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INTERNATIONALUNION FORTHEPROTECTIONOF NEWVARIETIESOFPLANTS



WORLDINTELLECTUAL PROPERTYORGANIZATION

WIPO-UPOVSYMPOSIUM ON THECO -EXISTENCEOFPATENTS ANDPLANTBREEDERS' RIGHTS INTHEPROMOTIONOF BIOTECHNOLOGICALDEV ELOPMENTS

organizedby theWorldIntellectualPropertyOrganization(WIPO)

and theInternationalUnionfortheProtectionof NewVarietiesofPlants(UPOV)

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LEGALANDTECHNOLOGI CALDEVELOPMEN TSLEADINGTO THISSYMPOSIUM:UPO V'SPERSPECTIVE

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I. INTRODUCTION

1. Plant breeding has always benefited from technological dev elopments. One of the most important recent developments in biotechnology is genetic modification which is a major factor leading to this Symposium. Genetic modification might, in simple terms, be explained as the process by which genesare introduced in toorganisms in a different way to that found in nature. It is increasingly becoming an important new tool for breeders in their quest to improve plant varieties.

2. As it was mentioned during the opening, plant biotechnology seeks to respond to the challenges posed by pests and diseases, limited resources (land, fertilizer, water, chemicals), the need to improve productivity and quality, and meeting more sophisticated consumer preferences. One way to identify the importance of modern biotech nology in plant breeding is to see the increase in the global area planted with transgenic crops. In 1996, this area was 1.7 million hectares reaching 39.9 million hectares in 1999, corresponding to a twenty -fold increase between 1996 and 1999.

3. It is important to clarify from the beginning that protection of the intellectual property assets associated with biotechnology developments is not related to the required approval mechanisms to commercialize products resulting from those intellectual property assets. Protection and commercialization procedures are separated and independent from each other. In this regard, a parallel could be drawn with protection and commercialization of pharmaceutical products. The neccesary assessments and control son environnmental effects before releasing genetically modified organisms belong to the applicable biosafety rules that have been or are in the process of being adopted at the national level. Biosafety concerns fall outside the scope of this Symposium.

4. The common objective of plant breeders' rights and patents is to provide an incentive forthed evelopment of innovative and useful products or processes. The patent system covers inventions in all fields of technology, whereas the system of plant variety protection, based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention)², has been specifically developed to cover plant varieties.

¹ Zarrilli, Simonetta, International Trade in Genetically Modified Organisms and Multilateral Negotiations" UnitedNationsConferenceforTradeandDevelopment,July5,2000,p.5.

² AsofOctober24,2002, therewere51 membersoftheUnion. TheirdatesofjoiningUPOV and the Actsofthe Convention by which they are bound are given in Table 1 in Annex I. Table 2 in Annex II lists the States or organizations which have initiated with the Council of UPOV th eprocedure for becoming membersof the Union (18) and other States who have been in contact with the Office of the Union with a view to develop ingle gislation inline with the UPOV Convention (39).

An indication of the progressive development of plant va protectionisprovidedbyFig. 1inAnnexIII.

riety protection in terms of the number of titles of

Table 3 below gives an outline comparison between protection ofan invention by patent andprotectionofavarietybyplantvarietyprotection.an invention by patent and

	PatentProtection	Breeder'srightbasedonthe UPOVConvention	
I.Objectofprotection	invention	plantvariety	
II.Requirementsforprotection			
1.documentaryexam ination	required	required	
2.fieldexamination	notrequired	required	
3.plantmaterialfortesting	deposit of material may be requiredonlyincertaincases	required	
4.conditionsforprotection	 (a)novelty (b)industrialapplicability (c)unobvi ousness (inventivestep) (d)anenablingdisclosure 	 (a)commercialnovelty (b)distinctness (c)uniformity (d)stability (e)anappropriatedenomination 	
III.ScopeofProtection			
1. determination of scope of protection	determined by the claims of the patent	fixed by the national legislation in accordance with the UPOV Convention	
2. use of a protected variety for breedingfurthervarieties	may require the authorization of thepatentee	does not require authorization of the right holder (breeder's exemption)	
3. use of propagating material of the protected variety grown by a farmer for subsequent planting onthesame farm	may require the authority of the patentee	often does not require authorizationoftherightholder	
IV.VarietyDenomination	notrequired	required	
V.TermofProtection	20yearsfromdateofapplication	18 years for trees and vines, 15 years for other species, from date of grant (increased respectively to 25 years and 20 yearsinthe1991Act)	

5. In some circumstances , the subject matter of protection covered by patents and plant breeders' rightsmightbethesame, namelyaplantvariety. However, this is a situation which has existed for many years. The 1991 Act of the UPOV Convention, in contrast to the 1978 Act, n olongerexcludes protection of new plantvarieties by the grant of a special title or apatent for the same botanical genus or species and there by recognizes that both systems may even be applied to the same variety. This may raise questions in particula rcases. They are, however, not in the focus of today's Symposium.

