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## INTERNATIONALUNIONFORTHEPROTECTIONOFNEWVARIETIESOFPLANTS GENEVA

### ADMINISTRATIVEANDL EGALCOMMITTEE

# Forty-SixthSession Geneva,October21and22,2002

#### **REPORT**

adopted by the Committee

#### OpeningoftheSession

1. The Administrative and Legal Committee (hereinafter referred to as "the Committee") heldits forty -sixth session in Geneva, on October 21 and 22, 2002, under the chair manship of Mrs. Nicole Bustin (France).

- 2. ThelistofparticipantsisgiveninAnnex Itothisreport.
- 3. The session was opened by the Chairperson, who welcomed the participants. She extended a special welcome to the Delegation of Latvia which had become a member of the Union sin ce the preceding session of the Committee. The Delegation of Latvia expressed its gratitude to the Office of the Union and the member States for the assistance given to Latvia in the process of its accession to the 1991 Act of the UPOV Convention.

<sup>\*</sup> The Committee decided at its forty -seventh session on April 10, 2003, to remove the information footnote concerning the word "h ybrid" which appeared in document CAJ/46/8, on page 8 and on page 1 of Annex III.

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#### AdoptionoftheAgenda

4. The Committee adopted the agenda as given indocument CAJ/46/1.

#### SpecificIssuesConcerningtheInterfaceBetweenPatentsandBreeders'Rights

- 5. Discussions took place on document CAJ/46/2, which had been based on document CAJ/45/3 with the same title. The Vice Secretary -General introduced the document and informed the Committee about the WIPO -UPOV Symposium on the Co -existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developmen ts, that was to be held in Geneva on October 25, 2002.
- 6. In relation to document CAJ/46/2, the Vice Secretary -General indicated that the basic purpose of the document was to illustrate the scope of protection and corresponding exceptions of the patent and plant breeders rights' systems; more precisely and, in particular, the comparison between the patent research exception and the breeder's exemption. It was important to raise awareness of the possible impact the presence of patented elements in plant material could have on the overall rate of progress in plant breeding.
- 7. Several delegations and organizations expressed their views on the issues that may arise if the patent right inhibits the breeder's exemption. Extensive discussions took place in relation to paragraph 25 which provided various cases to assist in the understanding of how certain uses might infringe a patent.
- 8. The Delegation of the United States of America suggested an amendment to the title and subtitle of Section I in order to provide a more accurate reflection of the issues. It wondered whether the cases to illustrate those problems were theoretical or supported by evidence. It added that infringement was a complicated area. The Delegation mad e different proposals suggesting the redrafting of paragraphs 3, 29 and 30, mainly in order to refer to the national laws and to avoid any interpretation of the TRIPS Agreement that could go beyond the scope of the UPOVC on vention.
- 9. In relation to the proposal of the Delegation of the United States of America to reduce paragraph 30(a) by ending it after the word "breeders," the Delegation of Mexico considered it important to keep the last part of paragraph 30(a) "ensures that the development of new varieties is not inhibited;".
- 10. The Delegation of France further suggested some reorganization of the cases in paragraph 25.
- 11. The Chairperson summarized the discussions indicating that there was general agreement that some redrafting of the document by the Office of the Union, with the assistance of the Delegations concerned, was needed in order to reflect the views expressed by the Committee.
- 12. The changes, as proposed by the Vice Secretary -General and agreed by the Committee, are reproduced in Annex II, for ease of reference.
- $13. \quad \underline{Conclusion}: The Committee agreed with the contents of document CAJ/46/2 as a mended by the Committee and:$

- $(a) \quad noted that the EDV provision in the UPOV Convention provided \\ \quad a mechanism for rewarding plant breeders and ensured that the development of new varieties was not inhibited;$
- (b) noted the potential difficulties in using cross addressthelackofabreeder's exemption in the patentsy stem; -compulsory licensing as a means to
- (c) noted the consequences for breeding progress if the breeder's exemption was negatedorinhibitedthroughthepresenceofpatented inventionsinplantvarieties; and
- (d) recommended to members of the Union to consider, where appropriate, whether nature of the research exemption in their patent laws concerning plants might inhibit the breeder's exemption.

