

Plant Breeder's Rights: a fair and balanced Intellectual Property Right for Plant Varieties

Contribution to an ongoing debate

Huib Ghijsen¹

Abstract

There is a general agreement that Intellectual Property Rights (IPR's) are important for promoting research in general and for practical plant breeding in particular. The design of a national IPR system for plant varieties requires a careful balancing of exclusive rights and exemptions.

The UPOV² based Plant Breeder's Rights (PBR) laws offer the most simple and adequate protection for breeders by combining a good scope of protection with a full freedom to operate by the provision of the breeder's exemption, which allows the use of protected varieties for further, commercial breeding. This free access can be regarded as an open source system, beneficial to all parties in the breeding industry. The scope of protection under UPOV 1991 is significantly improved by offering exclusive rights on all material of the variety and extending the protection to varieties essentially derived from the protected variety.

Although the farmer's privilege has, compared to UPOV 1978, been restricted under UPOV 1991, farmers have still the possibility to save their own seeds of the protected variety.

The utility patent, which is mainly in the USA available for conventionally bred varieties, offers a very wide scope of protection and restricts the freedom of research and breeding. This very strong form of protection can even be obtained while its requirements are in practice lower than compared to the requirements of PBR.

¹ The views expressed herein are those of the author alone and do not necessarily reflect the views of Bayer BioScience.

² L'Union internationale pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants). At present the UPOV Convention has been ratified by 63 member states.

The Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT) complicate the access to germplasm, which is notably unrestricted under PBR. New, improved and well adapted varieties are the best benefits resulting from the access to genetic resources.

Farmer's participation in breeding can be useful; they also have free access to PBR protected varieties. It is therefore not necessary and impractical to provide unrestricted access to breeding populations. It is better to develop specific, adapted breeding material for those farmers.

Keywords: *intellectual property rights, plant breeder's rights, breeder's exemption, farmer's privilege, patents, access and benefit sharing*

Introduction

Since the beginning of the 20th century increasing plant breeding activities by private companies called for protection of their investment in time and money. The USA was in 1930 the first country in the world to provide an Intellectual Property Right for plant varieties, the Plant Patent Act. This system was and still is restricted to vegetatively reproduced crops, excluding plants producing edible tubers, like potato. Germany (1935) and the Netherlands (1941) belonged to the first European countries introducing a PBR system, mainly used for agricultural crops.

The European PBR systems use an official, central testing procedure to test the technical requirements - Distinctness, Uniformity and Stability (DUS) for PBR as had been developed in the beginning of the 20th century by the seed certification and variety listing authorities for the purpose of variety identification.

In 1961 the first UPOV Convention on the protection of plant varieties was signed in Paris by six member states. The countries at the cradle of this Convention decided for several reasons to develop a 'sui generis' system and not to seek connection to the existing patent system. The two most important of these reasons were the complexities of dependencies under industrial patents - many varieties originate by crossing existing varieties - and the fact that the patent offices were not equipped to test the requirements for this kind of protectable subject matter. It has also to be noted that in this pre-biotech era there was little interest from the patent side in this odd field of inventions.

The UPOV Convention has been changed in 1972, 1978 and 1991. The most important changes, with the view to strengthen the protection, have been made in the Convention of 1991. The scope of protection under UPOV 1978 is limited to the exclusive right on the trading of propagating material, while UPOV 1991 covers all production and sales of all material, including harvested material of the protected variety.

The PBR contains two important exceptions: the breeder's exemption and the farmer's privilege. The breeder's exemption provides free access to protected and released varieties for the purpose of breeding and the subsequent exploitation of the varieties resulting from this breeding process. From a public point of view, the breeder's exemption has the important benefit that competitive breeding programs have access to each other's germplasm. By crossing his own germplasm with the newly released varieties each breeder is able to create a greater genetic variability than in case he would be restricted to his own germplasm.

The judicial decisions in the well known Chakrabarty, Hibberd and Ag Supply cases³, have enabled breeders in the USA to protect conventionally bred varieties through utility patents. The wide scope of protection in the patent system and, when compared to PBR, the generally more restrictive research exemption, do allegedly not allow a "breeder's exemption". The protection of many conventional varieties through utility patents in USA and the increasing number of varieties worldwide incorporating a patented trait or technology have provoked a debate on the breeder's exemption.

