Review

The Future of Essentially Derived Variety (EDV) Status: Predominantly More Explanations or Essential Change

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Abstract: This review examines the categorization of Essentially Derived Varieties (EDV) introduced in the 1991 revision of the Convention of the *Union internationale pour la protection des obtentions végétales* (UPOV). Challenges in the implementation of the concept and progress made on a crop-by-crop basis to provide greater clarity and more efficient implementation are reviewed. The current approach to EDV remains valid provided i) clarity on thresholds can be achieved including through resource intensive research on an individual crop species basis and ii) that threshold clarity does not lead to perverse incentives to avoid detection of essential derivation. However, technological advances leading to new varieties resulting from the simultaneous introduction or change in expression of more than "a few" genes will so challenge the concept to require a new Convention. Revision could include deletion of the concept of essential derivation and revision on a crop-by-crop basis of the breeder exception. Countries that allow utility patents for individual plant varieties *per se* should consider removing that possibility unless plant breeders utilize those encouragements for risk taking and investment to broaden the germplasm base upon which the long-term sustainability of plant breeding resides.

Keywords: intellectual property; intellectual property protection; plant variety protection, plant breeders' rights, essentially derived variety; utility patent; plant breeding; biotechnology.

1. Introduction

The capacity of research and product development in plant breeding is associated with interactions between the stage of technological development and resultant accumulation of knowledge, which together can enable progress in genetic gain thereby contributing to more productive crop production. The ability to obtain protection of newly developed plant varieties as intellectual property (IP) can encourage investments into plant breeding [1]. The most globally used form of IP to support the development of new plant varieties is a *sui generis*, or specially developed approach to IP known as Plant Variety Protection (PVP) or Plant Breeders' Rights (PBR). This approach to IP was introduced and continues to be further developed under the auspices of the *Union internationale pour la protection des obtentions végétales* (UPOV) or International Union for the Protection of New Varieties of Plants, a Convention adopted in 1961 [2]. The mission of UPOV is: "To provide and

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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" [3].

It is abundantly clear that the fields of plant breeding and associated biotechnologies have witnessed major changes in technological capabilities and knowledge base since the initial UPOV Convention in 1961. Such changes inevitably subject a *sui generis* IP system to pressure for adaptive change in order to maintain encouragements to undertake research and product development, their very raison-d'être [4]. An example of such change was the introduction of the concept of essential derivation resulting in an Essentially Derived Variety (EDV) in the 1991 Convention [5]. Since that time, and particularly during the last decade, the pace of technological change has increased providing diverse new capabilities available to those engaged in the research and development of improved varieties. The subject of this review is essential derivation. As growth in technological capabilities and the subsequent knowledge base continue apace, it is appropriate to question whether the introduction of essential derivation in 1991 remains the optimal solution to support a more productive agriculture. This review is also timely because it comes at a time when UPOV is in the process of hearing presentations from stakeholders prior to the preparation of a third set of explanatory notes on essential derivation [6–8]. This review examines the effectiveness of EDV to date, considers lessons learned and alternate proposals that have been made. The review concludes with identified conditions under which further revision of the sui generis approach would be warranted and includes major elements of such revision.

2. Aspects of IP in plant breeding and agriculture

2.1. IP and the origin of cultivated plants

IP protection is intertwined with human behavior. While an important element of human nature is to be charitable, it is also part of human nature to expect returns from personal endeavor. The use in pre-literate societies by, "inventors (who) used complex rituals tied to spiritual notions of magic to protect their intellectual property" have been cited as "IP-like" [9]. Indeed, "possession-based private property" has been invoked as an agent underpinning the origins of agriculture [10–13]. For, without a property right on harvested products to provide food and fiber, including saved grain for future sowing, the cyclical basis of investments and returns would break down.

2.2. IP and seed systems

Although informal seed exchange practices are not based upon systems of IP protection that are formally recognized today, certain parallels in behavior can be drawn. For example, "Although such networks are open systems, this does not mean that seeds are free or that seed flow goes unimpeded among communities, farmers, families, ethnic groups or politics" [14]. Seed selection practiced by women rice farmers of the Jola community in Senegal, West Africa has been described: "Jola women constantly exchange rice seed. A woman will trade a variety that is best suited to the rainfed fields for one that grows well in the mangrove fields" [15]. In other words, varieties are traded; they are not given freely. Similarly, in the U.S., inbred maize seed was shared via "gentlemen's agreements" up to the late 1970s [16,17]. These actions resemble cross-licensing in formal IP parlance. Farmers have reportedly chosen to protect special varieties, using "secret gardens" and "deception" [18–20]. These actions bring to mind the use of trade secrets as a form of IP.