#### <u>PublicationofVarietyDescriptions</u>

- Discussions were based on document CAJ/46/3. The Vice Secretary 14. -Generalintroduced the document and noted that, at its forty -fifth session, in Geneva, on April 18, 2002, the Committee approved the schedule of activities for the project related to the publication of varietydescriptions(seeSection6oftheAnnextodocumentCAJ/45/4).Hef urthernotedthat the project focused on two main aspects: firstly, the need for a model study to investigate and developsolutionstothetechnicalissuesconcerningthepossibledevelopmentandpublication evel, in an effective way; and secondly, that there of variety descriptions, at the international 1 were important legal, administrative and financial issues which would need to be resolved, by the Committee, before considering the possible introduction of an international system for the publication of variety descriptions. Document CAJ/46/3 dealt with the second aspect, namely the administrative, legal and financial matters and, in particular, the consideration by the Committee of adraft question naire to be sent to the authorities responsible for gra ntingplant breeders'rights.
- 15. The Delegation of Germany made are quest for the question naire to include information on whether authorities used photographs in the process of publication of variety descriptions and, if so, for which species. It considered that photographs could be very useful in the field of ornamental varieties.
- 16. The Vice Secretary -General confirmed that the appropriate modification to the questionnaire would be made in order to take up the suggestion made by the Delegation of Germany.
- 17. The Delegation of the Netherlands noted that the phenotype of varieties and, consequently, variety descriptions were closely related to the conditions under which varieties were grown. It wondered whether these a spects should also be included in the question naire.
- 18. The Technical Director clarified that this was a matter which would be dealt with by the Technical Committee in its work on this project.
- 19. The Delegation of Colombia sugges ted the inclusion of a question concerning varieties in commercial registers which are not protected by breeders' rights.
- 20. The Vice Secretary -General recalled that the project intended to deal with protected varieties as a first step. Thei nclusion of non-protected varieties would be considered at a later stage. It was a greed that it should be clarified that the question related to protected varieties.

- 21. The Delegation of the Republic of Koreaex pressed the wish that the question nnaire would take into consideration some technical questions in relation to reference varieties. The Vice Secretary-General suggested that those considerations be dealt with within the work of the Technical Committee on the proposals for species, or the *Ad hoc* Working Group on Publication of Variety Descriptions.
- 22. The Delegation of Belgium noted that some clarification might be needed for the second and the third box in question 22. Following a proposal by the Chairperson, it was a greed that an additional box requesting comments on the reply should be added at the end of question 22.
- 23. The Delegation of the Russian Federation suggested substitution of the slash in questions 18 and 19 by the word "and," and questioned whether "join tly" should be replaced by "combination" inquestion 18.
- 24. Itwasagreedthatthefootnoteinquestion 15shouldbereducedtoalistofwhatmightbe considered "interested parties." The remainder of the footnote would be deleted. Following this decision, the Delegation of France underlined the importance to clearly indicate the objectives and the context of this question naire.
- 25. The Chairperson summarized the discussions and identified all the amendments to the draftquestionnai re.
- 26. <u>Conclusion</u>: The Committee agreed with the proposed question naire as amended. This question naire would be sent to members of the Committee and one organization responsible for granting breeders' rights. A summary of the responses to the question naire, with a clear indication of the objectives and the context of this question naire, would be prepared by the Office of the Union and presented to the Committee for its consideration at its forty -seventh session in April 2003.