6. The Symposium centers around the scope of protection offered under the patent system and the UPOV system. In particular, this is explored in relation to the situation where, example, a genetic engineering development 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

for

protected by a patent (e.g. patented genetic element). The issues whic h arise from such protection are a result of differences in the scope and exceptions under the two systems. These differences and there levant issues are explored in the following section.

II. ISSUESARISINGFROM THEGRANTINGOFPROT ECTION

RightsConfe rredbytheProtection

7. 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(TRIPSAgreement). This Agreement aspart of the Agreement Establishing the World Trade Organization (WTO) sets international minimum standards on intellectual property protection and binds all Members of WTO(asof October 24,2002, 144 Members)

TRIPSAgreement (Article28)	UPOV (1991Act –Article14)	
"1. A patent shall confer on its owner the followingexclusiverights:	"(1) [Acts in respect of the propagating material]	
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:	(a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder :	
making,	(i) productionorreproduction	
using,	(multiplication),	
	(ii) conditioningforthepurposeof	
	propagation,	
offeringforsale,	(iii) offeringforsale,	
selling,or	(iv) sellingorothermarketing,	
importing ³	(v) exporting,	
	(vi) importing,	
forthesepurposesthatproduct;"	(vii) stockingforanyofthepurposesmentioned	
	in(i)to(vi),above."	

8. 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 authorizationoffhepatentholderandviceversa. One issue for a protected variety containing a patented invention(s) might be that authorization is required from both the breeder and patentholder(s). However, in practice, authorization is likely to be administered by one of the parties for each variety.

³ This right, like all other rights conferred under the TRIPS Agreement in respect of the use, sale, importation or other distribution of goods, iss ubject to the provisions of Article 6.

ExceptionstotheRightsConferred

9. 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:

Exceptionstothebreeder'sright

10. Article15(1)ofthe1991ActoftheUPOVConventionstatesthat:

- "(1) [Compulsoryexcep tions]Thebreeder'srightshallnotextendto
- (i) actsdoneprivatelyandfornon -commercialpurposes,
- (ii) actsdoneforexperimentalpurposesand

(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 respectof such other varieties."

11. The exception for the purpose of breeding other varieties, contained in Article 15(1)(iii), is a fundamental aspect of the UPOV syste mof 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 var iation. 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.

12. 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. Inshort, it is an essential aspect of an effective system of plant variety protection 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

13. Article30oftheTRIPSAgreementstatesthat:

"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 the rest."

14. 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.⁴ Itis, therefore, necessary to refer to national or regional patent legislation and to relevant jurisprudence.

15. 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 disti nguish 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 asfalling within an acceptable exception.

16. National systems that provide a wide research exemption will require that the research or experiments are directed towards the genera tion of information and in these situations only "commercial use" would be prohibited.

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

17. 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 inventionorprotected variety) as far as countries th at a restill 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 an eed to consider how to ma intain the ability to exercise the breeder's exemption in the case of varieties which contain patented inventions. These is use a construction of the upper second se

Balancingtherewardtotherespectiverightsholders(essentiallyderivedvarieties)

18. Thep otentialimbalancebetweentheexceptions 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 anew variety (VarietyB) without any obligation to reward the owner of VarietyA. However, if the owner of VarietyA wish edto 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.

19. To address this imbalance, the 1991 Act of the UPOV Convention introduced a provisionforessentiallyderivedvarieties. The sence 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

⁴ 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 freedomoftransport. These exceptions are not of direct relevance for the interface object of this document.

⁵ Recent Japanese Supreme Court decision in 1999 and German Constitutional Court decision in 2000 favor a wide researchexemption.

essential characteristic softhe initial variety. The 1991 Act states inits Article 14(5)(c) that "Essentially derived varieties may be obtained for example by ... transformation by genetic engineering."The introduction of this provision establishes amore equal balance between patent and UPOV systems. Thus, in the example above, the patent holder of Gen would not be able to exploit his new Variety B without the authorization of the owner of VarietyA, assuming that VarietyB was considered to be essentially derived.