2.3. IP and the conduct of plant breeding

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A fundamental dilemma faced by developers of self-pollinated plant varieties during the 19thC was the ability to obtain an adequate financial return from sale of seed of a newly developed variety in circumstances where large-scale increase, further distribution and sale during future years were options available to many others [21]. Several solutions were tried but none was found to be sufficiently satisfactory until the latter half of the 20th C. Measures introduced during the 19th C included setting a high seed price during the first 3-4 years of a variety's lifespan. However, use of this policy could result in market failure through over-pricing or might have encouraged yet more seed multiplication by others through a price-based assumption of high yield capability [21–23]. Consequently, during the 19th C most commercial plant breeders focused on root crops, the vegetative produce of which was consumed on farms prior to the initiation of seed development, or they introduced complex mixtures of grass seed protected *via* use of trade secrets, reputation (brand image), and with the promotion of regular sales to establish new pastures.

During the 1870s and subsequent decades, breeders who did venture into the improvement of varieties within self-pollinated species were increasingly vulnerable to: i) the sale by others under synonyms of seed multiplied from rogues or off-types, and ii) seed that was deliberately mis-labelled [23]. The most notorious early example being the pea variety "Telephone" selected as a rogue from the variety "Telegraph" [22]. Breeders developed additional approaches to protect reputations and sales including: i) contracted seed production coupled with quality assurances [**Error! Reference source not found.**], ii) direct sales to growers using specially labelled and bags [22,23], iii) lavishly illustrated catalogues, and iv) gaining special awards [23]. While modern usage of "intellectual property" traces to the establishment of the World Intellectual Property Organization in 1967, this terminology was used more than a century earlier to include "the labors of the mind" as being "as much a man's own ... as what he cultivates, or the flocks he rears" [24]. Plant breeders similarly understood the concept during the 19th C [23].

Formal IP measures for sexually reproduced varieties were delayed due to the state of art in plant breeding where it was deemed generally impossible to stably reproduce or to characterize varieties with sufficient precision until the first half of the 20th C. Time-lines of the development of formal systems of IP for varieties have been provided [25–27], the highlights being:

1. 1883 Paris Convention for the Protection of Industrial Property; agriculture agreed as an area with property rights using trademarks and indications of source.
2. 1895 early attempts in Germany to introduce variety protection
3. 1911 Fruit Developers Congress called for protection, calls continued including for additional species during the 1920s and 1930s, and which lead in 1938 to the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL).
4. 1922 early attempts in France to introduce variety protection
5. 1930 additional attempts in Germany
6. 1930 IP statute, the U.S. Plant Patents Act of 1930, a *sui generis* system for asexually reproduced non-tuberous plants, similar legislation adopted in Cuba (1937), South Africa (1952), and the Republic of Korea in (1973).
7. 1942 Formal legal seed system measures introduced in the Netherlands
8. 1953 Formal legal seed system measures introduced in Germany
9. 1956 ASSINSEL called for an international conference to develop an international system for the protection of new plant varieties.

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10. 1957 Conference recognized the legitimacy of breeders' rights and established criteria of distinctness, uniformity, and stability (DUS).
11. 1961 International Convention for the Protection of New Varieties of Plants, or Union pour la Protection des Obtentions Végétales (UPOV), was adopted.
12. 1968 The UPOV Convention came into force after ratification by the United Kingdom, the Netherlands and Germany.

Additional information on the evolution and implementation of the UPOV system is available at https://www.upov.int/portal/index.html.en and [28–31]. The UPOV system provides for PVP or PBR, which prevent unauthorized copying or repeated use of protected varieties during a time-limited period of protection during which further breeding using the protected variety and subsequent commercialization by non-title holders of the parental variety is allowable. PVP effectively provides a comprehensive open-source system for further breeding of self-pollinated crops and hybrids, although the public availability of parental lines of hybrids following expiration of their protection is not an UPOV requirement. As of February 22nd 2021, UPOV has 77 members [32]. The basic technical requirements to obtain a PVP have remained unchanged since the origin of UPOV in 1961 to today:

1. Distinctness (distinct from all other publicly known varieties),
2. Uniformity (with respect to and in accordance with biology), and
3. Stability (maintain its distinct characteristics during reproduction from generation generation); collectively known as the DUS criteria.