## $\underline{Issues Concerni\ ngthe Use of Material Submitted for Examination of Distinctness, Uniformity \\ \underline{and Stability}$

- 27. Discussions were based on document CAJ/46/4. The Vice Secretary -General introduced the document. Its purpose was to explore the importance of includi ng plant material of candidate varieties, submitted by the applicant, in the collections of varieties used by authorities for the examination of distinctness, uniformity and stability (DUS). Furthermore, it identified the issues which can arise when this practice cannot be freely undertaken. In particular, it considered the situation whereabreed ermight wish to attach conditions to the use of plant material for such practices, or where the breeder did not permit such a practice at all.
- 28. The representative of the International Association of Breeders of Ornamental and Fruit Plants (CIOPORA) requested a change in paragraph 5, in particular, the deletion of the sentence "... or use of plant material by the original authority after the DUS examination is complete ... candidate varieties." After the clarifications provided by the Chairperson, the Vice Secretary-General and the Delegation of France, paragraph 5 was retained unchanged, as it indicated the importance of this activity as the basis for the examination of other candidate varieties.

- 29. Discussion also took place in relation to paragraph 8. The representative of CIOPORA was concerned by the effect of the publishing of detailed descriptions on the novelty of varieties. The Delegat ion of the Netherlands stated that the UPOV Convention clearly established that novelty was not affected by the publication of a variety description. The Chairperson further clarified that a publication would be enough to establish common knowledge, but would not be enough to establish novelty.
- 30. In relation to paragraph 12, the Delegation of France and the representative of the European Community were concerned about the importance given to a published variety description in the examination o f distinctness in cases where varieties were unavailable for comparison in growing tests or other trials. In reply to this concern, the Vice Secretary General proposed to add the term "subject to technical reliability" after the words in the third sentence "importance of the publication of variety descriptions." In this regard, the Vice Secretary-General further added that this wording was in line with the wording used in paragraph 13(ii) in the conclusion of this document "a system of publishing variety descriptions may, if based on technical information considered to be reliable by the Technical Committee...."
- 31. Therepresentative of CIOPORA expressed certain concerns regarding the use of material supplied by plant breeders to technical examination centers if the examination centers were themselves involved in breeding activities.
- 32. The representative of the European Community indicated that, in those cases, the Community Plant Variety Office (CPVO) requested specific protocols to guarantee that the personsinvolvedinthetestingwerenotinvolvedinbreedingactivities.
- 33. The Chairperson proposed to include on the agenda for future work, a specific item to determine how UPOV should explore this matter, if appropriat e with the assistance of a questionnaire, and also whether to recommend draft model agreements concerning the use of material which might assist to clarify, provideguidance and offer reassurance to plant breeders.
- 34. The representative of the International Seed Federation (ISF) proposed its assistance to the Office of the Union by providing a model agreement concerning the use of the material submitted by the breeder.
- 35. The Delegation of Spainagreed with the proposal from ISF and encouraged the Office of the Union to work on the preparation of model agreements. It explained that, recently, when requesting material from breeders, the Office of Spainhadreceived contracts that restricted the supply of material to other authorities. This was not confined to material concerning parental lines, but also in relation to varieties which could be found in the market. The Delegation also emphasized the need for the breeders' community to facilitate the examination of varieties, for the benefit of the whole protection system.
- 36. The Delegation of France also indicated that they could make their experience available on similar types of matters and agreements, concerning testing and related obligations.
- 37. <u>Conclusion</u>: The Committee agreed with the conclusions in paragraph 13 of document CAJ/46/4. Inparticular, it noted that:
- (a) some authorities have established collections of plant material of varieties of commonknowledgeforthepurposesofexamination butneed to consider how to manage plant

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material of candidate varieties provided by the breeder, as a part of the application, if conditions are attached to its usefor such a purpose;

- (b) asystem of publishing variety descriptions may, if based on technical information considered to be reliable by the Technical Committee, offer an effective means of examining distinctness to address situations where plant material of varieties was unavailable for comparisoning rowing tests or other trials.
- 38. Furthermore, the following topics were identified for future discussion by the Committee:
  - (a) arrangementsforthetransferofmaterial
    - (i) from the breeder to the examination authority, and
    - (ii) between examination authorities.

