

Committee on Trade and Environment

ENVIRONMENT AND TRIPS

1. The April 1994 Marrakesh Ministerial Decision on Trade and Environment states that "the Committee on Trade and Environment will consider the work programme envisaged in the Decision on Trade and Services and the Environment and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights as an integral part of its work". This paper has been prepared in response to the request to the Secretariat by the Committee for a background document to assist its work in the latter area.

2. Section I of this paper notes that only one provision of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), i.e. Article 27.2, explicitly refers to environment. Section II provides a wider background for an assessment of the links between environmental concerns and intellectual property rights ("IPRs") by considering the main relevant features of an important recent international agreement that covers aspects of IPRs and environmental protection, the Convention on Biological Diversity (hereinafter "the Biodiversity Convention"). Section II also includes a short negotiating history of the Biodiversity Convention, with particular reference to Article 16 which addresses transfer of technology. Section III provides a summary of the relevant ongoing work in this area in other international organizations, and Section IV notes the provisions in inter-governmental environmental agreements that have implications for IPRs. The discussion of the Biodiversity Convention and activities in other international fora will indicate the IPR issues that have been raised as having a link with environment. Section V provides the provisions of the TRIPS Agreement relevant to matters raised in discussion in environmental fora. Section VI provides a negotiating history of the relevant provisions of the TRIPS Agreement. Section VII considers the exemptions provided under Article XX of GATT 1994 and the question of whether it has a bearing on TRIPS obligations. A short note on the International Convention for the Protection of New Varieties of Plants (hereinafter "UPOV Convention")¹ is provided in Annex 1 to this paper.

I. PROVISIONS OF THE TRIPS AGREEMENT THAT EXPLICITLY REFER TO THE ENVIRONMENT

3. Article 27.2 is the only provision in the TRIPS Agreement that makes an explicit reference to the environment. It states that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." Thus, if it is necessary to ban the

¹The acronym UPOV, which is the common reference to the UPOV Convention, is derived from the French name of the organization established by that Convention, namely, "Union Internationale pour la Protection des Obtentions Végétales".

commercial exploitation of an invention in order to avoid serious prejudice to the environment, a WTO Member is free to refuse a patent for the invention concerned.

II. THE CONVENTION ON BIOLOGICAL DIVERSITY: MAIN ASPECTS AND A BRIEF NEGOTIATING HISTORY

4. An important concern in the area of environment has been that global biodiversity (including genetic resources) is being depleted over time and hence a need to conserve and use it in a sustainable manner has been emphasized. Biodiversity is valued for maintaining the possibility of responding to new situations that may arise, for instance, in the area of agriculture and medicine, and because of its links to the sustainability of certain ecosystems. The initial response of the international community to the threat of genetic erosion was to build a network of "gene banks" where genetic materials, for example, seeds of abandoned varieties, could be stored and conserved *ex situ*.² However, this method of conservation led to some loss of viability and of characteristics and, over time, the focus has changed towards *in-situ*³ conservation of biodiversity. Therefore, incentives for conserving and sustaining animal and plant biodiversity in the natural habitats have been increasingly emphasized. For example, farmers and local communities are now being encouraged to conserve traditional plant varieties on-farm or *in situ*.⁴

5. The Biodiversity Convention was negotiated under the auspices of the United Nations Environment Programme ("UNEP") and was opened for signature at the United Nations Conference on Environment and Development in 1992. The Convention came into force on 29 December 1993. Countries that have signed or ratified the Convention are listed in Annex 2.

6. The Biodiversity Convention operates at three levels, i.e. genes, species, and ecosystems, and extends to all genetic resources, namely, plant, animal and microbial. It affirms that the conservation of biodiversity is "a common concern of humankind", and that States have sovereign rights over the biological resources in their territories.⁵ Under the Biodiversity Convention, States are responsible for conserving their biological diversity and for using it in a sustainable manner. Access to a Party's genetic resources must be on mutually agreed terms and on the basis of prior

²"*Ex-situ* conservation" is defined as the conservation of components of biological diversity outside their natural habitats.