UPOV 1991 introduced two major changes to the scope of protection previously afforded: i) scope extending to harvested produce and ii) scope of rights to commercialize without consent by the owner of an initial variety from which a variety deemed to have been essentially derived was developed. The ramifications of the former change have been discussed [31]. The focus of this review is upon the latter, the concept of essential derivation. Following a review of the rationale that led to its introduction, the discussion moves to the challenges of implementation, consideration of other options, and a recommendation for future change. Readers are directed to Helfer [33] for a detailed comparison of UPOV 1978 and UPOV 1991.

Most European plant breeders determined during the development of PVP that Utility Patents were not appropriate for IP of a variety *per se*. Arguments against the use of Utility Patents were two-fold: First, protecting incremental advances might devalue patent quality since an eligibility threshold of novelty was below the non-obviousness requirement for patentability. Second, it was considered that a delay of access for the purpose of further breeding during a patent-term would reduce overall progress in variety improvement. A detailed comparison of the UPOV Convention and Utility Patent has been provided [33]. Nonetheless, the UPOV system has been criticized, particularly in respect of its open-source nature resulting from the breeder exception clause [34]. Unlike most other countries, and unlike all others regarding regular implementation, the U.S. does include a variety *per se* as eligible subject matter for a grant of Utility Patents [1]. There is global agreement among members of the International Seed Federation that protection of newly developed varieties is essential to encourage research and product development while also acknowledging that a diversity among nations including in cultural histories, socio-economic conditions, state of technological development precludes implementation of a highly detailed and prescribed "one-size-fits-all" approach [35].

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3. The Concept of Essential Derivation

3.1. The need and rationale for the introduction of essential derivation and the category of an Essentially Derived Variety (EDV) in the UPOV 1991 Convention

The field of biotechnology began from basic research during the 1830s [36], which continued during the first decade of the 20th C , but did not begin in earnest until the 1960s [37]. The first transgenic varieties were introduced into cultivation during the 1990s and included tomatoes with delayed ripening and field crop varieties endowed with insect resistance and herbicide tolerances [36–38]. Prior to the release of transgenic varieties there were relatively few examples of single genes of positive economic effect that were not available on equal terms, including *via* the public domain to most, if not all breeders, e.g., native disease resistance genes. Consequently, the introduction of publicly available genes through crossing of the trait donor genotype and recipient variety with selection for the desirable trait during repeated cycles of "backcrossing" using the recipient parent did not disrupt or bias the level of IP among breeders afforded under UPOV 1978, regardless of their respective technological or economic capacities.

Subsequent advances in the field of biotechnology enabled a new category of simply inherited traits sourced from other phyla that provided resistances to insect and to herbicides, following their transgenic insertion into cultivated plants. These traits were thereby of great economic importance, strongly protected by Utility Patents and available under license from a small cadre of well-resourced and technologically enabled organizations. The introduction of these traits *via* transformation into varieties protected under UPOV 1978 would have provided an "enabling advantage" to developers using molecular tools compared to others who solely used "essentially biological," i.e., crossing and selection methodologies [30,39–43]. Consequently, remedial treatment was required to create a more equitable *sui generis* system, one that provided encouragement to undertake both crossing and selection and the development and integration of new, more effective traits. The solution adopted by UPOV 1991 exemplified a balance-based approach. This balance was achieved by the extension to developers of an initial variety (iv) from crossing and selection to the rights to commercialize a progeny variety that was deemed to be essentially derived from that iv, and thus to be an Essentially Derived Variety (EDV). Further details on the EDV concept have been provided, including [1,30,43–52].

3.2. Challenges that have arisen in the determination of a variety categorized as being essentially derived.

The most challenging aspects facing practical implementation are contained within Article 14(5)(b) of the 1991 Act of UPOV, with emphasis placed by this author on specific wording using bolded text:

"a variety shall be deemed to be essentially derived from another variety ("the initial variety") when:

1. 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,
2. it is **clearly distinguishable** from the initial variety, and
3. **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."