20. 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 underpatent. 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.

21. As explained above, the patent system may require that the permission of the Gen elem 1patentholderisobtained *beforeanybreedingworkcanbegin* .Insuchcircumstances, itmightbemoredifficult for agreement to be reached between the variety owner and patent holder because the value of the endvariety cannot be reliably estimated.

22. 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 UPOV to address an imbalance might fail to resolve the problem unless they ensure that the patent system allows the breeding of new variations rieties in the same way as provided by the UPOV Convention.

23. 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 introduction of a mechanism for a compulsory license on the basis of important techni cal advance of considerable economic significance, such as that provided in the TRIPS Agreement (Article 31(1)(i)) may not be justified, because if the new variety satisfied such a test, there would be a very strong incentive for the patentholder and vari ety owner to find a mutually beneficial arrangement.

24. 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 affect edby the EDV concept and that the introduction of the EDV concept maintains the access 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

25. The situation outlined relates to a situation where the starting point is a patent holder with a geneticelement 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 patentistoprotect the developer of the genetic element, and the purpose of the plantbreeder's right is to protect the developer of the unique combination of plant germplasm forming the variety. However, incertain circumstances, a lack of a similar provision in the patent system might, indirectly, constrain the exercise of the bree der's exemption for the protect dvariety.

26. Therapidprogress 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. Furt hermore, the varieties may contain several patented genetic 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 or gre atly weakened.

III. PROVISIONS WITHIN TH ETRIPS AGREEMENT WH ICHMIGHT 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 cont ribute to the *promotion of technological innovation* and to the *transferand 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 provision softhis Agreement, may be needed to prevent the abuse of intellectual property rights by rightholders or the resort to practices which unreasonably restrain trade or *adversely affect the international transfer of technology* "(emphasis added).

28. As explained above, 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 away that protects the breeder's exemption.

[AnnexIfollows]

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ANNEXI

InternationalConventionfortheProtectionofNewVari etiesofPlants * UPOVConvention(1961),asrevisedatGeneva(1972,1978and1991)

StatusasofOctober23,2002

State	DateonwhichState becamememberof theUnion	LatestAct*oftheConventiontowhichStateispartyanddateon whichStatebecame partytothatAct		
Argentina	December25,1994	1978Act	December25,1994	
Australia	March1,1989	1991Act	January20,2000	
Austria ¹	July14,1994	1978Act	July14,1994	
Belgium	December5,1976	1961/1972Act	December5,1976	
Bolivia	May21,1999	1978Act	May21,1999	
Brazil	May23,1999	1978Act	May23,1999	
Bulgaria	April24,1998	1991Act	April24,1998	
Canada	March4,1991	1978Act	March4,1991	
Chile	January5,1996	1978Act	January5,1996	
China	April23,19 99	1978Act	April23,1999	
Colombia	September13,1996	1978Act	September13,1996	
Croatia	September1,2001 January1,1993	1991Act	September1,2001	
CzechRepublic	October6.1968	1978Act	January1,1993	
Denmark ¹	August8,1997	1991Act	April24,19 98 August8,1997	
Ecuador Estonia	September24,2000	1978Act 1991Act	September24,2000	
Finland ¹	April16,1993	1991Act	July20,2001	
France ¹	October3,1971	1971Act	March17,1983	
Germany ¹	August10,1968	1978Act	July25,1998	
Hungary	April16,1983	1978Act	April16,1983	
Ireland ^{1,2}	November8,1981	1978Act	November8,1981	
Israel	December12,1979	1991Act	April24,1998	
Italy ^{1,2}	July1,1977	1978Act	May28,1986	
Japan	September3,1982	1991 Act	December24,1998	
Kenya	May13,1999	1978Act	May13,1999	
Kyrgyzstan	June26,2000	1991Act	June26,2000	
Latvia	August30,2002	1991Act	August30,2002	
Mexico	August9,1997	1978Act	August9,1997	
Netherlands ¹	August10,1968	1991Act	April24,1998	
NewZealand	November8,1981	1978Act	November8,1981	
Nicaragua	September6,2001	1978Act	September6,2001	
Norway	September13,1993	1978Act	September13,1993	
Panama	May23,1999	1978Act	May23,1999	
Paraguay	February8,1997	1978Act	February8,1997	
Poland ²	November11,1989	1978Act	November11,1989	
Portugal ¹	October14,1995	1978Act	October14,1995	
RepublicofKorea	December7,2001	1991Act	January7,2002	
RepublicofMoldova	October28, 1998	1991Act	October28,1998	
Romania	March16,2001	1991Act	March16,2001	
RussianFederation	April24,1998	1991Act	April24,1998	
Slovakia ²	January1,1993	1978Act	January1,1993	
Slovenia	July29,1999	1991Act	July29,1999	
SouthAfrica ²	November6,1977	1978Act	November8,1981	
Spain ^{1,2}	May18,1980	1961/1972Act	May18,1980	
Sweden ¹	December17,1971	1991Act	April24,1998	
Switzerland	July10,1977	1978Act	November8,1981	
TrinidadandTobago	January30,1 998	1978Act	January30,1998	
Ukraine	November3,1995	1978Act	November3,1995	
UnitedKingdom ¹	August10,1968	1991Act	January3,1999	
UnitedStatesofAmerica	November8,1981	1991Act	February22,1999	
Uruguay (Total:51States)	November13,1994	1978A ct	November13,1994	