The second important exception in the PBR, the farmer's privilege provides the option for farmers to use the produce (grain) of their own farm as seed for planting a following crop, without needing a license from the PBR holder. Although breeders do not favor this privilege, they do not oppose it either if this provision is applied in a reasonable way and some remuneration for the re-use of the seed is paid. Farmers from their side do not like to be restricted in the old habit of producing their own seeds.

The UPOV Convention of 1978 bans a double protection: varieties of a particular crop can be protected either by the UPOV system or by another system, not by UPOV and another system together. This ban has been lifted in the UPOV Convention of 1991 and consequently in the US-PBR act, modified in 1994 with the implementation of the UPOV 1991 Convention. Since this time, utility patents for plant varieties have been filed and granted in the US, espe-

³ Diamond v. Chakrabarty 206 USPQ 193 (Sup.Ct. 1980), Ex Parte Hibberd, 227 USPQ (BNA) 443 (1985), J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred, 534 U.S. 2001, No. 99-1996 (Sup.Ct. 2001)

cially in maize and soya bean on a regular basis. A number of these varieties have also been filed for the 'double' protection, both under the utility patent and the PBR Act. Other countries offering patents for plant varieties are Japan, Australia and the Republic of Korea, but the number of patented varieties in these countries is very limited.

In Europe the debate on the patentability of plants has been focussed for a number of years on the Novartis case⁴, where a plant variety contained a patented gene. The final decision of the enlarged board of appeal of the European Patent Office in December 1999 ruled that although a variety as such cannot be patented, because of the prohibition on patents for plant varieties of article 53b in the European Patent Convention, plants containing a patented gene will be patentable if the gene is not restricted to a particular variety. This means in practice that the patent on a gene may include several varieties. The European Biotech Directive (EC/98/44) provides the same principle and has incorporated the same farmer's privilege provision as present in the EU PBR Regulation (EC/2100/94).

The Convention on Biodiversity (CBD) and the International Treaty for Plant Genetic Resources of Food and Agriculture (IT) - resulting from the FAO International Undertaking, have -, in a different way, complicated the access to genetic resources. The IT provides free access to the genetic resources concerned if access for breeding to the variety, that incorporates a genetic resource, is not by any means restricted for further breeding. This mutual free access built into the PBR and the IT systems should be cherished.

This article will look at the importance of these two exemptions in the light of increasing criticism on IPR's on living organisms and the advancing patents on (biotech) varieties.

It will show that the UPOV based PBR system, especially the 1991 version is a well balanced system that takes into account the interests of breeders and farmers, wherein the breeder can obtain his rightful return on investment while both farmers and breeders have still enough freedom to operate.

In order to explain these issues it is important to describe briefly the PBR and Patent systems: the requirements, examination and granting, the scope of protection and the possibilities of opposition.

Requirements, Examination and granting of protection under PBR and Patents

Plant Breeder's Rights

Plant Breeders' Rights is granted to a plant variety if the variety is New, Distinct, Uniform and Stable (DUS) and has got an approved denomination.

A public disclosure of the variety, as required by the utility patent, is not foreseen in the PBR system. Most varieties are normally disclosed through commercialization, except the parent lines of hybrid varieties. Parent line varieties can even remain secret while they are protected.

Novelty

UPOV 1991 requires that material of the variety must not, before the date of application, have been traded more than one year within the country of application or four to six years outside this country. Under UPOV 1978 the one year 'grace' period is optional, but most UPOV 1978 based national legislation require the PBR application to be filed before trading or even before offering the variety for sale.

