difficult to determine reliable standard thresholds for the determination of essential derivation.

In the rare court decisions we have in this area, the controversial nature of these quantitative criteria has also been exposed, and the courts genuinely struggled to come to an informed decision based on quantitative methods—not to mention that they came to contradictory conclusions [36–42].

Furthermore, Sanderson points to the fact that the use of molecular markers to assess essential derivation can also be a mechanism to undermine the intention of the EDV system: "Ironically, a plant breeder may use marker-assisted breeding to evade a declaration of essential derivation. This could be achieved through the selection of a molecular marker profile that is 'sufficiently different' from the initial variety. For instance, if the threshold for variety Y is 90 per cent, it may be possible to ensure that subsequent varieties will show genetic thresholds 85 per cent or less, despite there only being minor changes made to the initial variety. While the new plant variety may be quantitatively outside the boundary established for essential derivation, it may still draw on the important or essential features of the existing variety for its commercial appeal to the industry" [10] (p. 221).

Quantitative methods can be "used" in a way that creates varieties that marginally differ from the initial protected variety so as to ensure that they do not meet the quantitative threshold levels.

Moreover, one of the underlying problems has always been that the EDV concept has been developed with phenotypical differences in mind. However, in an era of NBTs, new varieties can be developed that predominantly use the characteristics of the IV, which implies that more emphasis also needs to be placed on the genetic characteristics of the variety used for further breeding.

Finally, it must be admitted that the discussions about the ideal scope of the EDV could also be affected by the nature of the varieties at issue as well. Discussions for ornamentals and fruit could be different from those for food crops. The reader should be aware of the wide range of products to which the PBR system and hence also the EDV concept can be applied.

2.6. The UPOV 2017 Explanatory Notes

For many years, UPOV discussed with its member states the creation of guidelines. This finally led to the UPOV 2017 Explanatory Notes [43].

The Explanatory Notes say that:

"5. The phrase 'while retaining the expression of the essential characteristics' requires that the expression of the essential characteristics conforms to and be derived from the initial variety.

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

(i). essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety;
(ii). characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user;
(iii). characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics;
(iv).essential characteristics may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS);
(v). essential characteristics are not restricted to those characteristics that relate only to high performance or value (for instance, disease resistance may be considered as an essential characteristic when the variety has susceptibility to disease);
(vi).essential characteristics may be different in different crops/species."

The Explanatory Notes continue by saying that:

"8. A judgment on the question on the degree of conformity must be reached on the basis of the essential characteristics which result from the genotype of the initial variety."

There is a wide variety of such characteristics that qualify for this purpose.

From paragraphs 9 and 10 of the Explanatory Notes, it can be derived that UPOV had a narrow scope of the EDV concept in mind:

"9. The words 'except for the differences which result from the act of derivation' do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by Article 14(5)(b) (i) and (iii). *The differences must not be such that the variety fails 'to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety'.* (emphasis added)

10. The examples given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few. However, if there are only one or few differences that does not necessarily mean that a variety is essentially derived (emphasis added)."

Mutants, referred to in the UPOV 1991 Convention as an example of an EDV, can often have more than just a few or minor differences. This makes it difficult to reconcile the text of the UPOV Convention with the Explanatory Notes, which seem to suggest that more than a few such differences are assumed to be counter-indicative of an EDV.

The UPOV Explanatory Notes did consequently not only not clarify very well when there is essential derivation: there was also disagreement as to whether the approach taken in the Explanatory Notes, i.e., a quite narrow interpretation, was in line with the spirit of the UPOV Convention, and/or with the entire purpose of introducing the EDV concept in the UPOV 1991 Convention in the first place.

There has been dissatisfaction with the path taken by UPOV with the 2017 Explanatory Notes among the users of the UPOV system, and this has led UPOV in 2020 to open the 2017 Explanatory Notes for renegotiation. The latest draft of the Revised Explanatory Notes departs substantially from what was said in the 2017 Notes [44]. I will revert to the Draft Revised Explanatory Notes in Section 4 of this review.