³"*In situ* conservation" is defined as the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they developed their distinctive properties.

⁴*In situ* agro-biodiversity was seen by many to be a result of informal innovations, knowledge and practices of farmers, local communities and indigenous populations, and it was argued that they should get a return on these efforts. Such returns were also seen as important because they would provide incentives to continue to perform the task of preserving biodiversity.

⁵Article 15 recognizes the sovereign rights of States over their natural resources and the preamble reaffirms that "States have sovereign rights over their own biological resources". Article 15.1 states that "[r]ecognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". The question of ownership (or property rights) is not addressed by the Convention, and is subject to national law.

informed consent of the Party providing the resources.⁶ The objectives of the Biodiversity Convention are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".⁷ The Biodiversity Convention provides for sharing research and development activities, benefits from the results of research and development, and commercial use of these results on mutually agreed terms. Access to or transfer of technology has to be provided in line with the provisions mentioned below, and as far as possible and as appropriate, incentives have to be provided to preserve genetic diversity. Similarly, in order to preserve and make sustainable use of biodiversity, the Convention provides for increased encouragement and interaction with regard to information, research, training, public education and awareness, and technical and scientific cooperation. With regard to several aspects including, *inter alia*, sharing in research and development, in the benefits of the results of research and development and of the commercial application of these results, such sharing has to be on mutually agreed terms.⁸

7. In the negotiation of the Biodiversity Convention, issues related to IPRs were important in the context of provisions dealing with access to and transfer of technology (Article 16 of the Convention); in the Biodiversity Convention, the term "technology" includes biotechnology, and covers technologies that assist further conservation and sustainable use of genetic resources as well as technologies that do not cause significant damage to the environment and result from the use of genetic resources to which access is provided by Contracting Parties.

Relevant features of the Biodiversity Convention

8. The principles of the Convention are that "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction" (Article 3). The role of indigenous and local communities in conserving biodiversity is recognized in the preamble; the importance of maintaining their knowledge and practices relevant to the conservation of biodiversity and the sustainable use of its components is also recognized, as is the need to encourage equitable sharing of benefits derived from the use of their knowledge, innovations and practices (Articles 8(j) and 10(c)). Identification and monitoring of biodiversity is viewed as an ongoing process involving development of the capacity of the Parties to fulfil the objectives on a long term and sustainable basis (Article 7). The Biodiversity Convention provides that, as far as possible and as appropriate, incentives have to be provided for the conservation and sustainable use of components of biodiversity (Article 11). In order to preserve and make sustainable use of biodiversity, the Convention provides for increasing encouragement and interaction with regard to information, research, training, public education and awareness, and technical and scientific cooperation (Articles 12, 13, 14, 17 and 18). Article 18.3 provides that the Contracting Parties have to

⁶Prior informed consent under Article 15 is not an obligation, but an option to be exercised by the Contracting Party providing genetic resources. Article 15.5 states that "[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party".

⁷Article 1 of the Biodiversity Convention. This also reflects a view that such sharing of benefits would provide incentives for conservation of biodiversity in the regions where it exists (i.e. incentives for *in situ* conservation).

⁸See, for example, Articles 15.4, 15.7, 16.2, 16.3, 18.5 and 19.2.

determine at their first meeting how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

