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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

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

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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. Therefore, these two different systems have, in the majority of cases, different subject matters of protection. However, the objective of this document is to identify situations where there is an interface between the two systems, examine the issues which arise and consider measures which may need to be taken to ensure the systems are mutually supportive in future.

2. The document identifies two different situations. In part I, it considers the circumstance where the subject matter of protection is the same, namely a plant variety, but protection is available under different systems. In part II, it considers the circumstance where the subject matter of protection is different but there is an overlap in the protection provided.

I. PARALLEL SYSTEMS OF PROTECTION FOR PLANT VARIETIES

3. In some territories, protection is available for varieties both in the form of patents and plant breeders' rights. In this circumstance, the breeder can decide which is the most suitable form of protection for the variety concerned, in the knowledge that the criteria for, and scope of, protection differ to some extent. However, in these cases and in cases where a UPOV system of plant variety protection is unavailable, there may be certain aspects where harmonization of the two systems would be beneficial.

4. Both the patent system and the UPOV system provide an incentive for the development of new varieties of plants. Thus, Article 6(1) of the 1991 Act of the UPOV Convention states that:

> "[*Criteria*] The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety
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> "(i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and
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> "(ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date."

Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) indicates that one of the conditions to obtain patent protection is that the invention has to be "new."

5. The grace periods established in the UPOV Convention and, in particular, the longer grace period for filing applications in other territories, reflects the time taken to evaluate new varieties. Where the patent system is applied to plant varieties, it is clear that it would be beneficial for plant breeders if the grace periods were the same as provided in Article 6(1)(i) and (ii) of the UPOV Convention. A shorter grace period would not only complicate the work of the breeders but, more importantly, may mean that it is not possible for them to apply for patent protection in practice.

6. The Administrative and Legal Committee (hereinafter referred to as "the Committee") is invited to note the benefits for plant breeders if the grace period for filing applications for patent protection on plant varieties is harmonized with the UPOV system.

II. OVERLAPPING PROTECTION

7. The main focus of this paper is to examine the circumstances where the scope of protection offered under the patent system and UPOV system overlap despite the fact that the subject matter of protection is different. In particular, it considers 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 element protected by patent. The issues which arise from such overlapping protection are a result of differences in the scope and exceptions for the two systems. These differences and the issues which arise are explored below:

Rights Conferred by the Protection

8. The rights provided by the UPOV system and the patent system are very similar, as illustrated by the following summary table:

TRIPS (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."

9. It can be seen that there are no substantial differences between the rights provided by the two systems. Therefore, 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 element(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

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

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

Exceptions to the breeder's right

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

> "(1) [*Compulsory exceptions*] The breeder's right shall not extend to
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> (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."

12. 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.

13. 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

14. 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."

15. 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.

16. 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

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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.

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.

17. 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]

Issues Arising from the Lack of a Breeder's Exemption in Patents

18. Two main issues arise from the lack of a breeder's exemption in the patent system. Firstly there is an imbalance in the obligation to reward the right holder of the initial product (i.e. patented element or protected variety). This is addressed by the provision for essentially derived varieties in the 1991 Act of the UPOV Convention. Secondly, there is the risk that the breeder's exemption will be negated by the presence of patented elements within a variety. These issues are explained below:

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

19. The 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 gene (Gene 1) was free to insert his gene 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 Gene 1 into his variety to produce a new Variety C, he would be obliged to seek the permission of the Gene 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.

20. 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 Gene 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.

21. 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 development of the 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.

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

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.

22. In contrast, the patent system is likely to require that the permission of the Gene 1 patent holder is obtained *before any breeding work can begin*. In such circumstances, it is much 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.

23. The fundamental difference which exists between the two systems is not always recognized and mechanisms, such as cross-compulsory licensing arrangements between patent holders and plant breeders' rights holders, have been drafted to try to provide a balance. However, cross compulsory-licenses will fail to resolve the problem unless they ensure that the patent system allows free development of new varieties to the point of exploitation in the same way as provided by the UPOV Convention.

24. In allowing the development of varieties to the point of commercial exploitation, the UPOV Convention negates the need for a compulsory license for anything other than a narrow sense of public interest as provided in Article 17(1) of the 1991 Act. There is no 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)), 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. If a beneficial agreement could not be reached, it is unlikely that the variety could actually represent an important technical advance of considerable economic significance.

25. In conclusion, it is important to recognize that a basic principle of the breeder's exemption, which allows the development 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 but provides a mechanism to ensure a suitable reward for plant breeders. By contrast, the patent system does not make specific provision for free access to plant material for developing new varieties.

Negation of the breeder's exemption by patented elements within varieties

26. The situation outlined above relates to a situation where the starting point is a patent holder with a gene 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 element—let us say a gene for the purpose of discussion. The purpose of the patent is to protect the developer of the gene, 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.

27. If a variety (variety X) contains a patented gene, it will be necessary for a breeder to assess if the process of breeding a new variety (variety Y), using variety X as a parent, would infringe the patent covering the gene. Various cases may occur:

Case 1: The act of using variety X, containing the patented gene, to cross with another variety infringes the patent. In this case, 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.

Case 2: The act of using variety X in a breeding program does not infringe the patent, but testing and evaluation of variety Y does infringe the patent. In this case, 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.

Case 3: The act of using variety X in a breeding program does not infringe the patent but testing and evaluation of variety Y does infringe the patent. However, prior to the testing and evaluation of variety Y, the patented gene has been eliminated. The breeder's exemption has not been completely lost in this case but it has, in practice, been inhibited.

28. It is clear that, although the purpose of the patent in variety X is only to protect the gene, it has, in effect, conferred the protection onto variety X and as a result negated the breeder's exemption.

29. 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 elements. 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.

30. As explained in paragraph 14, the exceptions to the rights conferred by a patent under Article 30 of the TRIPS Agreement are not specific. This means that there may be scope for these to be interpreted in a way which will not undermine the UPOV system of plant variety protection and, in particular, the breeder's exemption.

31. Support for an interpretation of Article 30 in a way which provides a breeder's exemption is consistent with the objectives of the TRIPS Agreement which states that (Article 7) "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 principles contained in the TRIPS Agreement include (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).

32. The Committee is invited to note:

(a) that the EDV provision in the UPOV Convention provides a mechanism for rewarding plant breeders but, unlike the patent system, ensures that the development of new varieties is not inhibited;

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

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

(d) to consider what measures might be appropriate to address the risk to the breeder's exemption.

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