3. Discussion

3.1. Introductory Remarks

In the present section, it is evaluated whether a narrow interpretation of what is deemed to be an EDV, as suggested by the UPOV 2017 Explanatory Notes discussed earlier, is in line with what the framers of the UPOV Convention had in mind. In the second

instance, it is also evaluated, if the answer to the previous is negative, what should be the way forward to come to a fully functioning EDV concept in the UPOV system.

3.2. A Narrow or Broader Interpretation of the EDV Concept

As explained, the rationale of the EDV concept is to provide a fair protection to the breeder and PBR holder of the IV, to mitigate at least partly the commercially negative effects of the full breeders' exemption. As also emphasized earlier, the advent of new breeding technologies (NBTs) such as molecular technologies, genetic engineering, and genome editing technologies has made the requirement to obtain a fair scope of protection even more important and meaningful, as NBTs allow the relatively swift introduction of mutations, which can outcompete the variety of the IV PBR holder, whilst the new variety is predominantly derived from this IV. For instance, disease resistance could be incorporated into a variety, which would distinguish the IV from the later variety only by the presence of the disease resistance in the later variety. Introducing resistance against citrus canker (Xanthomonas citri) creates an important phenotypical difference, but the new variety will have a high degree of genetic conformity.

One critical question to discuss is how broad the scope of the EDV concept should be. Clearly, a very narrow scope would make it relatively easy for competitors to escape the "claws" of the EDV concept, and hence the requirement to obtain consent from the IV PBR holder to market his EDV. A broader scope would require the then EDV breeder to ask for consent in a wider variety of circumstances for the use of the IV in commercializing the EDV. Breeding of an EDV without consent will always be allowed under the full breeders' exemption.

We have seen that the UPOV 2017 Explanatory Notes have chosen the path of a narrow interpretation of the EDV concept. This is particularly made clear in paragraphs 9 and 10 of the Explanatory Notes, reproduced here once more for clarification:

"9. The words 'except for the differences which result from the act of derivation' do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by Article 14(5)(b) (i) and (iii). *The differences must not be such that the variety fails 'to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety'.* (emphasis added)

10. The examples given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few. However, if there are only one or few differences that does not necessarily mean that a variety is essentially derived (emphasis added)."

This seems to suggest that more than one difference will lead to the conclusion that the variety developed on the basis of an IV is no longer an EDV.

We have also seen that a number of quantitative tests have been developed, but as discussed at that occasion, these tests have equally often not led to results that provide more legal certainty. At least one reason that it has proven to be so difficult to implement is that the entire concept of EDVs is "a hybrid concept: creating scientific, legal and pragmatic questions" [10] (p. 206). Another reason is also that the statutory text is notoriously difficult to understand [45].

In other words, there are fundamentally two camps. Some have argued that the EDV concept should be interpreted very narrowly, i.e., that only those new varieties that have one or very few modifications from the initial variety can fall within the scope of protection of the right holder of the IV. In this context, reference is sometimes made to "plagiarism" [46] (p. 55) [13,45,47,48]. The term "plagiarism" has been cast deliberately in this context, as the word has a natural negative connotation. It purports to say that only those varieties that try to be very closely related to the IV are covered by the EDV concept, or in other words, those that try to "plagiarize" the IV, distinguishing only in cosmetic differences (and I have to say that by using the wording "cosmetic" differences, those who have cast the term "plagiarism" in the context of EDVs have made the situation even more confusing, as it is not clear what a minor cosmetic difference could be, especially in the area

of ornamentals). The use of the wording "plagiarism" is somewhat unfortunate and also confusing, but it is referred to in this review, as it has seen rather widespread use in the literature professing a narrow interpretation of the EDV concept. It is confusing as the term "plagiarism", well known in the area of copyright law, is, in legal reality, not necessarily limited to what is almost an identical copy of the original, or which has only cosmetic differences.