* "1961/1972 Act" meansthe International Convention for the Protection of New Varieties of Plants of December 2, 1961, as amended by the Additional Actof November 10, 1972; "1978 Act" meansthe Actof October 23, 1978, of the Convention; "1991 Act" means the Act of March 19, 1991, of the Convention.

¹ MemberoftheEuropeanCommunitywhichhasintroduceda(supranational)Communityplantvarietyrightssystembaseduponthe 1991 Act.

² Hasalreadyamendeditslawtoconformtothe1991Act.

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ANNEXII

Table2

<u>StatesorOrganizationswhichhaveinitiatedwiththeCouncilofUPOVtheprocedure</u> <u>forbecomingmembersoftheUnion(18)</u>

Azerbaijan, Belarus, Costa Ri ca, Egypt, Georgia, Honduras, India, Kazakhstan, Lithuania, Morocco, Tajikistan, The former Yugoslav Republic of Macedonia, Tunisia, Venezuela, Yugoslavia and Zimbabwe, as well as the European Community and the African Intellectual Property Organization (B enin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea -Bissau, Mali, Mauritania, Niger, Senegal, Togo(16)).

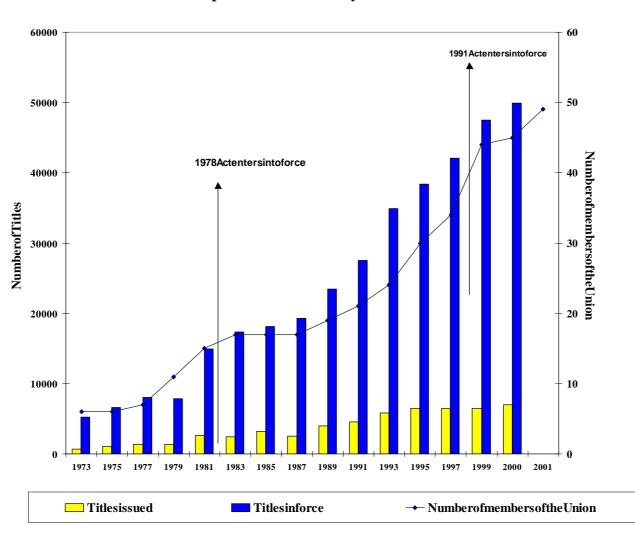
OtherStateswhohavebeenincontactwiththeOfficeoftheUnionwitha viewto developinglegislationinlinewiththeUPOVConvention(39)

Albania, Algeria, Armenia, Barbados, Burundi, Cuba, Cyprus, Djibouti, Dominica, Dominican Republic, El Salvador, Fiji, Ghana, Greece, Guatemala, Iceland, Indonesia, Jamaica, Kingdomof Bahrain, Madagascar, Malawi, Malaysia, Mauritius, Oman, Pakistan, Peru, Philippines, Saudi Arabia, Seychelles, Sri Lanka, Suriname, Thailand, Tonga, Turkey, Turkmenistan, United Republicof Tanzania, Uzbekistan, VietNam, Zambia

[AnnexIIIfollows]

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ANNEXIII



DevelopmentofPlantVarietyProtection

[EndofAnnexIIIandofdocument]