9. The Biodiversity Convention applies to *in situ* and *ex situ* genetic resources acquired in accordance with the Convention, but not those taken and deposited in gene-banks prior to the Convention's entry into force. It emphasises *in-situ* conservation (Article 8).⁹ *Ex-situ* conservation measures are called for principally to complement *in-situ* conservation (Article 9). Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation (Article 15.1). However, each Party to the Biodiversity Convention must endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties and must not impose restrictions that run counter to the objectives of the Biodiversity Convention (Article 15.2). Where access to genetic resources is granted, it has to be on mutually agreed terms and be subject to prior informed consent of the Party providing the resources, unless otherwise determined by that Party (Articles 15.4 and 15.5). Genetic resources provided by any Party to the Biodiversity Convention are only those resources that are provided by Parties which are countries of origin of those resources or by Parties that have acquired the genetic resources in accordance with the Convention (Article 15.3). For those Parties providing access to genetic resources, the benefits include possibility of participation in scientific research based on the genetic resource supplied (Articles 15.6)¹⁰, of sharing results of research and development and benefits arising from commercial and other utilization of genetic resources on mutually agreed terms (Article 15.7)¹¹, of participation in biotechnological research activities based on those genetic resources (Articles 19.1)¹², and priority access on a fair and equitable basis to the results and benefits arising from biotechnologies based upon those genetic resources, on mutually agreed terms (Article 19.2).¹³

⁹Article 8 of the Biodiversity Convention calls for measures ranging from the establishment of a system of protected areas to the rehabilitation of degraded ecosystems and recovery of threatened species, the protection of natural habitats and the maintenance of viable populations of species in natural surroundings.

¹⁰Article 15.6 states that "[e]ach Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties."

¹¹Article 15.7 states that "[e]ach Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be on mutually agreed terms."

¹²Article 19.1 states that "[e]ach Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties."

¹³Article 19.2 states that "[e]ach Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms." See also Article 8(j) which states that "[e]ach Contracting Party shall, as far as possible, and as appropriate, subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices."

10. Access to and transfer of technology is addressed by Article 16.¹⁴ Intellectual property rights are explicitly mentioned in the second, third and fifth paragraphs of Article 16. This Article was heavily negotiated and its text reads as follows:

"[16.]1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

[16.]2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

[16.]3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

[16.]4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

[16.]5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

¹⁴In order to get an overall perspective on different aspects related to transfer of technology under Articles 16, it is important to also bear in mind certain other provisions in the Biodiversity Convention, for example, Article 12 (research and training), Article 17 (exchange of information), Article 18 (technical and scientific cooperation), and Article 19 (handling of biotechnology and distribution of its benefits). These provisions emphasise both the soft component of technology (such as skills, know-how and design) and the hard component (machinery and equipment, and other tangible inputs). Experience with operation of technology has shown that the soft and hard components have to work in a complementary manner to result in successful transfer of technology.

11. Article 19 addresses handling of biotechnology (including biosafety aspects), access to information and research and distribution of benefits of biotechnology. Under Article 20, new and additional financial resources are to be provided to developing countries to enable them to meet the agreed full incremental costs to them of the measures needed to implement the Biodiversity Convention's obligations.¹⁵ The mechanism for providing financial resources to developing country Parties is set out in Article 21. The mechanism will operate under the authority of the Conference of the Parties (established under Article 23) to which it will be directly accountable, and funds will be provided on a grant or concessional basis. Article 25 establishes a subsidiary body on scientific, technical and technological advice for timely advice relating to the implementation of the Biodiversity Convention.

12. Regarding the relationship of the Biodiversity Convention to other international conventions, Article 22 states that the "provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity [and] ... Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea."

13. Resolution Three of the Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (22 May 1992) identified the need to seek solutions to some unresolved issues, e.g. farmers' rights¹⁶ and access to *ex-situ* collections not acquired in accordance with the Biodiversity Convention.

Drafting history of the relevant provisions of the Biodiversity Convention

14. The impetus for the Biodiversity Convention arose out of a number of concerns, including protection of tropical forests, conserving biodiversity and managing its sustained use, attempting to obtain international recognition of the sovereign rights of developing countries over their genetic resources, and on that basis these countries getting access to advanced technologies (in particular biotechnologies) in return for the access that they provide to their genetic resources.¹⁷

15. Work on a possible international agreement was carried out in the 1980s in a number of organizations, which worked either together or in collaboration to produce draft articles for an agreement. The World Conservation Union (IUCN) started exploring the possibility of a treaty on biodiversity in 1981. From 1984 to 1989, using both internal and outside expertise, the IUCN prepared successive drafts of articles for inclusion in a possible treaty. In 1990, the FAO developed an alternative to the 1989 IUCN draft articles.¹⁸ Meanwhile, in 1987, the UNEP Governing Council established an *ad hoc* Working Group to investigate the desirability and possible form of an umbrella convention to rationalize ongoing activities in the field of

¹⁵The agreement on the composition of these costs is to be bilaterally reached between each developing country Party and the institution chosen to handle the financial mechanism.