Distinctness

This is based on a clear phenotypic difference between the new variety and the most similar existing varieties that are commonly known in trade or still under test. Distinctness is a relative issue: it is valid for the particular location, the period tested and the reference varieties with which it is compared. The interactions often observed between varieties, locations, observers and years are typical for living organisms, which make variety testing complicated but also challenging and interesting. It is fundamentally different from non-living matter like cars, computers and chemicals: these items can be measured by anyone at any time at any location, always yielding the same results. The use of molecular fingerprinting in DUS testing was expected to resolve the problem of variety / environment interaction. These techniques are however not yet sufficiently robust and cannot totally replace the phenotypic traits. Furthermore, these techniques are, due to the extra costs, only interesting in a few big crops. Finally there is the important problem for the breeder of a reduced variety distance, in theory one has pair, resulting in a decreased scope

⁴ EPO Case G0001/98, decision of 20-12-1999

of protection. The molecular fingerprinting techniques may play an important role in the management of large reference collections by identifying the varieties most similar to the new variety and growing them side by side in field trials. The new 1991 UPOV Convention requires only a clear difference in the expression of at least one characteristic, while UPOV 1978 offers a somewhat wider scope by requiring a difference of one or more important characteristics.

Uniformity

Uniformity is always assessed in relation to the way of propagation. Vegetatively propagated and self pollinated varieties have the highest uniformity requirement for the relevant characteristics⁵ with a tolerance of 1% off-types on average. Seed certification requirements are often more strict with a tolerance of only 0.1%. Cross fertilized crops are judged on their variation around the average plant and in comparison with other existing varieties.

The UPOV uniformity requirement has yet met much criticism from various sides, mainly in developing countries, which fear that the broad adaptation of existing varieties (landraces) might be endangered by the development of strict uniform varieties with a narrow genetic basis. According to its variety definition however, UPOV 1991 acknowledges the existence of broad varieties. Article 1 (vi) says: "variety" means a plant grouping (..), irrespective of whether the conditions for the grant of a breeder's right are fully met (...)"'. An existing variety not sufficiently uniform for protection is therefore regarded as a public variety of common knowledge that has to be taken into account by determining the Distinctness of new varieties. The protection by PBR of broad, non-uniform varieties would result in a large scope of protection leaving little room for other new varieties. Furthermore it might be complicated to maintain the stability of such a variety and to defend its protection. Finally, if particular characteristics, like disease resistance, need to be heterogeneous in agricultural crops in order to be effective under field circumstances, such characteristics may simply be left out of the DUS testing⁶.

Stability

Stability is inherent to the system: if a variety changes significantly in the expression of one or more of its relevant characteristics with respect to its origi-

⁵ These are the characteristics that are suitable (polymorphic) and regularly used for distinctness.

⁶ As an exception this is not possible for some vegetable crops, e.g. lettuce and tomato, where due to lack of suitable morphological characteristics, distinctness must largely be based on disease characteristics

inal description and the initial seed or plant material sample, it has become a different variety, which is not protected. This stability requirement may become important if a PBR must be defended in an infringement case. Systematic testing of stability for PBR, as required in some PBR laws, is not necessary and a waste of resources.

For a different and public purpose, in order to provide the consumer (farmer) with seed of the true variety, seed lots of varieties of agricultural crops are often systematically checked in the seed certification process whether they belong to the claimed variety.

In the European UPOV-member countries all new varieties are tested in official grow-out trials to test the DUS of seed crops for national listing (admittance to seed trade) and the granting of PBR. This has resulted in large reference collections of existing varieties, -which are compared in field trials each year - and a strong accumulation of technical and variety knowledge. The national listing of seed crops is therefore an effective weapon against infringement. On the basis of the accumulated technical knowledge, UPOV has developed a set of technical guidelines for the DUS testing of crops, with the aim to harmonize and support the technical testing. These guidelines are being designed and discussed in the yearly meetings of crop specific technical working parties, which are open to breeders' organizations. The national listing of a variety requires besides a positive DUS test also an improvement of the variety in terms of yield, quality or disease resistance over the existing variety assortment. This requirement is tested in trials for Value Culture and Use (VCU). The VCU requirements, however have nothing to do with PBR, but are only meant to provide farmers with independent acquired data concerning the quality of the new varieties. It happens quite often that protected varieties do not make the national list and do not become commercial.

In the USA, Latin America, Australia and Canada the breeders provide a detailed variety description to the PBR-office. For this purpose the breeder performs the DUS-testing by himself. The descriptions are examined for Distinctness by the PBR office in a computer database. Uniformity and Stability are declared by the breeder as to be satisfactory. If this is not correct or not true, the sanction is that the PBR title can be requested to be annulled by anybody during the whole lifetime of the PBR. Nullification has the effect that the PBR has never existed. If the variety was not New or Distinct at the moment of granting the protection, the PBR of any variety can be nullified in a procedure at the PBR office. After a testing period of 1-3 years, depending on the crop a title of protection is granted for a minimum period of 15-18 years

(UPOV 1978) or 20-25 years (UPOV 1991) as from the date of granting. Some PBR laws provide a longer protection of 25-30 years⁷.