Others argue that limiting the EDV protection mechanism to "plagiarism" would be tantamount to introducing no additional scope of protection whatsoever in any meaningful way [15,49]. I would agree with the latter position, for reasons that I will elaborate on further below.

In determining the exact (desirable) scope of the EDV concept, it is useful to look at the text and context of the relevant provision. The text of Art. 14(5) UPOV 1991 in itself does not allow us to derive a very clear meaning of the scope of the EDV concept. This is also supported by what the Japanese delegation said during the 1991 Diplomatic Conference: "from a technical point of view it was rather difficult to decide what was an essentially derived variety and what was not" [17].

Coming back to the narrow interpretation, it should be made clear that the UPOV Convention and its preparatory works make no reference to this criterion of "one or very few" modifications of the IV. To the contrary, a suggestion to limit the scope of the EDV concept to very few differences was explicitly rejected during the UPOV 1991 Convention negotiations. Indeed, the German delegation made the following proposal: "(b) For the purposes of subparagraph (a) (iv), a variety shall be considered to be an essentially derived variety when (i) it is the direct descendent of another variety ('the initial variety') and retains, **subject to a very small number of modifications**, the expressions of the characteristics which result from the genotype or combination of genotypes of the initial variety and (ii) it is clearly distinguishable from the initial variety" [50] (p. 132). This proposal was rejected by a large majority: "The proposal of the Delegation of Germany, reproduced in document DC/91/92, concerning the definition of essentially derived varieties was rejected by four votes for, 14 votes against and two abstentions" [50] (p. 344).

Why, then, does some of the literature and the UPOV 2017 Explanatory Notes claim that the concept of EDV should be limited to "only one or very few" modifications? The "confusion" may stem from the fact that, in the Explanatory Notes prepared in 1989 by the Office of the Union in the context of the revision of the UPOV Convention, it was said that "(ii) The derived variety must retain almost the totality of the genotype of the mother variety and be distinguishable from that variety by a very limited number of characteristics (typically by one)" [51]. This position seems, however, to have been overruled by the aforementioned vote.

Taking the rejection during the negotiations of the narrow interpretation of "only one or very few", the only logical conclusion that can be drawn is that the legislature must have had a broader interpretation of the EDV concept in mind, and that the limitation of the EDV concept to "plagiarism" cases is not correct in law.

Marker-assisted breeding is an area that exemplifies how a test of plagiarism proves to be inadequate for determining essential derivation. A breeder can select a molecular marker profile that is "sufficiently different" from the initial variety [52]. An example from the literature is the following: "If the threshold for variety Y is 90 per cent, it may be possible to ensure that subsequent varieties will show genetic thresholds 85 per cent or less, despite there only being minor changes made to the initial variety. While the new plant variety may be quantitatively outside the boundary established for essential derivation, it may still draw on the important or essential features of the existing variety for its commercial appeal to the industry" [10] (p. 221). In a test of essential derivation that would be based on "plagiarism", such a derivation might not be a plagiarism, and hence an essentially derived variety, even though it still derives most of the crucial and essential features from the protected initial variety.

How broad the scope of the EDV concept then should be is unfortunately equally not clear from the preparatory works, but could probably be derived from a teleological interpretation of the intentions of the legislature. This is allowed under the Vienna Convention on the Law of Treaties, which is the Convention that is used to interpret international treaties.

We can find some clues in the fact that the aim of the revision of the UPOV Convention was, amongst other goals, to "strengthen the rights of the breeder" [53]. Considering that the narrow interpretation was rejected during the negotiations, and accepting the factually correct aim of the revision of the UPOV to strengthen the rights of breeders, it is logical to conclude therefrom that the aim of the legislature was to provide a more extensive scope of protection to the right holders compared to what existed in the absence of the EDV concept. Accepting this as a valid rationale for introducing the EDV concept in the UPOV 1991 Convention, any interpretation of the EDV concept that would be narrowly interpreted (and which would *de facto* not provide any reasonable scope of protection for IV holders beyond what already existed prior to the introduction of the EDV concept) would not be in line with the intention of the legislature as per the preparatory works.