¹⁶Please see the sub-section on FAO's ongoing work for more information on farmers' rights.

¹⁷For more details on the background concepts and on the provisions of the Biodiversity Convention, see Lyle Glowka and Françoise Burhenne-Guilmin, 1994, "A Guide to the Convention on Biological Diversity", Environmental Policy and Law Paper No. 30, The World Conservation Union.

¹⁸FAO, 1990, "Outline for a Draft International Convention on the Conservation and Utilization of Biological Diversity", April 1990.

biodiversity and to address other areas which might fall under such a convention.¹⁹ This *ad hoc* Working Group reached a consensus in 1990 that a new global treaty on biodiversity was needed. The discussions showed that several States were not prepared to limit the discussion to only conservation in a strict sense, and the scope of the discussions was broadened to include *in-situ* and *ex-situ* conservation of wild and domesticated species, sustainable use of biological resources, access to genetic resources and to relevant technology (including biotechnology), access to benefits derived from such technology, safety of activities related to modified living organisms and provision of new and additional financial support. During the negotiations, the UNEP Secretariat prepared successive drafts of articles to be considered for the convention.²⁰ Formal negotiations started in February 1991 under the *ad hoc* Working Group which was renamed the Intergovernmental Negotiating Committee for a Convention on Biological Diversity.²¹

16. Among the most difficult issues in the negotiations were those concerning access to and transfer of technology and the supporting financial framework. Developing countries emphasized the value of their genetic materials, which they felt had increased due mainly to progress in biotechnology and granting of intellectual property rights to the biotechnology products. They sought certain provisions relating to three types of access: access to genetic resources being subject to national sovereignty; access to relevant technologies, including biotechnology, by those conserving and providing the genetic resources; and, for the State providing the genetic material, access to benefits ultimately gained from the use of genetic material in the development of biotechnology. Further, some argued that developing countries should be assisted in developing their own technologies. There was also a proposal to consider setting up a clearing house mechanism for transfer of technology, including biotechnology.

17. During the early stages of the negotiations, several developed countries did not want the Convention to include any provision on technology transfer, on the grounds that there were parallel discussions of that issue and of related issues in other fora (such as the Uruguay Round); it was also argued by some that biotechnology and transfer of technology were issues that should be dealt with by the 1992 UNCED Conference and not be included in the Convention on Biological Diversity. Moreover, the industrialized countries did not want any requirement to be imposed under the Convention that their private sector be forced to transfer technology, including biotechnology.

18. The draft Articles prepared for the negotiations addressed the issue of transfer of technology separately as well as together with the issue of access to biodiversity.²² The importance of the negotiations on TRIPS within the framework of Uruguay Round was noted but there was no agreement on the link between the negotiations in the Uruguay Round and the negotiations on the Biodiversity Convention. Thus, one proposed draft Article stated that "The

¹⁹UNEP Governing Council Resolution 14/26 (1987). For more details on the work of the *ad hoc* group, see UNEP/Bio.Div/WG.2/1/1, dated 17 October 1990.

²⁰This process benefited from a number of studies commissioned by the UNEP on topics including biodiversity global conservation needs and costs (UNEP/Bio.Div.3/3), current multilateral, bilateral and national financial support for biological diversity conservation (UNEP/Bio.Div.3/4), an analysis of possible financial mechanisms (UNEP/Bio.Div.3/5), relationship between intellectual property rights and access to genetic resources and biotechnology (UNEP/Bio.Div.3/6), and biotechnology issues (UNEP/Bio.Div.3/7).

