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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

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Geneva, April 10, 2003

SPECIFIC ISSUES CONCERNING THE INTERFACE BETWEEN PATENTS AND BREEDERS' RIGHTS

Document prepared by the Office of the Union

1. This document contains two parts: the first deals with the possible adoption by the Council of UPOV of a position paper on "Specific Issues Concerning the Interface Between Patents and Breeders' Rights," based on document CAJ/46/2, as modified by the Administrative and Legal Committee (hereinafter referred to as "the CAJ"); and the second part, provides a report of the WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments (hereinafter referred to as the "WIPO-UPOV Symposium of 2002"), held in Geneva, on October 25, 2002.

I. Recommendation to Adopt a UPOV Position Paper on "Specific Issues Concerning the Interface Between Patents and Breeders' Rights"

2. At its forty-sixth session, held in Geneva, on October 21 and 22, 2002, the CAJ approved, with some amendments, the contents of document CAJ/46/2 on "Specific Issues Concerning the Interface Between Patents and Breeders' Rights".

3. The revised document, as presented in the Annex to this document, constitutes document CAJ/46/2, as amended by the CAJ (see paragraphs 5 to 13 and Annex II of document CAJ/46/8 Prov.), and further amended by the removal of the first paragraph of document CAJ/46/2, which provided information on the previous version of the document, by

updating the membership of the World Trade Organization (WTO) in paragraph 5 and by replacing the word "Committee" by the word "Council" in paragraph 29.

4. Due to the importance of the issues addressed in this document, it is proposed that the CAJ considers the presentation of the document to the Council of UPOV for its adoption, at its October session in 2003, as a UPOV position paper.

II. Report of the WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments, October 25, 2002

5. The WIPO-UPOV Symposium of 2002 had the objective of addressing the possible need for further action to ensure the effective co-existence of patents and plant breeders' rights. A total of 186 participants took part, 108 participants from the public sector and 78 from the private sector, coming from 55 different countries. Six intergovernmental organizations and 17 non-governmental organizations also participated.

6. The CAJ is invited to consult the UPOV Website (www.upov.int), where the following documents concerning the Symposium are posted:

- Program
- List of participants
- Presentations
- Records of the discussions.

The proceedings in English, French and Spanish of the WIPO-UPOV Symposium of 2002 are under preparation.

7. The "Conclusions by the Chair of the Panel Discussion" resulting from the presentations and discussions are reproduced below:

PANEL DISCUSSION

Conclusions by the Chair
Peter Lange
KWS SAAT AG, Einbeck, Germany

"1. Access to plant germplasm, be it patented or protected by plant breeders' rights (PBR), is of key importance for further innovation in plants:

- Within the PBR system, this is ensured by the breeder's exemption for entire plant genomes;

- As far as patents for biotechnological inventions (protecting elements or properties in plant material) are concerned and as far as patents for plant varieties *per se* are available, access can be assured by a well defined research exemption or experimental use defense;

- At present this seems to be ensured by the European system (and comparable systems in the world), but to a lesser extent in the system provided in the United States of America.

"2. The legal framework for the protection of plant innovations must offer efficient (enforceable) and adequate (fair) protection which ensures optimal incentives for investment and good working conditions for further innovation:

- In this respect deficiencies within or caused by the implementation and administration of plant breeders' rights and patent systems should be identified and eliminated;

- In the interest of an efficient technology transfer system-especially for developing countries-effective and adequate protection systems should be offered worldwide, being harmonized as far as possible.

"3. A broad majority of the participants of the WIPO-UPOV Symposium in Geneva, held on October 25, 2002, prefer a better harmonization and balancing of the interfaces of the systems by ensuring within the patent system a well defined and broad enough research exemption/experimental use defense, whereas any extension of existing compulsory licensing provisions is not acceptable:

- Compulsory cross-licensing systems may also be helpful, but need further consideration and clarification;

- Private "clearing house systems" for organized access to plant innovations should be encouraged."

8. The Consultative Committee will, in its April session in 2003, consider a document concerning a further WIPO-UPOV Symposium, to be held in Geneva, on October 24, 2003. More detailed information concerning the program and speakers will be shortly posted on the UPOV Website.