The scope of protection under the EDV concept should be that a variety is an EDV of an IV if—except for the differences which result from the act of derivation—the EDV conforms to the IV in the expression of the essential characteristics. Such an interpretation would do justice to the efforts made by the breeder of the IV, and it is only fair to the said IV breeder if he does not see a third party commercialize a variety that is predominantly based on the IV.

The above conclusion can be illustrated with a couple of examples. Mutations, but also new breeding techniques (NBT), do not aim at plagiarism (which is the name given in the literature to the narrow interpretation of the EDV, which only covers very minor differences), as they do not necessarily aim to provide just a minor cosmetic difference, whatever those who have cast the term "plagiarism" in the context of EDVs may have meant to say by using those terms. However, they could and should nevertheless still fall under the EDV concept. It is difficult to see how a color mutation could aim at plagiarism (in the meaning of a narrow interpretation of the EDV concept, being only a minor difference with the IV). A white and a red variety of roses are clearly not plagiarism to one another, as the color of the rose is an important difference between the two varieties of roses. However, the color mutation will be predominantly carried out on the variety (IV) used to breed a new variety with the new color. Equally so, it is also difficult to see how genome editing techniques using CRISPR-Cas could aim at plagiarism. Knocking out one or more genes, or introducing one or more mutations with genome editing, can hardly be called plagiarism, as meaning being only a minor difference. However, these technologies are applied to varieties developed by the IV breeder, and for which PBR rights could have been obtained. The varieties obtained by such technologies are predominantly derived from the IV. Moreover, such new varieties could still be an EDV, at least in our view.

Another example is the so-called Arctic Apple® [54]. According to the developers of the new variety, "when the cell of a typical apple is ruptured—for example, by biting, slicing or bruising—polyphenol oxidase (PPO) found in one part of the cell mixes with polyphenolics found in another part of the cell. (PPO is a plant enzyme. Polyphenolics are one of the many types of chemical substrates that serve various purposes, including supplying its aroma and flavor.) When PPO and polyphenolics mix, brown-toned melanin is left behind. Arctic® apples produce practically no PPO so that enzymatic browning reaction never occurs. This means Arctic® apples' polyphenols aren't burned up when the apple is bitten, sliced, or otherwise bruised" [54]. Further, according to the developers, the result was achieved by identifying the four genes that are responsible for apple browning, and by gene silencing to turn down the expression of PPO [54]. The Arctic Apple® can be seen as an EDV from an initial variety as—except for the differences which result from the

act of derivation—it conforms to the initial variety in the expression of the essential characteristics. It is an example in Art 14.5 (c): a natural or induced mutant, […] or transformation by genetic engineering.

It has been argued that a very narrow interpretation of the EDV should be retained, because a different interpretation—in other words, one which provides a broader (and in my view fairer) scope of protection—could have severe consequences on concentration in this field of business. The reasoning is that, by providing broader protection to the IV PBR holder, more market power would be given to the IV PBR holder, which may lead to a greater concentration of market power with a small number of companies [55].

It is indeed true that there is a worrying development that more and more market power is concentrated in a few companies, and this is a reason for concern. Intellectual property rights are, however, not necessarily the right tool to tackle these problems. All IP rights give, to some extent, a monopolistic type of position to the IP right holder (provided there is no substitution). Following the reasoning that a broader and fairer scope should not be given to a legal concept because it might have an effect on market power, ALL IP rights should be abolished. This is surely not what many people want, even though some of course do.