²¹Two sub-working Groups were set up to facilitate the negotiations. The issues of access and transfer of technology were handled by the second sub-working group.

²²See Draft Convention on Biological Diversity, UNEP/Bio.Div/WG.2/2/2, dated 22 January 1991, pages 44 to 52.

conditions of access shall be subject to mutual agreement between Parties concerned [without prejudice to the negotiations on intellectual property rights within the framework of WIPO and GATT]."²³

19. Regarding access to genetic resources, the important concepts that were suggested included "fair and equal" or "free" or "open" access to genetic material conserved *in-situ* and *ex-situ*, and that the access be provided on a commercial basis with due regard to ownership rights. Equitable or preferential sharing of benefits by countries of origin of genetic material was proposed. Regarding the rights of the countries which would provide access to genetic material, while the developing countries emphasized easy access to technology and information relevant to conservation and sustainable utilization of biological diversity, the developed countries were keen that due regard be given to "legitimate interests of public and private sectors" and to "patents and property rights derived from genetic diversity under as well as beyond national jurisdiction and control".²⁴ Also, there was no agreement on whether access to technologies should cover only those technologies which were relevant for conservation and sustainable use of biodiversity, or whether they should also include those which make use of genetic resources.²⁵ Thus, in a revision to the Draft Convention on Biological Diversity, the Article relating to transfer of technology included the following text: "The provisions of the present article do not apply to genetic technology".²⁶ An illustration of the different views on transfer of technology is provided by Article 16.1 of the revised Draft Convention, which stated that "The developed countries have an obligation to transfer [technology] [those technologies that support conservation and sustainable utilization of biological diversity as well as those technologies that make use of genetic resources for other purposes such as the production of pharmaceuticals] [including traditional technologies] [by means of technical co-operation in acquiring relevant technology] to the developing countries on a [preferential and non-commercial] [fair and favourable basis]. (*ibid.*, page 20)

20. There were two views regarding the role of the private sector in transfer of technology. One was that States had to ensure that private enterprises within their jurisdiction transferred relevant technologies to developing countries. The other was that the private sector could not be forced to undertake any obligations and that the legitimate interests of the private sector should be

²³See UNEP/Bio.Div/WG.2/3/7, dated 29 April 1991. Earlier, in the Draft Convention of 22 January 1991, this text was not in square brackets. See *op. cit.*, page 46.

²⁴*ibid.*, page 47. The concept of "outside areas of national jurisdiction" includes areas where international law recognizes the equal rights and freedom of all States (*res communis*) and areas outside the national jurisdiction of any State but which are also not under *res communis*. For more detail, see "Note on the Legal Instruments in Existence Relevant to Access to Biological Diversity Outside Areas of National Jurisdiction", UNEP/Bio.Div/WG.2/3/9, dated 7 May 1991.

²⁵The UNEP Secretariat prepared a note on "Description of Transferable Technologies Relevant To Conservation Of Biological Diversity An Its Sustainable Use", UNEP/Bio.Div/WG.2/3/10, dated 9 May 1991. The technologies cited in that note encompassed both hardware as well as other aspects such as training, managerial and scientific know-how, servicing agencies, consultancies, supportive institutional capacities, infrastructure, and fiscal and other policy frameworks of the nation in need of the technology transfers. The technologies also included "traditional technologies duly developed to work alongside the acquired technologies, as appropriate".