UPOV has sought to provide clarification, including for three critical issues [53,54], with emphasis placed by the author of this review using bolded text:

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1. **Predominantly derived**: "a variety **can only be essentially derived from one initial variety",** i.e., a direct parent-progeny relationship by pedigree and "a variety should only be essentially derived from another variety **when it retains virtually the whole genotype of the other variety."**
2. **Essential characteristics**: "**includes all heritable traits that contribute to the principal features, performance or value of the variety**; from the perspective of the producer, seller, supplier, buyer, recipient, or user; and essential characteristics may be different in different crops/species."
3. **Degree of difference to be within the EDV boundary of an initial variety: "be different from that variety by a very limited number of characteristics."**

The degree of difference requirement *per se* places no upper threshold on the number of differences that result from the act of derivation other than in respect to:

1. a limitation imposed by retaining **virtually the whole genotype of the other variety and** so reinforcing the "enabling advantage" to those using molecular tools compared to those who solely used "essentially biological," i.e., crossing and selection.
2. by the examples given in Article 14(5)(c), which comprise a non-exhaustive list: "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."…. which "make clear that the differences which result from the act of derivation should be one or very few."

To summarize, designation of a variety as an EDV requires: it to be Distinct, a progeny in a pedigreed relationship to the iv, to retain virtually the whole genotype of the iv, while differing from the iv by no more than a very limited number of characteristics from among those that are heritable and/or of economic value to all stakeholders, from producers to users.

3.3. Experiences during the implementation of UPOV 1991 to date and lessons accrued.

There have been a few, although very protracted court cases [55–59], unfortunately without providing clear precedence [60]. Nonetheless, important conclusions have been drawn regarding the importance of pedigree records. The maintenance of detailed pedigree records is essential to the conduct of a plant breeding program. An important conclusion from prior EDV cases is that the lack of pedigree data is at the very least highly problematic for the developer of an alleged EDV. For example, information on: "differences which result from the derivation is possible only through facts available exclusively to the person claiming to be the breeder of (a second) variety. Only he knows how the new variety was achieved" [61]. Consequently, "In the pertinent submission it will be necessary to demonstrate in detail which breeding program was used and how the process was applied. The frequent assertion by infringers, in particular in cases of vegetatively propagated plants, that the new variety resulted from seedlings of their own plant material, would not suffice" [61].

In the view of the ISF [35], evidence of high conformity of a second variety to an earlier bred variety should reverse the burden of proof so that it is then the responsibility of the developer of the putative EDV that it is not essentially derived. As experiences have accrued, the Community Plant Variety Office (CPVO) of the European Union noted that Courts have generally seemed to accept that a showing of high genetic conformity should reverse the burden of proof [62]. This rationale is sensible because the developer of the putative EDV has access to most of the relevant information required for determination of EDV status [35,62].

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The chances of developing an EDV have either been avoided or at least reduced by choice of initial germplasm, or by selection of progeny that might not reasonably be considered predominantly derived. The upfront negotiation of licenses avoids risks, uncertainties, potential costs from lawsuits, and delays in commercialization. Most EU holders of PVP ivs and PVP EDVs have agreed business-based solutions [62]. Crop specific methods and marker and/or traits thresholds developed by experts in the field are a fundamentally important resource that can be drawn upon to help make up-front agreements, or by decisions made later through arbitration, or the judicial process. Examples of these technical foundations are provided [63–70]. This author does not accept the argument that having to seek agreements up-front places undue burdens on the second developer [71]. For if a particular variety or varieties represent the optimum technical and/or commercial base-germplasm choice(s) for a later developer to access, then the worth of that specific genetic base deserves respect of its embodiment as IP. In contrast, if publicly available germplasm is equally or more desirable as source material for a later developer, then the need for an up-front agreement is moot and there is no prospect of developing an EDV.

4. Recent questions and concerns that have arisen leading toward the development of a 3rd set of UPOV explanatory notes on EDVs

4.1. Who decides?

It was never envisioned that determination of varietal status as an EDV would be made by examining offices but rather by plant breeders through mutual agreement, or failing that, as a result of litigation [72].

4.2. Use of partial UPOV text leading to determinations inconsistent with the language and intent of UPOV1991

Interpretations that an EDV must include **all** the essential characteristics of an iv (emphasis by author) are not compliant with UPOV 1991. For Article 14(5)(b) (iii) of the 1991 Act reads (bolded text emphasizes by author):

(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."