It is an inevitable consequence of an effective and enforceable IP right that it could potentially affect subsequent development. However, this is true for all IP rights, and PBR are not so fundamentally different from other IP rights that they should only attain IP protection that is virtually not enforceable. PBRs already provide for guaranteed access, one of the cornerstones of the right. The point is that an IP right that is very difficult or impossible to enforce effectively against competitors takes away all incentives to innovate in the first place. Moreover, if there is no initial innovation, there will be no subsequent innovation. It is not possible to provide meaningful and fair PBR protection to breeders without inadvertently having an effect on those other breeders who want to benefit from the innovation from the IV right holder; the latter may have been many years in the making at considerable cost and effort. One cannot have one's cake and eat it. Rights come with consequences and obligations. You cannot expect that you can benefit from the innovation from someone else without having to provide in some form for compensation. This is the fundamental principle on which all IP rights are based. It is very difficult to see why this rationale should not apply to the interpretation of the EDV concept. This is the reason also that the "plagiarism" test cannot provide an adequate form of protection. It is also the reason that until and unless a broader interpretation is given to the EDV concept, users will continue to question the fairness of the system and the suitability of it for their business activities. If no changes are made, the EDV concept will continue to haunt the legislature for many years to come.

It deserves furthermore mentioning that even though private investment in agricultural research and development (R&D) is growing considerably, public investment, due to market failures, is still important [56]. This should not detract, however, from the above argument made regarding the potential (whether this is in the near or more distant future) for market concentration, compounded by the existence of important IP portfolios (largely patent rights), which, in the case of more platform-based technologies (such as CRISPR-Cas), could lead to important market control.

For this reason, and adding to what has been said earlier, a broader interpretation of the EDV concept is required.

4. A Proposal for a Fairer and More Pragmatic Solution

4.1. Amend the UPOV EDV Explanatory Notes

It has been established above that a narrow, plagiarism type of interpretation of the EDV concept is not only not in line with the intention of the framers of the UPOV 1991 revision, but it is also fundamentally unfair towards the breeders. This is why a broader interpretation must be used.

The question is now how to implement such a policy. I propose a multi-layered approach. In the first instance, the UPOV 2017 Explanatory Notes need to be amended with a view to ensuring that the "one or very few" language is erased from these Notes. At the time of writing of this review, UPOV has indeed opened the Explanatory Notes, and I hope that a broader interpretation, which is fundamentally correct and fair, and which has been pleaded for in publications in 2020 [57], gains implementation into these Explanatory Notes. It is encouraging to see that the latest Draft of the Revised Explanatory Notes [44] seems to take such a broader approach indeed.

This Draft is mindful of the genetic source of the EDV. It states in paragraph 5 of the Draft: "In that respect,

(a) Varieties with a single parent ('mono-parental' varieties) resulting, for example, from mutations, genetic modification or genome editing are per se predominantly derived from their initial variety.
(b) Varieties involving the use of two or more parents ('multi-parental' varieties) may be predominantly derived from one parent (the initial variety) by selectively retaining the genome of the initial variety, for example through repeated backcrossing. In this case, crop-specific genetic conformity thresholds might be defined in order to determine predominant derivation, i.e., beyond a level that would be obtained by normal crossing and selection with the initial variety."

This suggests in any event that mutations made by NBTs are at least in this Draft per se considered to be EDVs.

Relevant in the Draft is equally the clarification of what is an "essential characteristic". Indeed, in line with the approach followed in this review, and indeed in earlier articles [57], a conclusion of EDV can be made if the essential characteristics of the IV can be found in the EDV. This is now explained in the Draft in paragraphs 7 and 8: "7. An essential characteristic is a characteristic that results from the expression of one or more genes or other heritable determinants and includes, but is not limited to, morphological, physiological, agronomic, industrial and/or biochemical characteristics.

8. An 'essential characteristic' is a characteristic that:

(i). contributes to the principal features, performance or value of the variety; and/or
(ii). is relevant for the producer, seller, supplier, buyer, recipient, or user of the propagating material and/or of the harvested material and/or of the directly obtained products; and/or
(iii). is essential for the variety as a whole." Noteworthy is that reference is made to characteristics that contribute to value, and/or which are relevant for the producer and seller. Paragraph 11 continues by saying that a "predominantly derived variety typically retains the expression of essential characteristics of the variety from which it is derived, except for those differences resulting from act(s) of derivation, which may also include differences in essential characteristics."