9. *The CAJ is invited to recommend to the Council of UPOV that, at its thirty-seventh session in October 2003, it adopt the Annex to this document "Specific Issues Concerning the Interface Between Patents and Breeders' Rights" as a UPOV position paper.*

10. *The CAJ is invited to note and comment on the report of the WIPO-UPOV Symposium of 2002.*

[Annex follows]

ANNEX

SPECIFIC ISSUES CONCERNING THE INTERFACE BETWEEN PATENTS AND PLANT BREEDERS' RIGHTS

1. The common objective of plant breeders' rights and patents is to provide an incentive for the development of innovative and useful products or processes. These two different forms of intellectual property right (IPR) have been developed to address different sectors. The patent system covers inventions in all fields of technology, whereas the UPOV system of plant variety protection has been specifically developed to cover plant varieties.

2. The purpose of this document is to consider the situation where, notwithstanding the fact that the subject matter of protection is different, the grant of a patent might inhibit the "breeder's exemption" provided by the UPOV system of plant variety protection. It then considers the issues which may arise and addresses how a State may be able to preserve the breeder's exemption within national legislation implementing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

3. In some circumstances, the subject matter of protection covered by patents and plant breeders' rights might be the same, namely a plant variety. However, this is a situation which has existed for many years and is not considered in this document.

4. It is necessary to start by examining the scope of protection offered under the patent system and UPOV system. In particular, this is explored in relation to the situation where, for example, the development of genetic engineering can result in a plant variety which will be protected as a plant variety, by a plant breeder's right, but will also contain an invention protected by patent (e.g. patented genetic element). The issues which arise from such protection are a result of differences in the scope and exceptions for the two systems. These differences and the issues which arise are explored in the following section.

I. ISSUES ARISING FROM THE GRANTING OF PROTECTION

Rights Conferred by the Protection

5. The rights provided by the UPOV system and the patent system are similar, as can be seen from the following table which compares the scope of protection in the UPOV Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This Agreement as part of the Agreement Establishing the World Trade Organization (WTO) sets international minimum standards on intellectual property protection and binds all Members of WTO (as of February 5, 2003, 145 Members).

TRIPS Agreement (Article 28)	UPOV (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[1]	(v) exporting, (vi) importing,
for these purposes that product;"	(vii) stocking for any of the purposes mentioned in (i) to (vi), above."

6. It can be seen that the rights provided by the two systems are similar. Therefore, in general, those acts requiring the authorization of the breeder would also require the authorization of the patent holder and vice versa. One issue for a protected variety containing a patented invention(s) might be that authorization is required from both the breeder and patent holder(s). However, in practice, authorization is likely to be administered by one of the parties for each variety.

Exceptions to the Rights Conferred

7. In contrast to the close correspondence between the two systems in terms of the rights conferred, there is a fundamental difference in the scope of the exceptions to the rights conferred. This is explained below:

Exceptions to the breeder's right

8. Article 15(1) of the 1991 Act of the UPOV Convention states that:

> "(1) [*Compulsory exceptions*] The breeder's right shall not extend to
>
> (i) acts done privately and for non-commercial purposes,
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> (ii) acts done for experimental purposes and
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> (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties."

[1] This right, like all other rights conferred under the TRIPS Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

9. The exception for the purpose of breeding other varieties, contained in Article 15(1)(iii), is a fundamental aspect of the UPOV system of plant variety protection. This exception is known as the "breeder's exemption." It recognizes that real progress in breeding—which must be the goal of intellectual property rights in this field—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 landraces and wild species, to achieve the greatest progress and is only possible if protected varieties are available for breeding.

10. The breeder's exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders. However, it also helps to ensure that the genetic basis for plant improvement is broadened and is actively conserved, thereby ensuring an overall approach to plant breeding which is sustainable and productive in the long term. In short, it is an essential aspect of an effective system of plant variety protection system which has the aim of encouraging the development of new varieties of plants, for the benefit of society.

Exceptions to the rights conferred by patent

11. Article 30 of the TRIPS Agreement states that:

> "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 account of the legitimate interests of third parties."

12. Open multilateral treaties in the field of patents do not provide for the extent to which those limited exceptions concerning the use of patented products or processes may be permitted.[2] It is, therefore, necessary to refer to national or regional patent legislation and to relevant jurisprudence.

13. Several laws establish that the rights conferred by the patent shall not extend to acts done for research or experimental purposes relating to the subject matter of the patented invention. Some national systems distinguish between experimental use for the purpose of obtaining additional scientific knowledge and uses aimed at obtaining marketing or other types of approval (e.g. approval for commercialization of generic drugs). Other systems consider that uses of the patent for selection and evaluation purposes may not be considered as falling within an acceptable exception.