 $In particular, it was \, sug \quad gested \, that \, UPOV \, might consider the \, development \, of \, standard \, model \, agreements for such transfers;$ 

- (b) recommendations to ensure the independence of those DUS examination centers whichhave, or have links to, breeding activities.
- 39. TheCommitteagreedwiththefutureworkasproposedinparagraph 38.

#### VarietyDenominations

- 40. Discussions were based on document CAJ/46/5. The Vice Secretary General introduced the document and reported on the third meeting of the Adhoc Working Group on Variety Denominations (the Working Group), held in Geneva on October 21,2002. In relation to the document, it was highlighted that, in parallel to the activities of the Working Group within UPOV, the CPVO and the International Union of Biological Scien ces (IUBS) Commission were also working on matters related to variety denominations. The Working Group had coordinated itselforts on this issue with those two Organizations.
- 41. The Vice Secretary -General further indicated that the two main interms of the agenda of the Working Group, during its third meeting, were a first round of discussions on the draft explanatory notes on Article 20 of the 1991 Act of the UPOV Convention concerning variety denominations (document WG -VD/3/2), and a second item providing information on the replies to the question naire seeking information on how the effectiveness of the UPOV -ROM might be improved (document WG -VD/3/3). The Vice Secretary -General gave the floor to the Senior Legal Officerto inform on the advance ment of the discussions of the draft explanatory notes.
- 42. The Senior Legal Officer indicated that, at this stage, it was too early to provide any results on the discussions concerning the draft explanatory notes. She indicated that the draft explanatory notes were clearly linked to the relevant provisions of Article 20 of the 1991 Act of the UPOV Convention and, whenever possible, they also referred to the existing recommendations. The current draft had the objective to provide clarity and t he required flexibility to allow for a harmonized approach in decisions concerning variety denominations. In particular, the intention was to follow, as far as possible, the principle provided in

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Article 20(5) of the 1991 Act that, unless the proposed den omination was unsuitable in the particular territory, the same denomination should be proposed and registered in all members of the Union. The different drafts of the explanatory notes would be made available for consultation by the Committee members int here stricted area of the UPOVW ebsite, where the documents of the Working Group were posted.

- The Technical Director informed the Committee on the decision of the Working Group, made at its second meeting, to prepare a question naire to inve stigatehowtheeffectivenessof the UPOV -ROM might be improved. A power point presentation was made to the Committee in order to illustrate the summary of the responses to the question naire. The analysis of those repliesledtoaproposal,bytheOffice of the Union, for a program to improve the effectiveness ofthe UPOV -ROM. This proposal was made in relation to existing projects already underway, matters specifically concerning variety denominations and general improvements. Regarding variety denominations, the results of the questionnaire suggested that further consideration should be given by the Working Group to allow, under certain circumstances, different varietydenominations in different territories. Furthermore, it suggested that the Working G examine the feasibility of the UPOV -ROM becoming one means by which authorities could 20(6) of the 1991 Act of the UPOV Convention, to comply with the requirement of Article informothermembersoftheUnionofmattersconcerningvarietydenomin ations. Adocument containingananalysis of the responses to the question naire will be presented to the Committee in a separate agenda item with a corresponding document for consideration by the Committeeatitsnextsession.
- 44. <u>Conclusion</u>: The Committee noted the contents of document CAJ/46/5 and the oral reports made by the Vice Secretary -General, the Technical Director and the Senior Legal Officer.