The exclusion of the part of Art 14(5)(b)(iii) that is bolded above when written into national PVP laws, either reads or is interpreted as and EDV must "conform to the initial variety in the expression of **all** the essential characteristics". However, using the broad definition of "essential" in this context, as interpreted by UPOV [54], then retention of **all** characteristics is a biological impossibility. For when a distinct new variety is developed by either the addition of a new characteristic or through a change in expression of an existing characteristic, then such changes must inevitably cause a change in the essential characteristics of the iv. For example, to add the characteristic of disease resistance to a derived variety means that it no longer retains the essential characteristic of susceptibility to that disease that is a feature of the iv. Hence, use of the language in UPOV 1991: "except for the differences which result from the act of derivation".

Requiring all the essential characteristics to be expressed has problematic implications when characteristics are distinguished for their qualitative degree of essentiality, which runs counter to the definition of "essential" provided by UPOV. Furthermore, if a qualitative distinction is made, then the following questions and added uncertainties arise, including: Who makes the determination, and how is the determination made? What, if any degree of difference in expression is sufficient to designate a previously non-essential characteristic as now being essential? What, if any, degree of difference in expression is sufficient to make a trait even more essential than it previously was?

Determination of EDV status by the Australian PVP office is made according to such a qualitative interpretation of their essentiality. If a later developed variety only differs from an iv by non-essential characteristics then it is deemed to be an EDV, and its commercialization is controlled by the developer of the iv. If, however a derived variety differs from the iv for an "essential" characteristic then it is deemed by the PVP office not to be an EDV and can be freely commercialized by the later developer. However, such an interpretational basis reverts circumstances back to those under UPOV 1978, thereby undermining incentives to undertake crossing and selection and contradicting the very raison-d'être of the balanced approach for which the concept of essential derivation was introduced by the UPOV 1991 Convention.

4.3. Persistent questions and additional recent concerns regarding determination of essential derivation.

Persistent challenges noted above together with concerns related to the rapid acceleration of technologies have led to the current preparation by UPOV of a third set of explanatory notes on EDVs. Concerns come from i) developers who make significant use of crossing and selection that advances in capabilities to rapidly and simultaneously modify and improve the phenotypic expression of several genes may undo the current balance of enabling toward benefitting the later developer and undermining incentives to invest in crossing and selection, and ii) concerns by those who are well-equipped to make phenotypic changes by modifying the genetic basis of specific traits in a rapid and parallel fashion that the current or a potential future implementation of essential derivation could be tipped against their activities, thereby reducing their incentive to invest in and contribute to the development of improved varieties. Among the former, greatest concerns are expressed by developers of asexually propagated varieties because mutants provide the source for many new varieties, whereas the creation of new diversity and subsequent selection of segregants and recombinants usually occurs a very long-term, which then has the potential to be "captured" by the making of one or a very few additional mutations. Consequently, there are concerns that an escalation of EDV-related disputes in the near future. If this were to occur, there would be negative consequences on the progress that could otherwise have been made in an alternate environment where all useful technologies could be applied to the maximum of their individual and collective effect.

Consequently, while there is an immediate focus is on developing greater clarity through a further revision of EDV explanatory notes. Other approaches that include more comprehensive revision to the current UPOV approach deserve urgent consideration. Many such proposals have been proposed, these are presented and commented upon below in their order of increasing departure from the current state.

5. Major proposals that have been made for the revision or elimination of the concept of essential derivation.

5.1. Judicial decisions [73]

It has been proposed that determinations of essential derivation should be made by the judiciary, primarily on phenotype with use of a compulsory license [73]. However, this approach is flawed by i) requiring all essential characteristics to be retained, ii)

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removing the initial prerequisite of determining predominant derivation, and iii) being imbalanced by placing an over-reliance upon phenotypic compared to genotypic data.

It is technically incorrect to assert that "Absolute measures of genetic similarities are not scientifically feasible" [73]. However, the assertion that "Quantitative thresholds have to be constantly monitored in order to comply with the innovations concerning new breeding technologies" [73] is certainly true and underlines the immensity of technical effort required to establish sound technical guidelines. And while it may be conceded that "A juridical approach is dynamic, as it can adapt to the evolution of plant breeding practices and variety production" [73], the quality of any resulting decision, whether it be made through mutual agreement or in the courts, is surely highly dependent upon there being a sound technical foundation. The use of compulsory licenses is not supported by the global seed industry [35].