14. National systems that provide a wide research exemption will require that the research or experiments are directed towards the generation of information and in these situations only "commercial use" would be prohibited.[3]

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[2] Article 5*ter* of the Paris Convention for the Protection of Industrial Property of 1967 (Paris Convention) provides for limitations to the exclusive right conferred by the patent in certain cases of public interest in order to maintain the freedom of transport. These exceptions are not of direct relevance for the interface object of this document.

[3] Recent Japanese Supreme Court decision in 1999 and German Constitutional Court decision in 2000 favor a wide research exemption.

Issues Which May Arise from Inhibition of the Breeder's Exemption by the Granting of a Patent

15. Two main issues may arise if a patent inhibits the breeder's exemption. Firstly, there might be an imbalance between the UPOV system and patent system concerning the obligation to reward the right holder of the initial protected subject matter (i.e. patented invention or protected variety) as far as countries that are still bound by the 1961/72 and 1978 Acts of the UPOV Convention are concerned. This has been addressed by the provision for essentially derived varieties (EDV) in the 1991 Act of the UPOV Convention. Secondly, there is a need to consider how to maintain the ability to exercise the breeder's exemption in the case of varieties which contain patented inventions. These issues are explained below.

Balancing the reward to the respective rights holders (essentially derived varieties)

16. The potential imbalance between the exceptions under the patent system and the UPOV system was known at the time of the development of the 1991 Act of the Convention. In particular, it was recognized that, under the breeder's exemption, the holder of a patent on a genetic element (Gen-elem 1) was free to insert his genetic element into a protected variety (Variety A) to develop and protect a new variety (Variety B) without any obligation to reward the owner of Variety A. However, if the owner of Variety A wished to insert Gen-elem 1 into his variety to produce a new Variety C, he would be obliged to seek the permission of the Gen-elem 1 patent holder and would, in all likelihood, only be given permission to do so if the patent holder was satisfied that he would be adequately rewarded.

17. To address this imbalance, the 1991 Act of the UPOV Convention introduced a provision for essentially derived varieties. The essence of this provision (see Article 14(5) of the 1991 Act of the UPOV Convention) is that the scope of the breeder's rights for a variety extends to any varieties which are essentially derived from it. An essentially derived variety ("EDV") is one which is predominantly derived from an initial variety and retains the essential characteristics of the initial variety. The 1991 Act states in its Article 14(5)(c) that "Essentially derived varieties may be obtained for example by … transformation by genetic engineering." The introduction of this provision establishes a more equal balance between the patent and UPOV systems. Thus, in the example above, the patent holder of Gen-elem 1 would not be able to exploit his new Variety B without the authorization of the owner of Variety A, assuming that Variety B was considered to be essentially derived.

18. Having stated that the EDV concept establishes a more equal balance between the systems, it is important to note that there is still a significant and important difference between the EDV provision in the UPOV system and the right conferred under patent. The EDV provision does *not* prevent the breeding of new Variety B; it only requires that the authorization of the owner of Variety A is obtained to allow its exploitation. This means that the essence of the breeder's exemption is retained, i.e. access for breeding is maintained. If the new Variety B represents a significant improvement over other varieties, it is very likely that the variety owner and patent owner will come to a mutually beneficial agreement for exploitation of the variety.

19. As explained in paragraphs 11 to 14, the patent system may require that the permission of the Gen-elem 1 patent holder is obtained *before any breeding work can begin*. In such circumstances, it might be more difficult for agreement to be reached between the variety owner and patent holder because the value of the end variety cannot be reliably estimated.

20. The nature of the difference which exists between the two systems is not always fully understood. Thus, certain mechanisms, such as cross-compulsory licensing between patent holders and plant breeders' rights holders, which have been introduced by some members of the Union to address an imbalance might fail to resolve the problem unless they ensure that the patent system allows the breeding of new varieties in the same way as provided by the UPOV Convention.

21. Furthermore, with regard to the possible development of such mechanisms, it might be noted that the UPOV Convention makes it unnecessary to obtain a compulsory license for anything other than that strictly justified by public interest, as provided in Article 17(1) of the 1991 Act. Bearing in mind the breeder's exemption in the UPOV Convention, the need to introduce a mechanism for a compulsory license on the basis of important technical advance of considerable economic significance, such as that provided in the TRIPS Agreement (Article 31(l)(i)) may not be justified, because if the new variety satisfied such a test, there would be a very strong incentive for the patent holder and variety owner to find a mutually beneficial arrangement.