#### Protection of Hybrid Varieties Through Protection of Parent Lines

- Discussions were based on document CAJ/46/6. The Vice Secretary -Generalintroduced the document and indicated that its purpose was, in response to a request from the Technical Committee, to consider the protection of hybrid varieties through protection of parent lines. He recalled that this request had arisen, in particular, because of the development of hybrid varieties in the ornamental sector. In some cases, the same parent line was used in many different hybrid varieties and breeders, conscious of the cost of protecting all the individual hybrid varieties, noted that, in such cases, protection of a series of hybrid varieties could be achieved by protection of the single parent line common to all the hybrids in the series, provided that the parent line fulfil led all the conditions for, and protection is granted. The Vice Secretary-General highlighted the difference between the protection provided by Article 14(5)(a)(iii)ofthe1991 ActandthatprovidedbyArticle 5(3)ofthe1978 Act.
- 46. With r egard to paragraph 5 of the document, it was noted that it was a matter for each State party to the 1978 Act to interpret Article 5(3) of that Act and to decide whether, in the example given, a hybrid would be covered by the protection of one or more of the eparent lines.
- 47. It was agreed that the document should emphasize that the 1991 Act of the UPOV Convention only allowed extension of protection to a hybrid variety, by protection of one or moreoftheparentlines, if there is "repeated use" of such parentlines for the production of the hybrid varieties. Thus, it should be clarified that repeated use of parent lines might not be required if a "hybrid" variety can be produced by vegetative propagation or a pomixis.

- 48. The Delegati on of the Netherlands proposed that, in paragraph 6, the phrase "... obtain protection for his hybrid varieties ..." should be replaced by "extend protection to his hybrid varieties." The Delegation of Switzerland noted that that proposed change would need to reflected throughout the document and, in particular, in the title of the document. Thus, it was agreed that the title should read "Extension of protection to hybrid varieties through protection of parentlines."
- be
- 49. <u>Conclusion</u>: The Chair person concluded that the situation with regard to hybrid varieties under the 1991 Act was clear, but that the situation under the 1978 Act was a matter to be interpreted by each State party. Furthermore, with regard to the 1991 Act, it had been agreed that the protection provided by a breeder's certificate for a parent line would extend to hybrid varieties, provided the rewas repeated use of such a parent line for the production of the hybrid varieties. She furthernoted that it was for each plant breede rto determine whether it would be appropriate to make use of the extended protection of parent lines or to seek to obtain protection of the hybrid variety itself. Annex III presents document CAJ/46/6 as a mended by the agreed changes.

#### The Notion of "Ess entially Derived Variety" in the Breeding of Ornamental Varieties

50. The Chairperson informed the Committee that due to time constraints it was not possible to deal with the last item of the agenda concerning "The notion of 'essentially derived variety' in the breeding of ornamental varieties" (document CAJ/46/7). Following the proposal by the Chairperson, the Committee decided to defend is cussions on this item to its April 2003 session.

#### ProgramfortheForty -SeventhSession

- 51. It was agreed that the program for the forty -sevenths ession would include the following items:
  - 1. Thenotionof "essentially derived variety" in the breeding of ornamental varieties
  - 2. Specificissuesconcerningtheinterfacebetweenpatentsandbreeders' rights
  - 3. Publicationofvarietydescriptions
  - 4. Transferofmaterialforthepurposesofexaminationofdistinctness, uniformity and stability
  - 5. ReviewoftheUPOV -ROMPlantVarietyDatabase
  - 6. Varietydenominations.
- 52. Before closing the session, the Chair person gave the floor to the Delegation of the United StatesofAmericaattherequestofsomedelegationsthatwantedtoreceiveinformation of the currentsituation on how the novel typrovision was applied under the Plant Patent Act.

