

Protection of Plant Novelties[©]

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PLANT VARIETY RIGHTS

English terminology often uses the abbreviations PVP (Plant Variety Protection), PVR (Plant Variety Rights), or PBR (Plant Breeders' Rights), which is a protection offered by means of either a national or territorial legislation of plant novelties or breeders' rights.

Most of the existing PVR systems are based on one of the versions of the UPOV Convention; UPOV, the International Union for the Protection of New Varieties of Plants, is an intergovernmental organization with headquarters in Geneva (Switzerland). The first Convention adopted by this organization dates from 1961. It was revised in 1972, 1978, and 1991. There are at the moment 55 members in UPOV, of which Singapore is the latest one.

Other recent member states in Asia are China, Japan, the Republic of Korea, and Kirgizistan. Many countries in the world have adopted PVR legislation, which — although partly inspired by it — is not in all aspects in conformity with the UPOV system.

The subject matter of a UPOV-type-plant breeders' right is a plant variety, which is defined by Article 5 of the the UPOV 1991 Convention: "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."

In order to be eligible for protection a variety has to be *new, distinct, uniform,* and *stable*.

PATENTS

The classical definition of a patent is referred to in Article 27 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement: »patents shall be available for any invention Provided that they are new, involve an inventive step and are capable of industrial application«

BIOTECHNOLOGY

There is no internationally accepted legal text defining the notion of "biotechnology". When you try to find a definition on the Internet, many options are offered. For the purpose of this paper I would define "biotechnology" as follows: "The use of biological processes to create (improved) products considered to be useful and/or of economical value."

Early biotechnology includes traditional plant breeding techniques. Modern biotechnology includes the industrial use of recombinant DNA and cell fusion.

In my presentation I would like to concentrate on the issues in respect to protection of plants or plant varieties, including biotechnological inventions by means of

an intellectual property right as well as a comparison between the scope of protection offered by a plant variety right and a patent right, respectively.

PLANT BREEDERS' RIGHTS

"Plant inventions" and plant varieties can in most countries be protected under patent law and plant variety rights law, respectively.

As follows from article 52 (b) of the European Patent Convention (EPC), to which a large majority of European countries are a contracting party, plant varieties are excluded from patent protection.

The scope of the exclusion from patentability has not only been subject to jurisprudence, but the European Community Biotech Directive also contains a provision meant to clarify the demarcation line between nonpatentable subject matter and "inventions which concern plants...". Such inventions "may be patented if the application of the invention is not technically confined to a particular plant ...variety."

The decision of the Enlarged Board of Appeal of the European Patent Office in the *Novartis* case can be summarized as follows: "A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though the claim may embrace one or more varieties not specified."

This is why a patent can be granted under the EPC when a claim relates to plants that can be part of an indefinite number of plant varieties.

THE SCOPE OF PROTECTION OFFERED BY PATENTS AND PVR RESPECTIVELY

The rights provided by a plant variety right, UPOV type, and a (utility) patent are quite similar, as can be seen from the following table, which compares the scope of protection of a PVR and a patent as laid down in the UPOV Convention and the TRIPS agreement, respectively.

TRIPS Agreement	UPOV
(Article 28)	(1991 Act – Article 14)
"1. A patent shall confer on its owner the following exclusive rights:	"(1) [Acts in respect of the propagating material]
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:	(a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder
Making,	(i) production or reproduction (multiplication)
Using,	(ii) conditioning for the purpose of propagation
Offering for sale	(iii) offering for sale
Selling , or	(iv) selling or other marketing
Importing	(v) exporting (vi) importing
For these purposes that product;"	(vii) stocking for any of the purposes mentioned in (i) to (vi), above."

Although the rights resulting from the two intellectual property right systems do not differ much, it is generally accepted that patents offer a stronger protection than plant variety rights. The reason is that the plant breeders' right does not extend to acts done for experimental purposes and acts done for the purpose of breeding other varieties, the so called breeders' exemption, whilst such an exemption does not exist to the same extent in the patent systems in Europe and the U.S.A.

The clear demarcation line between the scope of the patent and PVR system has in Europe had the effect that in principle, only the results of modern biotechnology are subject of European patent applications. Patents protect especially gene sequences, which code for specific characteristics such as resistances against pest or tolerance to herbicides, and the techniques to introduce the sequence in plant material. Such inventions could be applied in respect to an indefinite number of plant varieties and are for that reason not excluded from patentability under article 53, b, of the EPC.

The objects of PVR protection, new varieties of plants, are mostly the result of the application of traditional breeding techniques. Only in a few cases has the CPVO received applications for plant variety right protection in respect of genetically modified varieties.

