

RELATION BETWEEN PVP AND PATENTS ON BIOTECHNOLOGY

1. Introduction

The title of my presentation being "Relation between PVP and patents on biotechnology" I would like to start with a short explanation of the most important terms in this title.

- PVP
 - o These letters are the abbreviation of Plant Variety Protection as offered by plant variety rights (also called plant breeders' rights) systems. Most of the existing PVP 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. UPOV has at the moment 52 members. From the Asian and Pacific regions I mention China, Japan, South Korea, Kyrgyzstan, Australia and New Zealand. Other countries in this part of the world have adopted PVP legislation which although partly inspired by it, is not in all aspects in conformity with the UPOV system. The subject matter of a plant breeders' right, UPOV -type is a plant variety¹. In order to be eligible for protection a variety has to be new, distinct, uniform and stable².
- Patents
 - o With "patents" the classical patents are meant as referred to in article 27 of the 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
 - o 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 presentation I would like to define "biotechnology" as follows:
"The use of biological processes to create (improved) products considered to be useful and/or of economic value."

¹ The definition of a plant variety given by 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."

² Article 5 UPOV 1991 Convention.

Early biotechnology includes traditional plant breeding techniques. Modern biotechnology includes the industrial use of recombinant DNA and cell fusion.³

In my presentation I would like to concentrate on three issues:

- Protection of plants or plant varieties with an intellectual property right, the situation in Europe and the USA.
- The scope of protection offered by a patent and a plant variety right respectively.
- The review of Article 27.3(b) of the TRIPS Agreement.

2. Protection of plants or plant varieties by an intellectual property right.

- **The European situation.**

Apart from trade mark protection - not to be dealt with in this presentation - "plant inventions" and plant varieties can in most of the European countries be protected under patent law and plant variety rights law respectively.

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

The exception that plant varieties as such cannot be protected by a patent has been confirmed in a directive of the European Community (the "Biotech Directive").⁴

The prevailing reason to close the door on patentability for plant varieties, seems to be (the history of article 53(b) is not very clear) the fact that in most European countries specific, tailor made protections systems were available for plant varieties based on the UPOV Convention, which contained at that time a ban on double protection.

Another, rather opportunistic reason, to exclude plant and animal varieties from patentability was that no consensus on this subject seemed possible. The whole Convention might have been in jeopardy if this controversial topic had not been excluded.

The scope of the exclusion from patentability has been subject to jurisprudence of the Enlarged Board of Appeal of the European Patent Office (EPO). In the *Novartis* case,⁵ the board of appeal had to answer the question: "Does a claim (in a patent application) which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?"

The decision 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

³ See website Washington Biotechnology & Medical Technology Association, <http://www.wabio.com>

⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological invention, OJ L 213, 30.7.1998, p. 13

⁵ G0001/98, 20 December 1999 (O.J. EPO 3/2000, p 111-171)

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 border line between the domains of the patent and the plant variety rights systems is not only drawn by case law. The Biotech Directive also contains a provision meant to clarify the demarcation line between non-patentable 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." (see Article 4(2)). This provision has been guiding the EPO Enlarged Board of Appeal when developing its doctrine as mentioned before.

Most of the European countries have adopted legislation based on one of the versions of the UPOV Convention. In parallel with those national systems a Community plant variety protection system has been created that offers plant variety protection for the whole territory of the European Community. On the basis of one application a Community plant variety right can be obtained, that is valid in all the 15 (soon 25) Member States of the European Community.

The Community system, based on UPOV 91, is rather successful. In 2003 more than 2500 applications for Community plant variety rights were received by the Community Plant Variety Office (CPVO) that is responsible for the management of the system. At present around 8500 Community plant variety rights are in force.

The clear demarcation line between the scope of the patent and PVP system has in Europe had the effect that in principle, only the results of modern biotechnology are subject of European patent applications. 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, are protected by patents. Such inventions could be applied in respect of 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 ipr 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. A

corresponding provision is foreseen to be introduced to the plant variety right system by the EU legislator.

- The situation in the USA⁶

In the United States the legislative situation as regards ipr protection of plants and plant varieties is quite different from the European situation. Breeders or inventors of new plant varieties have the choice between three kinds of intellectual property rights to protect their creations. For plant inventions not expressed in the form of a plant variety only the utility patent system is available.

The Plant Patent Act (PPA) of 1930 provides protection for asexually reproduced, novel plant varieties, not consisting of tuber propagated plants or plants found in an uncultivated state.