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- The De legation of the United States of America explained the situation in that country 53.  $and the three forms of protection available for plant varieties. One form of protection was the {\it the protection} and {\it the protectio$ standardpatent, also known as the utility patent. It clarified that the issu estobediscusseddid not concern applicants filing for utility patents and, in particular, the novelty provision remained the same. The second form of protection was the Plant Variety Protection Act, which was consistent with the UPOV Convention and onwhich no concerns had been raised. What hadraisedconcernanduncertaintyamongstbreederswasasituationconcerningthethirdform of protection, the Plant Patent Act which was applied to asexually reproduced plants. The novelty provisions applicable to utility patents were also applied to the Plant Patent Act. In that regard, there had been a case law which applied the novel typrovision sunder utility patents to a plant variety and had an impact on the way the Plant Patent Act was implemented. The Delegation indicated that examiners in the United States Patent and Trademark Office (USPTO) were making rejections based on the evidence of a breeder's certificate in combination with the evidence of "on -saleinaforeigncountry" commercial availability o fthe plantvariety in a foreign country. A regulation in United States law provides examiners with the ability to request further information from applicants. Thus, if examiners find a breeder's certificate that was evidence of prior art, "they would th en ask whether there was evidence of "on-saleinaforeigncountry." If this were the case, then examiners might retain a rejection of novelty, indicating that the plant variety was not novel. That was a change because previous to thatcaselaw, abreede r'scertificatewas not considered to bean "enabling publication." Based onthatcaselaw, evidence of "on -saleinaforeign country," in combination with a "breeder's certificate," was now considered to be an enabling publication, therefore defeated nov elty. This hadraised uncertainty amongst breeders in the plant variety circles, and breeders who had previously received a breeder's certificate in a foreign country and had started marketing that plant variety in foreign countries, could not file in the United States of America without fear thattheywouldreceivearejectionastheplantvarietywouldnotbeconsiderednovel. Indeed, rejectionswerenowbeingmadeiftherewasevidenceofabreeder'scertificateandevidenceof "on-saleinaforeignco untry."
- The Delegation further added that there was a hearing in the United States Congress under one of the Sub -committees where constituent Congressman Issa introduced a Bill that presented a 10 -year grace period indicating that "Prior Art" would not defeat novelty for a 10-year period. However, the Bill did not receive sufficient support with other constituents. The Bill was being reexamined, but it was unclear whether it was dead in the Subsection 1 and 1 and 1 and 2 andnot.NotingthattheDirectorofU SPTOwastheUnderSecretaryforIntellectualPropertyand, as such, responsible for handling the legislative issues that went before the Congress, the Delegationrequestedthatbreederswhohadanyevidenceofthenegativeimpactofthischange ontheirb usinessessendsuchevidencetotheUSPTOtosupporttheircause. This would make iteasier to convince Congress that the situation was having an impact on industry rather than justcreating an uncertainty about the legislation. The Delegation expressed itswishtoclarify the situation and indicated its willingness to discuss the matter further after the meeting of the Committee.
  - 55. The present report has been adopted by correspondence.

[Annex Ifollows]

#### ANNEXEI/ANNEXI/ANLAGEI/ANEXO I

## LISTEDESPARTICIPANTS/ LISTOFPARTICIPANTS/ TEILNEHMERLISTE/ LISTADEPARTICIPANTES

## I. <u>ÉTATS MEMBRES/MEMBER STATES/VERBANDSSTAATEN/</u> <u>ESTADOSMIEMBROS</u>

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[L'annexeIIsuit/ AnnexIIfollows/ AnlageIIfolgt/ SigueelAnexoII]

#### CAJ/46/8Rev.

#### **ANNEXII**

## SPECIFICISSUESCONC ERNINGTHEINTERFACE BETWEEN PATENTSANDPLANTBR EEDERS'RIGHTS

AmendmentstodocumentCAJ/46/2asagreedonOctober21and22 ,2002, bytheAdministrativeandLegalCommittee atitsforty -sixthsession

. . . . .

- "3. The purpose of this document is to consider the situation where, notwithstanding thefactthat the subject matter of protection is different, the grant of apatent mi ght in hibit the "breeder's exemption" provided by the UPOV system of plant variety protection.

  an overlap in the protection provided

  The considers the issues which 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).

  The purpose of this document is to consider the situation where, notwithstanding the "mover that the patent and plant breeder's exemption with a subject to preserve the breeder's exemption within national legislation implementing the Agreement on Trade -Related Aspects of Intellectual Property Rights (TRIPS Agreement).