In practice the coexistence of these two Intellectual Protection Rights systems available for the protection of the results of biotechnology, early and modern, does not create too many problems. In theory a conflict could arise when a plant variety is at the same time covered by a PVR, for the variety as such, and a patent, for a component of the variety, for instance a gene sequence. In such a situation the variety can only be commercialized with the authorization of the two right holders. The Biotech Directive contains a provision that if one of the right holders prevents the other from exploitation of his invention/plant variety a compulsory exploitation license could be granted, albeit only if certain quite restrictive criteria are fulfilled. Since 2000, specific clauses in respect of such compulsory licenses have been incorporated in the Danish legislation, i.e., Law on Plant Novelties and Law on Biotechnological Inventions.

In reality, the question of access to genetic resources as well as the right to breeding (Breeders' Exemption) will only be actual in the following situations:

Access to Plant Varieties Protected by Patent. This is a case mainly occurring in the USA and, in fact, little formal discussion has officially taken place. However, a few companies consider the research-exemption is too narrow and that some flexibility should be given for specific breeding purposes.

Access to Plant Varieties Protected by PVR. Through valid national and territorial PVR legislation, the protected plant material is freely available for further breeding purposes, however regulated through the provisions of Essentially Derived Varieties (EDV) in the latest UPOV-Convention.

The objective of this concept was to discourage the plagiarism and "easy breeding" made possible due to the difficulty of defining the necessary "minimum distance" for declaring a new variety distinct from other varieties of common knowledge.

Technically, for a variety to be considered an EDV, it must fulfill together three requirements in relation to the initial variety:

- Clear distinctness in the sense of the UPOV Convention.
- Conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety (IV).
- Predominant derivation from the IV.

Legally speaking, concerning dependency:

- The IV must be a protected variety.
- Dependency can only exist from one single variety.
- An EDV can be directly derived from the IV or from a variety that is itself essentially derived from the IV. It is possible to have a »cascade« of derivation; however, each EDV shall only be dependant on one, the protected IV.
- According to the general rule of burden of proof, the owner of the IV must prove essential derivation and then claim dependency. However, if the owner of the IV can give reasonable evidence of essential derivation (for example, by finger-printing) the proof of non-predominant derivation should fall on the breeder of the putative EDV.

There is — so far — no jurisprudence on essential derivation, but to my knowledge a number of cases have been solved amicably using the prima facie proof.

It must also be noted, that the introduction of the concept of EDV has certainly changed breeding schemes and consequently “close” breeding is becoming rare — much to the benefits of breeders and the diversity of plant varieties at the disposal of growers.

Access to Plant Varieties Protected By PVR and Containing Patented Elements. This is most probably the most controversial issue on intellectual property. According to the Patent System, an approval from the holder of right is necessary to exploit the variety in question for further breeding purposes, whereas the Plant Variety Rights legislation is approving this on specific conditions.

In this respect, the international Seed Trade Federation adopted a position paper during the Congress in Bangalore India in June 2003: “ISF considers that Breeder’s Right (and patent for plant varieties where allowed by law) and patent protection for biotechnological inventions, are efficient protection systems. It is thus necessary to define a fair coexistence of the two rights.

The introduction of the concepts of essential derivation and dependency in the 1991 Act of the UPOV Convention is a welcome initiative to bridge the two systems, in the interest of all the actors involved.

However further clarification is needed as regards the use of transgenic varieties containing patented elements and protected by Breeder’s Right for further breeding. ISF is strongly attached to the breeder’s exception provided for in the UPOV Convention and is concerned that the extension of the protection of a gene sequence to the relevant plant variety itself could extinguish this exception.

Therefore ISF considers that a commercially available variety protected only by Breeder’s Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent’s claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an EDV or if it is inside the scope of the patent’s claims, a consent from the owner of the initial variety or of the patent must be obtained.

ISF is not generally in favor of compulsory licensing. Unrestricted compulsory licensing would make meaningless the new concept of dependency as well as the protection by patent on "biotechnological inventions". ISF acknowledges the principle of compulsory licensing in case of public interest as provided for in patent laws. ISF has also considered the concept of compulsory licensing in case of "significant technical progress of considerable economic interest", as provided for in the European Directive for the protection of biotechnological inventions and which is in line with the provision of the TRIP's agreement. However, the implementation of such a clause would have to be left to courts and thus be time-consuming and expensive. ISF considers that in any case, the best solution is to encourage contractual voluntary licensing for both essentially derived varieties and patented traits."

The progress in genetic engineering raises the prospect that, in the foreseeable future, an ever-increasing number of plant varieties will contain patented inventions. The practical consequence would be that unless modifications in the patent legislation are introduced both the breeders' exemption and, in the U.S.A. situation, the farmers' privilege would be lost or greatly weakened. Article 30 of the TRIPS agreement offers a basis for such modifications: "Members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties."

CONCLUSION

In conclusion, it should be emphasized that the breeders' exemption is considered as an essential element of the UPOV intellectual property rights system, since "it recognizes that real progress in breeding relies on access to the latest improvements and new variation. Access is needed to all breeding materials in the form of modern varieties, as well as land races and wild species, to achieve the greatest progress and is only possible if protected varieties are available for breeding."