5.2. A 4 pillar approach [71]

This approach is based upon the following premises:

1. characteristics can be categorized according to whether they exhibit essential characteristics or not,
2. the addition or change of a characteristic that represents added value automatically results in the derived variety being outside the realm of an EDV, and
3. change that is non-essential or insubstantial is plagiaristic and therefore an EDV

Each premise is problematic. With regard to:

1. UPOV does not differentiate among characteristics according to a qualitative interpretation of "essential" or "value-added", and ii) one can foresee prospects of endless arguments with poor to no legal precedent being set on the categorisation of traits and their relative expression levels as being essential or adding value.
2. according to this approach, being value-added results in being outside the scope of EDV thereby reverting to the UPOV 1978 Convention which thereby promotes free-riding by the second developer, and
3. while plagiarism can be further enforced against, it was never the motivating force leading to the introduction of essential derivation. Indeed, plagiarism or cosmetic breeding can be dealt with during the determination of distinctness, e.g., as practiced by the GAIA, an approach that differentially weights the relative importance of characteristics in their contribution to the determination of distinctness [74]. Equally problematic is the proposed basis for determining EDV status for varieties that are said to result from incremental breeding steps and thus according to [71] do not express essential characteristics. With regard to these crops and according to the premises previously stated, the addition of a value-added characteristic would allow the developer of the derived variety to free-ride as per the UPOV 1978 Convention.

5.3. Utilize the Doctrine of Equivalence [43]

This approach is based upon essential derivation being treated as similar to the doctrine of equivalence in patent law [43]. A 3-step sequential procedure is utilized to determine EDV status; 1) "Does the derived variety achieve substantially the same result in substantially the same way as the initial variety, i.e., does it retain the essential characteristics of the initial variety? If so, then 2) Would such a determination be obvious to a person skilled in the art? And if so 3) Did the PVP holder of the iv intend the relevant characteristics to be an essential requirement of the application? This approach was ultimately rejected for not being practically feasible, nor relevant to the PVP system [43].

5.4. Free access but obligation to pay compensation for use [43]

This approach [43] places responsibility upon the initial developer to provide evidence that their protected variety had been used to develop another variety. Use by a

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third party would then trigger a "use payment" which could only be voided by the third-party providing proof that use of the protected variety was not an essential component of its development, a reversal of burden of proof. However, this approach is problematic because it remains subject to all the outstanding and inherent questions and challenges underlying a determination of essential derivation status.

5.5. Categorization of characteristics in relation to varietal performance [75]

This approach [75] proposed that characteristics could be categorized according to their contribution to varietal performance. For example, initial variety status would not be achieved until the contribution of one or more expressed traits provided added value. The proponents [75] considered that such an approach would be especially applicable to complex traits, such as those developed through individually measurable advances. However, the level of precision required to measure iterative progress in quantitative traits such as drought resistance or yield, would render such an approach impractical with regard to field crops. Furthermore, addition of a value-added trait allows the second developer to free-ride capturing the germplasm developed by the initial breeder thereby reverting to UPOV 1978.

5.6. A special research exemption [75]

The adoption of a special research exemption for patented plants has also been proposed [75]. This proposal envisages that IP for varieties that exhibit incremental improvements would continue to reside under UPOV with no EDV regime. In contrast, varieties exhibiting "improvements of greater significance" [75] could be eligible for patent protection providing the patent regime included a statutory research exemption. A critical problem with this approach is that most genetic gain for field crops has been and will likely continue to depend upon incremental advances for traits such as yield and drought resistance that are under complex genetic control. Implementation of this approach would reinstate the imbalance that led to UPOV 1991 and simply revert to UPOV 1978 thereby making developers of initial varieties vulnerable to free-riding.

Others [71,76,77], have also proposed that characteristics be defined in respect of being essential or not. The essential problem remains: Who makes the definition and upon what basis? All the subsequent challenges noted above then still remain, how to define "predominant": and how to define "a few" on a species-specific basis. Such proposals cannot provide further clarity to the determination of essential derivation.

5.7. Revision of the breeder exception [78–81]

This approach [78–81] proposed a revision of UPOV whereby open source use for further breeding would not be available immediately upon commercialization but instead be delayed by a number of years, e.g. between 3-10 years dependent upon crop species. All varieties and parental inbred lines would then be available in the public domain once their period of protection had expired; a guarantee of access that is not currently provided by the UPOV.