Patents

Patents are granted in respect of products or processes, which are:

- New
- Inventive or non-obvious
- Useful or capable of industrial application

New

An invention must be new in comparison with the prior art, which is everything, world-wide, made available to the public by description, or in use within the USA. Inventions are usually compared with existing publications in international accessible databases. In the USA such a data base for plant varieties with full descriptions is available at the US-PBR office in Beltsville but this is not being used for testing the newness of utility patent applications for plant varieties. A plant variety may not be new if its application for a foreign PBR was published and material was made publicly available more than one year before filing the application in the USA⁸.

Useful

The invention must have a practical purpose in any kind of industry, including agriculture. Methods of medical treatment for instance are defined as being incapable of industrial application. This utility requirement is marginally tested: usefulness is assumed present unless the opposite is obvious.

Inventive

The invention must be inventive or non-obvious to a person skilled in the art with respect to the state of the art. In utility patents this is a difficult criterion, predominantly subject to the judgment of the patent examiner, which results in office to office differences in the granting of patents. The US patent

⁷ The longest term is according to the UPOV Conventions only granted for vines and trees, although some jurisdictions provide the longest term for other species like potato and tulip.

⁸ In *Re Elsner*, No. 03-1569 (Fed. Cir. Aug. 16, 2004)

examiner considers plant varieties as the 'unexpected' and therefore non-obvious result of a systematic breeding process. This statement is true for all plant varieties, as no breeder is able to predict precisely the result of his crossing and selection work. In this way, the inventiveness requirement has become a dead letter.

The patent application procedure requires an enabling disclosure of the invention by a full description, which is published 18 months after application. It must be in such a way that it enables a person skilled in the art to reproduce the invention. Soon after patents for living organisms were being granted it was recognized that it is virtually impossible to reproduce a bacterial strain or plant variety from a written description. To overcome this problem a living sample is deposited in a recognized and public accessible culture collection or seed bank, e.g. ATCC in the USA. The majority of the developed countries have adopted the Budapest treaty of 1977, which rules the formalities of the deposit and the maintenance of the samples.

Seed of varieties protected by PBR is not publicly accessible, unless sold on the market.

The claims

An important part of the patent application is the formulation of the claims, which define the scope of protection. It is this part which makes utility patents fundamentally different from PBR. Claims are also examined for the general patent requirements. This topic will further be discussed in the next paragraph dealing with the scope of protection of PBR and patents.

Examination

The examination of the patent requirements for plant varieties in the USA is in practice limited to novelty or distinctness from the prior art. Although the scope of its protection is significantly greater than PBR, the requirements are in practice clearly lower than those for PBR where uniformity is generally a greater hurdle than distinctness. Moreover patent offices are not equipped to test plant varieties against the prior art.

Utility patents are in force from the day of granting until 20 years after the date of filing, except for pharmaceuticals and agro chemicals, for which the period can be extended to 25 years due to long testing time for marketing approval.

SCOPE OF PROTECTION

The scope of Plant Variety Protection

The scope of protection for PBR is very well defined and rather limited, although there is a great difference between UPOV 1978 and 1991. The right in both Conventions however is an exclusive right like in any other Intellectual Property Right and not as suggested by Hughes and Deibel⁹ just a right to collect royalties from the users of the variety. This opinion may be caused by the historical relationship in the agricultural sector between breeders, seed producers and farmers, where excluding others from using the protected variety was (and still is) "not done". In other areas, like ornamentals, production and trading is restricted to a few companies under stringent license conditions. The fact that ornamentals cannot be protected by PBR in the USA¹⁰ may have caused this erroneous conception of PBR. The original UPOV scope of protection in the 1961-1978 Conventions concerned only the exclusive right on production of propagating material for commercial purposes, its offering for sale and its trading. Farmers may under these old UPOV Conventions freely use their harvested grain to seed the next crop as it is not covered by the scope of protection. This is known as the farmer's privilege. Even the seed production for other farmers was allowed under the former UPOV 1978 based US-PBR act by the provision of a 'crop exemption'.