The Plant Variety Protection Act (PVPA) of 1970 as amended in 1994 is based on the UPOV 1991 Convention and provides protection to the breeder of any sexually or tuber propagated plant variety if the UPOV requirements for protection are met.

Apart from these specific protection possibilities, breeders of new plant varieties may obtain utility patent protection, provided of course that the substantive utility patent requirements of utility, novelty, non-obviousness and disclosure are met.

A recent Supreme Court decision (*J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*) of December 10, 2001, has confirmed that the fact that the PPA and the PVPA offer protection by a specific intellectual property right for plants, does not evidence the legislator's intent to deny broader utility patent protection for such plants. As in Europe, biotechnical inventions, not in the fixed form of a plant variety, are protectable under the utility patent system only.

I have the impression, that due to the rather liberal approach of the US Patent Office as regards the patent requirements, especially the non-obviousness requirement, the balance between these systems has been somewhat upset. The threshold for patentability is not as high as assumed by the US Supreme Court in the *Pioneer* decision mentioned above. This has led breeding companies to protect varieties with a utility patent, for which a plant variety right UPOV-type would be more appropriate.

⁶ The description of the legal situation in the USA is based on presentations made by Prof. Charles R. McManis and Mrs. Victoria Henson-Apollonio at the occasion of the WIPO-UPOV symposium on the co-existence of patents and plant breeders' rights in the promotion of biotechnical developments that took place on October 25, 2002 in Geneva, Switzerland.

3. The scope of protection offered by patents and pvr's 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 respectively⁷

<u>TRIPS Agreement</u> (Article 28)	<u>UPOV</u> (1991 Act – Article 14)
"1. A patent shall confer on its owner the following exclusive rights: (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:	"(1) [Acts in respect of the propagating material] (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, Using,	(i) production or reproduction (multiplication) (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 varieties⁸, the so called breeders' exemption, whilst such an exemption does not exist to the same extent in the patent systems in Europe and the USA.

Furthermore the UPOV Convention contains an optional exception as regards the use of farm saved seed. Contracting parties to the UPOV Convention may under certain conditions "restrict the breeders' right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they

⁷ Table presented by Rolf Jördens, Vice Secretary-General of UPOV, at the WIPO-UPOV symposium, October 25, Geneva mentioned in the previous footnote.

⁸ Article 15(1) UPOV Convention.

have obtained by planting, on their own holdings, the protected variety..."⁹ , the so-called farmers' privilege.

The US patent system does not include an equivalent provision. In this context the following extract of the above mentioned *Pioneer* decision of the USA Supreme Court is illustrative: "" Because of the more stringent requirements, utility patent holders receive greater rights of exclusion than holders of a PVP certificate. Most notably, there are no exemptions for research or saving seed under a utility patent."

The situation in the European Union in respect of the farmers' privilege in the framework of patent protection differs from that in the USA.

The Biotech Directive obliges the Member States of the European Community to introduce in their patent laws a provision with the following bearing: "the sale or other form of commercialization of plant propagating material (of a number of important agricultural crops) to a farmer by the holder of the patent (components of that material) ...implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm". As follows from the directive the farmer has to pay an equitable remuneration to the patent holder for such re-use of patented plant material. Herewith the farmers' privilege has been introduced in European patent law.

A different scope of protection offered by a patent and a plant variety right might especially create problems in the situation where a variety as such is covered by a plant breeders' right and a component of that variety by a patent. The patent system may require the authorization of the patent holder for the use of the variety for breeding purposes, where this use is permitted under the plant breeders' right in question. The plant breeders' right may allow the use of farm saved seed; the patent may exclude this use.

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 US situation, the farmers' privilege would be lost or greatly weakened. Article 30 of the TRIPS agreement offers a basis for such modifications.¹⁰

In this context it should be emphasized that the breeders' exemption is considered as an essential element of the UPOV intellectual property rights system. "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

⁹ Article 15(2) UPOV Convention.

¹⁰ "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."

and wild species, to achieve the greatest progress and is only possible if protected varieties are available for breeding.”¹¹

The International Seed Federation (ISF) has expressed its attachment to the breeders' exemption and its concern that the extension of the protection of a gene sequence to the relevant plant variety itself could extinguish this exemption.¹²

The farmers' privilege is less popular in breeders' circles. The possibility opened by the UPOV Convention to permit farmers to use farm saved seed of protected varieties without previous authorization of the right holder in question was nevertheless for a lot of countries, developed and developing, an essential condition for the acceptance of this intellectual property system. A limitation of this privilege as a consequence of the scope of patents granted in respect of (elements of) plant varieties might have serious political implications.