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- "5. It is necessary to start by examining 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, this is explored in relation to this concerns—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 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 in the following section.
- "I. ISSUES ARISING FROM OVERLAPPING THE GRANTING OF PROTECTION

"Issues WhichMayArisefromInhibitionoftheBreeder'sExemptionbytheGrantingof
aPatent ArisingfromtheLackofaBreeder'sExemptioninPatents

"16. Two main issues <u>may</u> arise <u>if a patent inhibits</u> <u>from the lack of a the</u> breeder's exemption <u>in the patent system</u>. Firstly, there <u>is might be</u> 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 is sues are explained below.

Balancingtherewardtother espectiverightsholders(essentiallyderivedvarieties)

"17. The <u>potential</u> 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...

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- "20. As explained in para graphs 12 to 15, 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 is much more difficult for agreement to be reached between the variety or nerand patent holder because the value of the end variety cannot be reliably estimated.
- "21. The nature of the difference which exists between the two systems is not always fully understood. Thus, <u>certain</u> mechanisms, such as cross -compulsory licensing arrangements between patentholders and plant breeders' right sholders, <u>which have been introduced by some members of the Union to address an imbalance</u> <u>might will</u> 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.
- "22. Furthermore, with regard to the possible development of such mechanisms, it might be noted that he UPOV Convention makes it unnecessary to obtain a compulsory license for anything of her 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 technic aladvance 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 patent holder and variety owner to find a mutually beneficial arrangement.
- "23. 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 patent system does not make specific provision for free a ccess to plant material for breeding new varieties.

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

- "25. Ifavariety(varietyX)containsapatentedgeneticelement, 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 Various cases may occur:
- Case 1: The act of using variety X, containing the patented genetic element, to cross with another variety *infringes* the patent Furthermore, and:
  - (a) the permission of the patent holder is required to remove the patented geneticelement 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 patentholder.

or

Case2: The act of using variety X, containing the patent ed genetic element, to cross withanothervariety infringes the patent. However,

(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

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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 patent edgenetic element before starting the breeding work.
- Case3: The act of using variety X, containing the patented genetic element, to cross with another variety does not infringe the patented ent, but evaluation of the progeny infringes 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 cannot be used for breeding other varieties without the permission of the patent holder.
- Case 2 3: 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 patent edgenetic element.
  - -Inthiscase, 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 patentholder.

#### Case4: (b)Ifthebreeder isable toscreenalltheprogeny,

- <u>-t</u> he 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, 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.
- "26. Itisclearthat <u>patentprotectionofthe</u>, <u>althoughthepurposeofthepatentinvariety-X is only to protect the</u> genetic element <u>it</u> can, in effect, confer the protection onto varietyXandasaresultnegateorinhibitthebreeder's exemption.
- "27. The rapid progress in the development of genetic cengineering 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)and2(b) 2and4—, difficultor impossible in practice. The practical consequence of this development may be that the breeder's exemption, which is an essential principle in the UPOV system of plant varie typrotection, would be lost or greatly weakened.
- "II. PROVISIONS WITHIN THE TRIPS AGREEMENT WHICH MIGHET ALLOW THE PRESERVATION OF THE BREEDER'S EXEMPT ION MEASURES WHICH MIGHT BETAKEN TO EN SURE THAT THE PATENT AND PLANT BREEDERS' RIGHTSSYSTEMS CONTINUETO BE MUTUALLY SUPPORTIVE INFUTURE

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- "28. 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 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 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 restraint radeor adversely affect the international transfer of technology" (emphasis added).
- "29. As explained in paragraph 12, the exceptions to the rights conferred by a patent under Article 30 of the TRIPS Agreement are not specific. This means that a Statemay be a ble to implement Article 30 there may be scope for these to be interpreted in a way that protects which will not under mine the UPOV system of plant variety protection and, in particular, the breeder's exemption.
  - 30. TheCommitteeisinvited tonote:
  - (a) <u>to note</u> that the EDV provision in the UPOV Convention provides a mechanism for rewarding plant breeders and but, unlike the patent system, ensures that the development of new varieties is not inhibited;
  - (b) <u>to note</u> the potential difficulties in using cross-compulsory licensing as a means to address the lack of a breeder's exemptioninthepatentsystem;
  - (c) <u>tonote</u> the consequences for breeding progress if the breeder's exemption is negated or inhibited through the presence of patented inventions in plan tvarieties and;
  - (d) to recommend to members of the Union to consider, where appropriate, whether the nature of the research exemption in their patent laws concerning plantsmightinhibitthebreeder's exemption to consider what measures might be appropriate to address the threat to the breeder's exemption."