5.8. Compensation Liability Regime [82]

This approach [82] proposed radical change through the introduction of a "compensatory liability regime" (CRL) that would avoid concerns of increased speed to market by second developers at the potential detriment to the interests of and further incentives to invest by the initial developer. Under such a scheme, a second developer "would obtain a license to compete by paying to the originator a prescribed multiple of the measured investment which the original breeder had made under uncertainty and high risk. The follower would in fact be sharing in that investment and its risk retrospectively" [82]. Under such an approach it is anticipated that benefits would accrue to multiple stakeholders: i) varieties endowed with higher economic will attract more licensees thereby encouraging further investments including in relatively high-risk research , ii) all new germplasm would be accessible for further development thereby increasing follow-on investments, and iii) when germplasm is used under the terms of the International Treaty or the CBD, then a portion of license fees could accrue back to those providers [82].

6. Concluding Comments and Proposed Path Forward

6.1. The current and evolving technology environment that informs the conduct and effectiveness of plant breeding.

The UPOV 1991 Convention was introduced to balance approaches to variety improvement by crossing and selection of anonymous genes and the insertion or changes of specific genes and associated regulatory sequences from other species that became available from technological advance. The technological environment within which UPOV 1991 was developed and introduced has continued to undergo rapid change providing additional capabilities and knowledge.

As previously noted, several approaches have been proposed to implement or to revise essential derivation. However, most proposals either fail to resolve outstanding questions on thresholds or are more problematic because they effectively revert to outcomes that undermine incentives to select improved phenotypes that result from selection upon genotypic diversity released by recombination and segregation during meiosis.

Selection upon a broad array of genomic diversity, anonymous with respect to specific genes and functionality, has contributed the vast preponderance of genetic gain for quantitative traits. Phenotypes that result from interactions among genes and expression sequences of individually small effect with environmental factors makes individual gene identification and measurement of their effects very challenging. However, such identification is a prerequisite for affecting change in gene expression through mutation, alteration of expression, or from the addition of new genetic elements. An alternate, or complementary approach to increased breeding efficiency has been effected through the targeted selection of anonymous genes using marker assisted selection (MAS) and Genome Wide Selection (GWS).

Genes involved in the expression of heat and cold shock proteins can modify the expression of quantitative traits. However, the progression of single-gene mutants into commercial varieties lags several decades behind simply inherited traits that provide insect resistance and herbicide tolerance. Reports citing the improved expression of drought tolerance by the modification or addition of single genes have been criticized due to a lack of rigor in sufficiently demonstrating underlying physiological and genetic mechanisms [83]. However, to date there has been a relative lack of progress in developing drought resistance through single gene modifications due in part to insufficient testing using physiological and genetic models that are biologically relevant [84]. Numerous candidate genes associated with many diverse QTL have been listed, however most citations were at an elementary stage with a focus on yield drag [85]. Recent reviews [86,87] indicate that alterations in the expression of specific genes may contribute to the agronomic improvement of quantitative traits. Additional capabilities to simultaneously insert 10 or more additional and/or edited genes have been developed [8889] and open-source methodologies to insert genes are available [90]. It can be anticipated that varietal improvement through the introduction of single gene changes that result in economically important phenotypes will continue [91,92]. The UPOV approach has been criticized for failing to solve a basic contradiction, that being to

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"provide protection for two very different forms of genetic enhancement, discrete and complex, within a single system" [75]. Further progress in capabilities to improve varieties through the addition or change to an increasing number of specific genes, including by multi-gene cassettes will further exasperate categorizations of characteristics or traits as either "discrete" or "complex" and so render those definitions increasingly meaningless in the context of essential derivation.

An additional concern regarding implementation of EDV status stems from capabilities to pursue perverse incentives to undertake misappropriation of IP by cosmetic breeding and/or the development of EDVs while avoiding their detection. For example, increased metrical clarity on a crop specific basis for thresholds on predominant derivation and/or retainment of essential characteristics triggering potential EDV status enables more effective implementation of the concept. However, technologies could also be used to develop derivatives selected to have all the desirable performance attributes of the iv and genetic and phenotypic distances that exceed potential EDV triggering thresholds. These technologies include: i) high through-put molecular marker laboratories, ii) genotyping parental lines of hybrids using maternally inherited tissue [80], iii) isolation of the female parent of a hybrid by a strategy known as "chasing selfs" [93,94], and iv) use "reverse-breeding" [95,96] that allows reconstruction of hybrids through a "shuffling" of the initial parental genotypes.