The 1991 UPOV Convention has extended the scope of protection by including the following acts in the exclusive rights of the breeder:

- all production and all handling with the propagated material of the protected variety.
- the same for the harvested product of the protected variety.
- the same for the (end)product made from the harvested material (Optional provision)
- all handling with all material produced and the harvested product of varieties

⁹ Steve Hughes and Eric Deibel: "Opinion Piece: Plant Breeder's Rights, Room for Maneuver?", Tailoring Biotechnologies, Vol. 2, Issue 3, Winter 2006/07, pp: 77-86.

¹⁰ Although the scope of protection under PVP is larger than under plant patent, ornamental varieties can only be protected by plant patent in the USA. The number of applications for ornamental varieties was in 2005 in the EU two times the number of seed crop varieties on a total of 2734 and in the USA (for plant patent) three times the number seed crop varieties (for PBR) on a total of 1570.

essentially derived from the protected variety and of varieties that need the repeated use of the protected variety (hybrid varieties produced by the protected parent lines are covered by the PBR on these lines).

The extension of the protection to all material produced, irrespective whether it is for trade or own use, means that in principle any (re)production requires a license from the PBR holder. UPOV 1991 provides for the farmers an optional exemption on this exclusive right that restricts the farmer's privilege to produce seed on the farm to be used on the same farm. This item will be further discussed in the next paragraph.

The extension to the harvested product is of special interest for the cut flower industry in order to capture the import of flowers produced in countries where no PBR exists. The right on the harvested product can only be exercised if the propagating material was illegally used *and* if the breeder had no reasonable opportunity to exercise his right on the propagating material. This 'reasonable opportunity' does not require that the breeder is obliged to obtain PBR in all countries where PBR is available and his variety might be produced or sold. This can be concluded from a decision of the German Supreme Court in February 2006¹¹. On top of this article 16 of UPOV 1991 determines that if material of the variety is sold the Right is exhausted, except for the acts of reproduction and the export to a country where the crop involved cannot be protected.

The extension of the protection to harvested material is therefore completely different from so called "reach through claims" in patents, whereby each new developed product containing the patented invention can be claimed separately, without the exhaustion provisions as in the PBR.

The notion of essential derivation originates from the mutant problems in the field of ornamentals and the concern of breeding companies in the 1980's that the new technique of genetic engineering would result in easy development of new varieties by just inserting a gene in a good existing varieties. A variety is essentially derived from an initial variety if it is predominantly derived from that initial variety, is distinct and remains unchanged in the expression of the essential characteristics, except for the differences caused by the act of derivation. Examples of essential derivation are the selection of a mutant, a (somaclonal) variant, genetic engineering and back crossing. The discussion within the crop sections of the global seed industry association, the International Seed Federation (ISF) focuses on the genetic distance between

¹¹ Bundesgerichtshof German Federal Republic, Case XZR 93/04 Melanie, 14 February 2006

varieties, measured by DNA fingerprinting techniques. The aim is to agree on a threshold per crop beyond which a variety may be considered as essentially derived. In contrast to the initial variety, the protection of the essentially derived variety confines only to the variety itself. This means that it is also important to determine whether a claimed initial variety is a true initial variety. In this respect the threshold as established for essentially derived varieties influences also the position of the initial varieties: the lower the threshold, the wider the scope of protection and the greater the chance that a variety, claimed to be an initial variety, may eventually appear to be essentially derived from another, older and possibly even non-protected variety.

The scope of protection of Patents

Besides that any use of the invention is covered by the patent protection, the formulation of the claims mainly determines its scope. Usually the patentee tries to formulate his patent claims as broad as possible.

It is the task of the patent office to examine these claims and revoke the ones that cover the prior art or do not meet the non-obviousness criterion. The applicant may appeal to decisions of the examiner. In Europe other parties may file an opposition at the European Patent Office against patents after the grant of the patent. This is not possible in the USA. In order to revoke a granted patent in the USA, a very costly court case is the only and mostly impossible way to go. The US Patent and Trademark Office (USPTO) still grants broad process claims in the case of utility patents on conventional plant varieties, which cover the method of crossing the patented plant with any other plant until the 8th breeding generation, which in fact block the breeder's exemption on the patented varieties. This is the more peculiar in the light of the factual lower requirements for variety patents as compared to PBR for plant varieties, as shown in the former paragraph.

