Plant Breeders' Rights

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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. This review introduces a fair interpretation of the EDV concept and a new access reward model.

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

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][2][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 which by 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.

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.

2. PBRs and EDVs: Concepts and Determination

According to the UPOV Convention [5], a plant 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

Under the essentially derived variety (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.

The introduction of the EDV concept must be seen in the light of the pivotal full breeders' exception concept under PBR law, according to which breeders are allowed to use the PBR protected variety for further breeding, and commercialize the thus newly created variety, all without consent of the PBR holder for the IV.

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.

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 abovementioned three criteria to qualify as an EDV. 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.

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" [6].

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" [7] (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 [8] (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 [9][10][11][12].

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” [13] (p. 36).

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.

3. Current Insights

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.

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. 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

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 [14] (p. 344).

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.

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.

It has been established above that a narrow 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 [15], gains implementation into these Explanatory Notes. It is encouraging to see that the latest Draft of the Revised Explanatory Notes [16] seems to take such a broader approach indeed.

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.

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 is based on a liability model, originally conceived in a different context by Reichman [17]. In developing this model, I have equally taken inspiration from collaborative models already in place for (plant) innovations in the patent space.

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.

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.

4. 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.

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