I interpret this to include a situation where a new variety is developed through NBTs, and wherein most of the essential characteristics of the IV are retained in the variety derived therefrom, except for the differences resulting from the NBT change, which could, for instance, be a mutation of a gene, or knocking out a gene in the plant variety.

Crucially, at least in the present Draft, the "one or very few" feature has been abandoned. Indeed, the Draft now states that "13. Article 14(5)(b) (iii) does not set a limit as to the number of differences which may exist where a variety is still considered to be essentially derived. The number of differences between an EDV and the initial variety is therefore not limited to one or very few differences but may vary taking into account different methods of derivation. The differences may also include essential characteristics." This once again confirms the approach advocated by the present author since 2019, i.e., that a narrow interpretation of the EDV concept is fundamentally against the will of the legislature and is unfair.

4.2. A Reward Model for EDVs

The second prong of my multi-layered approach is related to the question of how a policy incorporating a broader interpretation of the EDV concept can practically be given shape. Amending the Explanatory Notes, however important, as these provide guidelines for users and courts, will very likely still lack the required level of detail to resolve a specific practical EDV claim. I have explained earlier (see sub 2.5) that many quantitative methods to determine predominant derivation have not necessarily led to the desired level of legal certainty. This implies that those quantitative methods will continue to present issues, even with a broader interpretation of the EDV concept as proposed here. In the latest Draft Revised Explanatory Notes, reference is also made to those quantitative methods: "33. With regard to establishing whether a variety is an EDV, the existence of a relationship of essential derivation between varieties is a matter for the titleholder of the breeder's right in the initial variety concerned. The titleholder of the initial variety may establish predominant derivation (e.g., evidence of genetic conformity with the initial variety by DNA-based genetic analysis) or conformity of the essential characteristics. These are both possible starting points in providing an indication that a variety might be essentially derived from the initial variety."

The consequence is that, even if the new Draft Revised Explanatory Notes would become final in their present form, the determination of what would now be a broader concept of EDV would still, to some extent, require an evaluation of essential derivation by quantitative methods.

Therefore, a more creative but also more experimental alternative solution is suggested in the form of a reward model whereby access will always be guaranteed (as this remains a central pillar of the PBR system), but payment of a user fee will be required for commercialization. This alternative model starts from a voluntary collaboration in the model scheme in the first phase of the model, but it could easily develop into an obligatory sector-specific model, which would require all players in a specific breeders' sector to participate in the model. The model does not determine whether it should be made obligatory, but this option is open. Even though I do not currently envisage that this model would be incorporated into statutory law, this does not take away any of the advantages of the model, as voluntary or sector-specific obligatory models can equally be effective. The major advantage of the model is that it will at least partly do away with the quantitative methods to determine whether there is essential derivation. As the basis of the model starts from the principle that a conclusion of EDV is given once the alleged EDV uses most essential characteristics of the IV in the EDV, it does not require a further determination of whether it is an EDV based on quantitative methods. One could argue that it might become necessary in the future to set some standards for this determination. This could or could not be true, but as my model lays down the principles, the details can be worked out in future projects. In any event, as the scheme is based on a collaborative and contractual relationship, it might provide, in fact, more legal certainty than an uncertain outcome to be determined in a court decision, based on quantitative methods.

The model is based on a liability model, originally conceived in a different context by Reichman [58]. The aim of the model, conceived in the context of what he called sub-patentable inventions (i.e., inventions which should in fact never have received patent protection because they are not or marginally new and inventive) was to "avoid measures that impoverish the public domain or that otherwise foster legal barriers to entry, while empowering entrepreneurs to prevent free riders from rapidly appropriating the fruits of their investment in small-scale innovations without contributing to the cost of development" [58] (p. 1777). His idea was to replace the patent system for certain types of sub-patentable inventions with a type of liability system, where inventors can claim some sort of exclusive right into their inventions, but they could not prevent third parties from using their inventions for further development. Third parties using the innovations for further development would then be liable to compensate the original inventor for the use of the

invention. The model presented here borrows some features of the model developed by Reichman, but it differs substantially in other aspects.