As mentioned before the European Patent Office does not allow patents for plant varieties. This has been clearly reconfirmed in the above mentioned Novartis decision of the enlarged Board of Appeal of the European Patent Office: " the exception to patentability in article 53(b), 1st half sentence, EPC applies to plant varieties irrespective of the way in which they were produced; a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under article 53(b) EPC, even though it might embrace plant varieties ". The motivation to maintain the prohibition of patenting plant varieties is based on the availability of the specific UPOV

based PBR acts at the national and supranational level in the EPC member states. Although this may be regarded as a formal and not a substantial reason it has the advantage that the protection of plant varieties is dedicated to a legislation of its own kind (*sui generis*) that is specifically tailored for this purpose.

Exemptions under Plant Variety Protection

The breeder's exemption.

The UPOV Convention of 1961 introduced a very important exemption to the exclusive rights of the breeder, the so called 'breeder's exemption'. This implies that breeders may unrestrictedly make use of protected and released varieties for breeding new, commercial varieties. The background of this provision was the existing habit of breeders to build upon the best available varieties present. This is still an important way for breeders to create the necessary variability in their breeding material. Without this possibility breeders would end in a cul-de-sac situation, even the breeders having a dominant position in a particular crop! Also the notion that most varieties were (and are) as a result interrelated and that claiming further breeding with the protected variety as an exclusive right would lead to a not-to-unravel jumble of relations between varieties, led to this notion of breeder's exemption. From a society point of view it bore the advantage of competition and the avoiding of monopolization of specific breeding goals. For successful companies it has sometimes the disadvantage of closely being followed by 'me too' varieties, although the marketing position of the first product is mostly much better than the remakes. For the problem of the very close, almost identical varieties, the notion of essential derivation has been introduced as discussed in the former paragraph.

The farmer's privilege.

A much discussed exception is the farmer's privilege: notwithstanding the exclusive rights of the breeder the national legislator may, under UPOV 1991, allow the farmer or grower to use for his own farm the harvested product from his own farm for the seeding of the next crop, without the consent of the breeder. But the legitimate interest of the breeder has to be taken into account. This last requirement has resulted in different implementations in the PBR laws. For instance in the EU this provision is limited to agricultural food and feed crops

and farmers have to pay a modest royalty¹² for the 'farm saved seed' (FSS). In the USA no royalty is paid for the FSS and all crops are included in this privilege. However, by protecting varieties by patents, companies can still obtain a royalty for the FSS. The royalties on the farm saved seed in the EU are to be collected on the level of the EU Member State by the breeder or organizations mandated by the breeders. Until now the collection of royalties in the UK, Sweden, Denmark, the Netherlands, Germany and France is quite successful, although decisions of the European Court of Justice¹³ have complicated the necessary collection of information from farmers. Farmer's resistance is quite strong in some, most southern European countries, where the seed saving in cereals can be as much as 90% of the total seed market.

Although on the one hand the habit of farmers to save, exchange and produce seed for their families and neighbors is a millennia old habit, it is on the other hand fully understandable that breeders need some return on their breeding investments. A complicating aspect is the sensitive relationship between breeders and farmers: farmers are clients in the first place!

Part of the resistance from farmers may be caused by the interference between material property and intellectual property. The Farmer who produces the seed has the material property of the seed - and he clearly regards himself as the rightful owner -, but the specific genetic content of the seed as created by the breeder provides also some rights to this breeder: the right to reproduce the genetic content. Similarly with books and copyrights: the person who buys a book may do with it what he likes, even sell it. But copying the book and selling the copies, although the copies are made and paid by that person, is not allowed because the author of the book created the content and has a copy right on that content. Another complicating factor is that the seed price of certified seed, being much higher than the grain price, is based on costs for production, certification, cleaning, storage, transport, selling etc., and only for a very small part on the fee paid for the breeding work.