4. Review of article 27.3(b) of the TRIPS agreement.

As an annex to the Marrakech Agreement Establishing the World Trade Organisation of 15 April 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights was concluded. Article 27.3(b) contains the provision that members may exclude from patentability

“(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the entry into force of the WTO Agreement.”

This provision is not one of the clearest of the TRIPS Agreement. In respect of all of the intellectual property rights mentioned in the Agreement the scope and the substantial elements of every such right are clearly indicated, mostly by reference to the relevant Convention governing such a right. However, in respect of the sui generis (of its own kind or specific) system for the protection of plant varieties, the scope and the substantial elements are not mentioned. Neither is reference made to the UPOV Convention, nor are the conditions for protectability listed. The only requirement laid down in this subparagraph is that the system has to be effective. The Agreement gives no further guidance of what has to be understood by such a system and there is no agreed interpretation of this notion among WTO members. The obligation that this provision be reviewed is a clear indication that the fathers of the Agreement were not convinced that it would serve its purpose.

The reason that such a vague wording was chosen is probably, that there was no political consensus about the scope of intellectual property rights for living subject matter.

The different views expressed by Members of WTO and NGO's at the occasion of the review of this subparagraph ,started in 1999, confirm that still no common opinion exists on

¹¹ Rolf Jördens, WIPO-UPOV symposium, October 25, Geneva.

¹² ISF View on Intellectual Property (Bangalore, June 2003)

this issue. In the so called DOHA ministerial declaration of November 2001 the TRIPS Council has been instructed to continue the review of article 27.3(b), and to examine the relationship between TRIPs and the Convention on Biological Diversity and the protection of Traditional Knowledge.

In the framework of this presentation I want to concentrate on the question, what is an effective *sui generis* protection system for plant varieties.

In my opinion the UPOV Convention offers, certainly in its 1991 version, a protection system that is effective and creates a proper balance between breeders' and farmers' interests. In this context once again the breeders' exemption and the farmers' privilege should be mentioned.

A growing number of WTO members have signed one of the versions of the UPOV Convention which can be taken as a sign that countries find the Convention an effective system., As mentioned above, UPOV has now more than 50 members, a large number of which is in the category of developing countries.

However, while UPOV 1978 and UPOV 1991 should be considered as meeting the standard of effectiveness under Article 27.3(b) of the TRIPs Agreement, they are not necessarily the only valid "effective *sui generis* systems" for plant variety protection. Other models may exist. Several countries have adopted or are preparing to adopt plant variety protection systems which differ to a lesser or a greater extent from UPOV.

In order to be effective, any regime establishing intellectual property rights over a certain subject matter, be it inventions or plant varieties, must fulfil a certain number of criteria. These criteria could in my opinion be the following¹³:

- the protectable subject matter (i.e. plant variety) must be clearly defined;
- the conditions for granting protection must be clearly defined;
- the rights with respect to the protected subject matter need to be clearly spelled out; the right-holder should at least be able to prevent third parties from carrying out certain acts in relation to the protected subject matter over a certain period of time;
- the law must provide for national treatment and most favoured nation treatment; it is logical that Articles 3 and 4 of the TRIPs Agreement apply to plant variety protection as well;
- the procedure to be followed by the breeder to obtain these rights should be spelled out in a detailed and transparent way;
- an administrative organisation needs to be set up to ensure that these rights can be effectively obtained within a reasonable time frame;

¹³ List based on a Draft Communication by the European Communities and their Member States to the TRIPS Council.

- limitations and exceptions to the rights of the right-holder need to be clearly defined; typical examples of such exceptions are experimental use, the right to use a variety for further breeding, compulsory licences (in which case Article 31 TRIPs provides a useful yardstick) and certain exceptions to the benefit of farmers;
- the duration of the rights must be determined and should be sufficiently long to allow breeders to recover costs and to invest in new research;
- the law must provide for legal and institutional implementation procedures to allow the right-holder to enforce his rights and to create an effective deterrent to infringement; the legal actions spelled out in the TRIPs Agreement should be available to the right-holder for this purpose.

The opinion of the WTO member states regarding the notion of an effective *sui generis* system vary importantly. Especially the question whether UPOV '91 should be mentioned explicitly in the TRIPs agreement, as an example of such an effective system, gets very different answers. An agreement does not seem within reach.

Bart KIEWIET
President Community Plant Variety Office

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