How could one then implement such a model? As noted, it starts from a rather broad definition of what is an EDV, also as this is in line with the intention of the legislature, as set out earlier, and is now adopted in the latest Draft of the Revised EDV Explanatory Notes. All varieties that use most of the essential characteristics of the initial variety would be deemed to be EDVs. The concept that the developer of the IV obtains some sort of exclusivity in the IV is also retained in this model. All the developers of such EDVs would then be under an obligation to pay compensation to the IV right holder for the use of the IV in the development of their EDVs. The model is based on a reversed burden of proof. Once the IV PBR holder has provided evidence that its protected PBR has been used to develop a new variety, the model enters into force, and the use by a third party of a protected variety will trigger the payment of a use right. It is up to that third party to prove that the protected variety has not been used for the development of the new variety. If this proof is successful, no use right, and hence no payment, is due.

What are the advantages of the model?

(1) It gives a concrete application to the EDV concept as laid down in the treaty.
(2) The developer of the IV receives compensation for the use of his variety.
(3) The developer of the IV is capable of sharing in the proceeds of the EDV that has been developed on the basis of the IV and which EDV will, in many cases, be in competition with the IV. By providing an obligation to give compensation to the IV PBR holder, the loss of profits that typically accompanies the entering into the market of the competing EDV can at least be compensated, introducing an element of fairness into the system.
(4) It largely does away with the complexities and uncertainties of evidencing what is exactly an EDV. The present model largely eliminates the need for such complex and uncertain analyses, thus providing more legal certainty, and moreover providing adequate remuneration for the initial plant variety right holder.
(5) Importantly, it respects one of the fundamental principles underlying the PBR system that guarantees access to germplasm for further breeding.
(6) Innovation in breeding will be stimulated, as everyone benefits from the system. The EDV breeder gains access to valuable germplasm, and the IV PBR holder can share in some of the proceeds when the EDV is commercially successful.
(7) The ISF Regulation for the Arbitration of Disputes concerning Essential Derivation [59,60] could also become the starting point for the development of a Dispute Resolution Scheme under the proposed model. This Regulation would obviously require amendments, as the current Regulation assumes that the prima facie evidence of EDV is determined by means of largely quantitative factors, which, under the model proposed here, would no longer be necessary.

The model presented above will require further implementation, which can be done once there is sufficient support for the principles underlying the model. In developing this model, I have equally taken inspiration from collaborative models already in place for (plant) innovations in the patent space. Patent pools are one good example, which are based on the principle that holders of patents pool their respective technologies together (as they might need access to each other's patents), and license those patents to each other. This provides legal certainty, as negotiating licensing agreements individually can be expensive and laborious. There is also the risk that some patent holders do not want to license their patented technology. By entering into a patent pool (and for competition law reasons, such a pool may not be a closed shop), all the parties voluntarily agree to share their patented technology by granting licenses to one another. It will normally also lead to lower licensing rates, as the participants in the pool can save on the transaction costs to seek and enter into individual licensing deals.

One of the elements that will require further research is the fee structure. Various implementations can be conceived. One method could be a constant fee. Another embodiment could be to charge a declining fee over the lifespan of the PBR. However, another possible implementation could be a fee that rises up to a certain period in time (for instance, up to the top of the life cycle of the product), to decline thereafter. As implementation of the model first requires support from the players in the business community, it is currently premature to fix views on the nature of the fee structure, which will equally need further negotiations between the players. Further empirical research is required to determine which fee structure is the most promising implementation vehicle for this reward model. It can also be conceived that sector-specific fee structures could be developed with the support of the relevant sector organizations. As certain products have shorter life cycles, which could be the case for certain ornamentals that are more susceptible to changing "fashions", fee structures will likely need to vary between sectors and likely even within sectors. It is believed that a workable fee structure can be achieved though, also in view of what follows below.