Finally farmers are not obliged to use protected varieties, they can use old or outdated, non-protected ones and they will have the full freedom to produce as much as they like! But most farmers do value the benefits of the newly bred varieties with their improved yield and quality, which provide much more money than the royalty to be paid.

¹² This is in most cases 50 % of the commercial royalty, e.g. about € 1,50 - 2,50 per 100 kg wheat seed.

¹³ See inter alia Case C-305/00, Christian Schulin / Saatgut-Treuhandverwaltungsgesellschaft GmbH, April 2003

The use of plant material for private, non-commercial purposes is free. Farmers may for instance always re-use seed of a protected variety to produce grain for their own food or feed. This freedom is important for small subsistence farmers in developing countries.

Exemptions under Patents

In the USA the mere use of a patented product usually constitutes infringement under Section 271(a) of the Patent Act: "except as is otherwise provided in this title, whoever without authority makes, uses offers to sell, or sells any patented invention within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent". Based on the jurisprudence in the USA the research exemption or experimental use defense is allegedly very narrow. It is assumed that in the case of plant breeding, the testing and describing of the patented variety is allowed even though DNA fingerprinting may be claimed by the patentee as an exclusive right. Although crossing with the patented variety is hard to control by the patentee, the commercialization of such a variety can with the aid of DNA fingerprinting nowadays be detected more easily and most maize companies analyze all new varieties that enter the market. In case of patented traits or elements, the plant containing these elements falls under the patent. After crossing this plant with another plant the plants without patented elements can be selected in the F2 generation. The narrow research exemption in the USA may prevent the making of the necessary cross, although one can wonder whether the patent law is intended to prohibit an act that leads to a product without the patented invention.

The national European patent laws formulate the research exemption explicitly. In the case of varieties falling under the patent of a trait, it is assumed that experimenting (crossing) with the plants containing the trait is permitted, but not the unauthorized commercialization of varieties in which the trait is present. Nevertheless the German and French patent laws provide a specific exemption which allows breeders to use the biological material for breeding, or discovering and developing, new varieties.

Access and Benefit Sharing in the IT and CBD

This political important and complicated issue is discussed here as it is directly influencing the development of Intellectual Property Rights for plant varieties in the world.

The FAO International Undertaking preceding the IT formulated the notion of Farmer's Rights (not to be confused with the 'farmer's privilege') in 1989 as 'the rights of farmers, especially in developing countries, to benefit from their contributions in conserving the agro biodiversity in the past, the present and the future'. Farmer's Rights were to be implemented through international funding on plant genetic resources, which would support plant genetic conservation and utilisation programmes.

The IT provides a multilateral system for Access and Benefit Sharing (ABS) for 65 food and feed crops. The genetic resources falling under this treaty can be accessed on the basis of a standard Material Transfer Agreement (sMTA) in which the rights and obligations of provider and recipient are laid down. The most important ones concern the payments to an FAO fund for genetic conservation, which has been agreed on 1.1% of the net sales of the commercial product derived from a genetic resource. In the case the access to this product (variety) is not restricted for further plant breeding - e.g. only protected by PBR -, the payment is voluntary and obligatory if this access is restricted, e.g. by patent or contract. The access to the newly bred varieties for further breeding has been acknowledged as the Benefit Sharing for the use of the genetic resources. Breeders are nevertheless burdened by the administrative requirements of the system and to trace all accessed material through their 10 - 15 years lasting breeding programs.

The farmer's rights remain in force as an obligation to the national governments to provide for equitable benefit sharing arising from the utilization of plant genetic resources and to respect the rights of farmers based on national law for using and exchanging farm saved seed. This does not exclude that the national law may be changed in accordance with UPOV 1991.

The CBD is valid for all crops except the ones falling under the IT. These are all fibre crops, ornamentals a number of vegetables, including tomato and soya bean. The issue of ABS is also part of the CBD wherein the national sovereignty of genetic resources has resulted in a Prior Informed Consent (PIC) for companies to obtain in the country of origin before they collect germplasm in - mostly - developing countries. The CBD has not yet a workable and practical system of Access to the national genetic resources. On the other hand there is much effort put in control systems to check the presence of genetic resources in the relevant products. For this purpose the 'declaration of origin' at the moment of patent filing was launched, which meets still resistance from the industry as this may lead to legal uncertainty and disclosure of confidential information. The latest development in the CBD in this field is the propos-

al for a 'Certificate of Origin' or 'Certificate of Compliance' as a means to track the use of genetic resources. The transaction costs of the PIC or any Certificate may however be disproportional high, especially for the smaller companies, which may result in less competition and only few benefits to share. There are various examples of breeding and research projects been cancelled by the sheer insurmountable hurdles to access plant genetic resources in a proper, legal way.