22. In conclusion, it is important to recognize that a basic principle of the breeder's exemption, which allows the breeding of new varieties of plants using protected varieties, is not affected by the EDV concept and that the introduction of the EDV concept maintains the access of all varieties for breeding. However, it does provide a mechanism to ensure a suitable reward for plant breeders.

The ability to exercise the breeder's exemption in the case of varieties containing patented inventions

23. The situation outlined above relates to a situation where the starting point is a patent holder with a genetic element and a variety owner with a protected variety. However, it is clear that another situation will arise where there is a protected variety which contains a patented invention—let us say a genetic element for the purpose of discussion. The purpose of the patent is to protect the developer of the genetic element, and the purpose of the plant breeder's right is to protect the developer of the unique combination of plant germplasm forming the variety. However, in certain circumstances, the lack of the breeder's exemption in the patent system might, indirectly, constrain the exercise of the breeder's exemption for the protected variety.

24. If a variety (variety X) contains a patented genetic element, it will be necessary for a breeder to assess if the process of breeding a new variety, using variety X as a parent, would infringe the patent covering the genetic element. The following hypothetical situations are intended to illustrate real outcomes:

Case 1: The act of using variety X, containing the patented genetic element, to cross with another variety *infringes* the patent and:

(a) the permission of the patent holder *is* required to remove the patented genetic element from variety X.

- In this case, in practice, there is no longer any breeder's exemption available on variety X because it cannot be used for breeding other varieties without the permission of the patent holder.

or

(b) the permission of the patent holder *is not* required to remove the patented genetic element from variety X and the breeder removes the patented genetic element before using variety X (minus the patented genetic element) for breeding.

- The breeder's exemption has not been completely lost in this case because a new variety could be bred without the permission of the patent holder. However, in practice, the breeder's exemption has been inhibited because of the need to remove the patented genetic element before starting the breeding work.

Case 2: The act of using variety X, containing the patented genetic element, to cross with another variety *does not infringe* the patent. Evaluation of the progeny infringes the patent, but only where the progeny contains the patented genetic element.

(a) If the breeder *is unable* to screen all the progeny resulting from the cross, the evaluation of the progeny might be feared by the breeder to infringe the patent, regardless of whether the progeny contains the patented genetic element.

- In this case, in practice, there is no longer any breeder's exemption available on variety X because it would not be used for breeding other varieties without the permission of the patent holder.

(b) If the breeder *is able* to screen all the progeny,

- the breeder's exemption has not been completely lost because a new variety could be bred without the permission of the patent holder, providing it did not contain the patented genetic element. However, in practice, the breeder's exemption has been inhibited because of the need to identify the progeny which contain the patented genetic element and remove these from the program.

25. It is clear that patent protection of the genetic element can, in effect, confer the protection onto variety X and as a result negate or inhibit the breeder's exemption.

26. The rapid progress in the development of genetic engineering raises the prospect that, in the foreseeable future, an ever increasing number of plant varieties will contain patented inventions. Furthermore, the varieties may contain several patented genetic elements, which would make the removal of the patented genetic elements, envisaged in cases 1(b) and 2(b), difficult or impossible in practice. The practical consequence of this development would be that the breeder's exemption, which is an essential principle in the UPOV system of plant variety protection, would be lost or greatly weakened.

II. PROVISIONS WITHIN THE TRIPS AGREEMENT WHICH MIGHT ALLOW THE PRESERVATION OF THE BREEDER'S EXEMPTION

27. Article 7 of the TRIPS Agreement states that "The protection and enforcement of intellectual property rights should contribute to the *promotion of technological innovation* and

to the *transfer and dissemination of technology*, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a *balance of rights* and obligations" (emphasis added). Furthermore, the TRIPS Agreement provides (Article 8(2)) that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or *adversely affect the international transfer of technology*" (emphasis added).

28. As explained in paragraph 11, the exceptions to the rights conferred by a patent under Article 30 of the TRIPS Agreement are not specific. This means that a State may be able to implement Article 30 in a way that protects the breeder's exemption.

29. *The Council:*

(a) notes that the EDV provision in the UPOV Convention provides a mechanism for rewarding plant breeders and ensures that the development of new varieties is not inhibited;

(b) notes the potential difficulties in using cross-compulsory licensing as a means to address the lack of a breeder's exemption in the patent system;

(c) notes the consequences for breeding progress if the breeder's exemption is negated or inhibited through the presence of patented inventions in plant varieties and;

(d) recommends to members of the Union to consider, where appropriate, whether the nature of the research exemption in their patent laws concerning plants might inhibit the breeder's exemption.

[End of Annex and of document]