In the plant space, there is an already functioning model relating to patents in the form of the International Licensing Platform Vegetable (hereinafter ILP) for plant patents [61]. According to the webpage of the Platform, "There has been increasing discussion about patents on vegetable plant traits over the past years, especially in Europe. Proponents of such patents claim that they foster innovation, knowledge-sharing and continued investments in research and development. Opponents argue that such patents are unnecessary because of the intellectual property protection offered by plant breeders' rights and that patents impede the work of breeders because they can no longer gain access to biological materials, or can do so only after a delay or at a high cost. […]. The ILP Vegetable provides a straightforward, easy way for vegetable breeders to license the traits they need at a fair and reasonable cost so they can bring new products to the market that meet demands from growers and consumers. The members of the ILP Vegetable will make all of their patents related to vegetable plant traits accessible to their fellow members under the conditions of the ILP. The goals of ILP Vegetable are:

To guarantee access to patents covering biological material for vegetable breeding,

To safeguard that incentives to innovate, which depend on the availability of patent protection, remain intact.

Membership is open to all interested parties, regardless of whether they own patents or not" [61].

The ILP model could in fact also, in some form, be implemented for EDVs. Under the conditions outlined above, i.e., there is a PBR to the IV, the breeder uses most essential features of the initial variety in developing its own new variety, leading to the result that this new variety will be deemed to be an EDV, and such a breeder will be able to use the protected variety to develop its new variety, but it will be subject to the payment of a user fee. This means that the ILP platform template could be used to develop the model envisaged in this review for EDVs.

5. Conclusions

PBRs are an important IP right and deserve our attention. This is because PBRs play an essential role in innovation in plant breeding, and innovation in plant breeding is, in turn, of paramount importance, in an era where sustainability is at the forefront of most agendas. Some features of PBR protection are quite unique for IP rights. The most important one is the full breeders' exemption, which ensures that there is always free access to the plant variety protected by a PBR for developing new varieties. This feature comes at a price, however, which is that PBR holders cannot prevent third parties from taking advantage of their efforts and investments in developing a new variety. It was recognized during the UPOV 1991 negotiations that not providing any form of extra protection against third parties who use most or all of the essential characteristics of a protected variety to develop a new variety was fundamentally unfair, and could negatively influence

innovation in new plant varieties (whether crops or flowers and fruits). It would invite free-riding, at the detriment of the PBR holder. This is why a "fix" was conceived, in the form of the concept of EDV. This would allow PBR holders to extend, at least to some extent, the scope of protection of their PBR to those varieties that use all or most essential characteristics of the initial protection variety. A long discussion followed on the exact interpretation of what is an EDV, and, in particular, what is essential derivation. Decades have passed, and no adequate solution has been found. It became more and more clear that the solution advocated by some to give a very narrow interpretation to the EDV concept, i.e., covering only plagiarism, was a fundamentally unfair interpretation, which moreover did not find support in the preparatory works of the UPOV 1991 Convention. Unfortunately, this narrow interpretation also made it into the UPOV EDV Explanatory Notes 2017.

The advent of NBTs has made the discussion about a fair scope of protection of PBRs all the more relevant, as these technologies would allow targeted genetic changes in a protected IV, whilst using most characteristics of the IV. These NBTs also allow the development of these newly developed varieties much faster compared to traditional breeding methods, implying that PBR holders would face competition from new varieties developed on the basis of the IV much faster than was the case in the past.

These new developments have necessitated a rethink of the EDV concept, if the PBR system is to remain relevant and remain an innovation-incentivizing mechanism.

In this review, I have argued that a broader scope of the EDV concept is essential and fair. It is encouraging to see that the negotiations on the revision of the UPOV EDV Explanatory Notes seem to go into the direction of broadening the scope of protection of the EDV concept indeed. Realizing that determining what essential derivation is will remain a difficult task also in the future (irrespective of whether one uses a narrow or broad definition of what an EDV is), I have additionally proposed a collaborative reward model, which will, in my view, facilitate the functioning of the EDV system and is capable of doing away with legal uncertainty in this area.

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