As the CBD offers a more complicated, more expensive and less certain system as compared to the IT, plant breeders in general prefer to have all species with breeding activities under the IT.

Access to protected varieties: an open source provision

The best benefits from the use of genetic resources are improved varieties for farmers with a higher and more reliable yield and a better disease resistance compared to the existing varieties. Farmers may also start breeding by themselves like their European colleagues did in the beginning of the 20th century, or participate in institutional or private breeding programs. There is no graduation required for plant breeding, only a breeder's eye, a lot of patience and a long life. Farmer's participation can make sense for instance in small crops, specific uses, or remote areas where there is a niche market. Companies or institutions could develop breeding populations for this purpose. To provide access to all breeding populations of breeders for this aim, as proposed by Hughes and Deibel¹⁴, is not practical and would not be welcomed by the breeders. Not practical because most of the breeders' material would not be suitable for the specific aim of the farmer's breeding program. It is then better to use the best adapted commercially available varieties as a start for the breeding work. And breeders would not like to provide their early breeding material as that would disclose their breeding goal and way of working to the competition. Landraces in this respect can not be regarded as breeding populations, while these are built on crosses between well chosen parents. Landraces are (heterogeneous) varieties in use, just like the commercial varieties of the seed companies.

Access to plant genetic resources is a vital part in the breeding process, needed by all breeders and as provided for by the PBR system, a keystone in the plant breeding industry. As the provision of essential derivation in the PBR can be used to act against close remakes of successful varieties, it is not nec-

¹⁴ 6 supra

essary to block the breeder's exemption by patents on conventional varieties or patents on varieties containing patented elements.

A number of useful traits from landraces and related wild species have been bred into new varieties. It takes however a lot of effort and many years of breeding, especially in the case crosses between species, to combine these traits with other important characteristics in such a way that the best possible combination in a new variety can be reached. Although the outcome of a breeding program can be influenced by the breeder the final result is unpredictable. Therefore a fair protection system like PBR is indispensable, which provides, as should be stated over and over again, full access to the protected varieties - like an open source provision - for further breeding. The term 'open source' originating from the computer software, refers to open access to the source codes of software, which enables software developers to alter and improve existing computer programs, without further obligations to the original manufacturer of the program. Likewise the unrestricted access to the genetic codes of plant varieties and genetic resources in general as a common ownership¹⁵ is the best way to guarantee the continuous creation and development of new, improved varieties in a competitive environment for the benefit of farmers, consumers and breeders.

¹⁵ See also Eric Deibel: "Common Genomes: open source in biotechnology and the return of the common property", *Tailoring biotechnologies*, Vol. 2, Issue 2, Summer-Fall 2006, pp: 49-84.

Most important differences between UPOV 78, UPOV 91 and US Utility Patents			
Topic	UPOV 78	UPOV 91	US Utility Patent
Novelty	0-4 yrs after first sale or offering for sale.	1 - 4 years after first sale	1 year after any disclosure by publication in the world + use in the USA
Breeder's Exemption	+	+	None
Essential Derivation	-	+	May fall under claims
Scope of Protection - of the variety - of the inbred line or parent	only the propagating material traded repeated use for hybrid production	all acts with propagating or harvested material + EDV's includes all hybrids	all material of the variety idem
Farmer's privilege	extensive	limited None	None
Minimum number of protected species	24	all crops	Only seed crops(?)
Duration of protection	15-18 years from granting	20-25 years from granting	20 years from filing
Double protection Patent/PBR	No	Yes	Yes
Seed Deposit Public accessible?	No	No	Yes

References

Hughes, Steve and Eric Deibel: 'Opinion Piece: Plant Breeder's Rights, Room for Maneuver?'

Tailoring Biotechnologies, Vol. 2, Issue 3, Winter 2006/07, pp: 77-86.