6.2. A proposal

Plant breeders must determine their relative expenditure of resources among i) identifying and manipulating specific known genes compared to crossing and selection upon anonymous genes, and ii) working with known well-adapted and already widely-used germplasm compared to less immediately well-adapted, including exotic germplasm. IP policies establish important parameters which inform investment decisions and influence breeding strategies. The making of germplasm access and use agreements upfront makes sound business and technical sense in circumstances when the initial variety has characteristics that are also preferentially desired by the second developer. Otherwise, subsequent developers have access to publicly available germplasm thereby making moot the occurrence of essential derivation.

If the preceding discussion on which categories of genes might be the most precise or optimal to use in the development of improved varieties appear nonsensical, or may be increasingly difficult to demarcate, then such conclusions support an approach to IP protection that is independent of such categorization. It is important to provide an IP regime whereby all breeding approaches can coexist in a balanced symbiotic relationship to provide optimal outcomes in terms of improved products for the benefits of all stakeholders.

This author anticipates that the concept of essential derivation will remain a valid and increasingly useful approach provided:

1. breeding methods modify or change "a few" genes and which result in differences that are readily observable and/or measurable,
2. metric thresholds have a high degree of consensus on a crop-specific basis,
3. definition of "essential" is at least agreed on a crop specific basis,
4. accurate and sufficiently detail pedigree data are a prerequisite and the absence of which demonstrates culpability,
5. that attempts are not made to evade essential derivation through use of "reverse breeding" or other technologies with equivalent outcomes,

6. that molecular marker comparisons help determine predominant derivation provided that the technical basis of usage has been established on a crop specific basis, and
7. demonstration of predominant derivation causes the reversal of burden of proof to be upon the developer of the putative EDV who is best placed to provide pertinent evidential responses.

However, as technological progress continues, variety development through the simultaneous addition and/or changes in expression of more than "a few" genes will occur [87–92]. Also, it may be that judicial precedent on the definitions of: "a few", "predominant", and "essential" becomes problematic or contradictory in terms of supporting the advancement of genetic gain through plant breeding. Furthermore, there are significant technical challenges and resources required to establish the technical foundations required for the degree of clarity required to facilitate up-front agreements and/or the smooth resolution of disputes. Consequently, it may well be impossible to develop such a technical foundation for more than a few crop species.

Plant breeders and farmers thoroughly understand the enduring need for varieties that are increasingly better adapted to an environment comprised of changing and unpredictable biotic and abiotic factors. IP systems also adapt and evolve as a result of interactions with accumulated knowledge and technological capabilities. Consequently, it would be wise to consider potential elements of further evolution and adaptation of the *sui generis* system beyond UPOV 1991. Elements that members might consider include:

1. deletion of the concept of essential derivation,
2. a revision of the breeder exception on a crop specific basis so that open access for further breeding is delayed on a crop specific basis,
3. allow breeders to provide access under mutually agreed terms before open access is provided, and iv) ensuring access to varieties and parental inbred lines once their period of protection has expired.

While the outcome of such revisions might be similar to those envisioned in proposed changes to the Utility Patent system by the introduction of "petty patents" [75], they may be more appropriate to be made concordant to the raison-d'être of a *sui generis* system.

Attention has also been drawn to the relatively low bar of the non-obviousness test for grants of utility patents to varieties per se [97–99]. The granting of utility patents (UP) to plant varieties *per se* under the tenets of i) DUS status and ii) the inability to predict the genetic or phenotypic outcomes from crossing and selection, has effectively created a new *sui generis* system that is fundamentally different from that provided by UPOV. Plant breeders in the US have used the high level of IP available through UP to develop insect resistant and herbicide tolerant varieties using transgenic approaches and to protect varieties *per se*. However, for example, maize breeders have generally failed to take advantage of UP to broaden the repertoire of useful germplasm [100–102] even as diversity within heterotic pools has declined [103] and the loss of genetic variance will accelerate as improved selection methods are implemented [104]. This reviewer sees no valid public policy rationale to maintain eligibility of plant varieties per se for UP protection unless plant breeders take on board the potential protection provided by UP and undertake the risks and challenges associated with the introduction of new exotic genetic diversity.

No newly developed variety is perfect. Pests, pathogens, and weeds continue to evolve. Agronomic practices and the requirements of consumers change. Other demands upon agriculture to contribute more sustainably vis à vis ecosystem services become increasingly paramount. It is surely a crucial element of public policy that all approaches to varietal improvement, both public and commercial, should be enabled. The challenges for agriculture to contribute levels of production that are sustainable and in harmony with ecosystem services places even greater emphasis on the most effective use of the widest possible repertoire of breeding skills, technologies, and genetic resources.

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