[AnnexIIIfollows]

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#### **ANNEXIII**

#### <u>EXTENSIONOF</u> PROTECTION <u>TO</u>HYBRIDVARIETIESTH ROUGH PROTECTIONOFPARENT LINES

DocumentagreedonOctober21and22,2002, bytheAdministrativeandLegalCommittee atitsforty -sixthsession

- 1. The purpose of this document is, in response to a request from the Technical Committee (hereinafter referred to as "the TC"), to consider the protection of hybrid varieties through protection of parentlines.
- 2. Atitsthirt y-eighthsession,heldinGenevafromApril15to17,2002,theTCheardfrom theInternationalSeedFederation(ISF)thatbreedersofseed -propagatedornamentalplantsare considering how to utilize the UPOV system of plant variety protection in a way tha twould servethebreedingactivities and economics in their sector. This discussion has, at least in part, been triggered because the development of seed -propagated varieties by breeders of ornamental plants is a relatively new development, compared to the more traditional approach of breeding vegetatively propagated varieties.
- 3. One particular development in seed -propagated ornamental plant varieties has been the introduction of hybrid varieties. In some cases, the same parent line is used in many different hybrid varieties and breeders, conscious of the cost of protecting all the individual hybrid varieties noted that, in such cases, protection of a series of hybrid varieties could be achieved by protection of the single parent line common to all the hybrids in the series, provided that the parent line fulfilled all the conditions for, and is granted, protection.
- 4. The UPOV Convention does indeed provide protection with regard to the use of the protected variety as a parent for the production and exp loitation of a hybrid variety. Thus, Article 14(5) (a)(iii) of the 1991 Act states that the provisions for protected varieties extend to varieties (i.e. hybrid varieties in this case) "whose production requires the repeated use of the protected variety"—the protected variety being the parent line. This wording establishes that, regardless of whether the seed of the hybridis produced in another country plant variety protection —seed of the hybrid must not be imported, marketed or sold in a country where a parent line is protected, without the authorization of the breeder. This is because the seed of the hybrid is the propagating material of the variety whose production requirestherepeateduseoftheprotectedvarietyandtheactscovered inArticle14(1)(a), such as selling, marketing and importing, require the authorization of the breeder. However, it should be noted that, for example, the use of parent lines might not be required if a "hybrid" varietycanbeproducedbyvegetativepropa gationorapomixis.
- 5. Similarly, the 1978 Act provides protection for the hybrid through protection of a parent line in Article 5(3), which provides that authorization of the bree deris required with respect to a protected variety for the "utilization" of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties ... when the repeated use of the variety is necessary for the commercial production of another variety." However, in this case the protection of a parent line in country A might not provide effective protection of the hybrid in country A if the seed of the hybrid is produced in country B, where country B

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does not apply the UPOV Convention. This is because, in country B, there is no restriction on the use of the parent line in country A. Thus, it will be a matter for each State party to the 1978 Act to interpret Article 5(3) of that Act and to decide whether, in this situation, a hybrid would be covered by the protection of one or more of the parent lines.

6. Thus In conclusion, on the basis described in this document, the UPOV Convention allows abreeder and not just breeders of ornamental plants, to obtain extend protection for to his their hybrid varieties by protection of one or more of the parent lines, if there is repeated use of such parent lines for the production of the hybrid varieties. It will be for each breeder to decide whether this is the most appropriate route to protection according to their particular circumstances.

[EndofAnnexIIIandofdocument]