²⁶UNEP/Bio.Div/WG.2/3/3, dated 30 April 1991, page 20. A footnote to the text quoted here stated that the precise meaning of the term "genetic technology" required clarification.

protected in all activities, including when technology is transferred through the private sector's investment in developing countries.²⁷

21. As the negotiations progressed, developing countries continued to emphasise that they should benefit from access to and transfer of technologies which make use of genetic material, that their special needs should be considered in providing access to technology and information to them, and that the access to and transfer of technologies should take place within the framework of the financial mechanism provided in the Convention. They also wanted lower IPR protection in this area, including for biotechnology; some argued that plants and animals, and biotechnology should not be patented. In contrast, those favouring a patent regime (in particular for biotechnology) emphasized the need for conformity with other international agreements, including possible results of the Uruguay Round.²⁸

22. In view of the difference of opinion regarding access to and transfer of technology, it appeared that somewhat weaker conditions would be required to achieve an agreement, namely that the Parties undertake to facilitate, or endeavour to encourage, the access to and transfer of technology.²⁹ Similarly, it was suggested that a compromise could be reached by agreeing that Parties take legislative, administrative or policy measures, as appropriate, to achieve the objective of the private sector facilitating access to joint development and transfer of technology.

23. By early 1992, with regard to access to genetic resources, there was general understanding that such access, where granted, would be on mutually agreed terms and would be subject to prior informed consent of the Party providing such resources, unless otherwise determined by that Party. Mutual agreement was also emphasized in the context of access to and transfer of technology, and it was generally agreed that it would be an important element for reaching any compromise in that context. However, there was still no agreement on the importance of intellectual property rights in the context of access to or transfer of technology.

24. In early 1992, similar to the final text of the Biodiversity Convention, the suggested draft text incorporated access to and transfer of technology in a single Article. However, the proposed text for the Article which corresponded to Article 16.2 of the finally agreed Biodiversity Convention did not contain any reference to intellectual property rights.³⁰ The developed countries did not agree to the suggested text because it left open the issue of the link with other agreements in the IPR area. This lack of agreement was also reflected in the different options for the draft text that were presented to the negotiators regarding the relationship of the Convention with other international agreements.³¹ Discussions continued on the manner in which IPRs had to be taken into account in providing access to or transfer of technologies under the Biodiversity

²⁷The two views with regard to the private sector are shown in the proposed text on pages 9 and 10 of the "Note to Facilitate Understanding of Issues Contained in Articles Under Consideration By Sub-Working Group II", UNEP/Bio.Div/WG.2/3/7, dated 29 April 1991.

²⁸Thus, for access to technology, a suggested draft text read "... The Contracting Parties shall also eliminate [to the extent possible in conformity with international law] and refrain from imposing restrictions [such as patents and intellectual property rights] that run counter to the principles of this Convention." See UNEP/Bio.Div/N4 - INC.2/5, dated 2 October 1991, page 22.

²⁹See for example, UNEP/Bio.Div/INC.3/11, dated 4 July 1991, pages 20 and 21.

³⁰UNEP/Bio.Div/N6 - INC.4/4, dated 18 February 1992, page 36.

³¹See UNEP/Bio.Div/N7 - INC.5/2, dated 20 February 1992, pages 22 and 23.

Convention, and a compromise was reached on the inclusion of the following sentence in Article 16.2 of the Convention: "In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."

25. Furthermore, the provisions in Article 16.2 were linked to the other Articles relating to access to and transfer of technology by including the sentence that stated: "[t]he application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below." This link was made in addition to similar text in other provisions (i.e. Articles 16.3 and 4) which refers back to Article 16.2.³² Moreover, Article 16.5 of the Convention states, *inter alia*, that "[t]he Contracting Parties recognising that patents and other intellectual property rights may have an influence on implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

26. A number of delegations made declarations at the time of the signing or adoption of the Biodiversity Convention. Annex 5 reproduces the declarations that address the issue of access to and transfer of technology.

III. RELEVANT ONGOING WORK IN OTHER INTERNATIONAL ORGANIZATIONS

27. This section reports on certain ongoing work at United Nations Environment Programme, Biodiversity Convention, Consultative Group on International Agricultural Research, Food and Agriculture Organization, World Intellectual Property Organization and UPOV that is relevant for a discussion of environment and TRIPS.

United Nations Environment Programme (UNEP)

28. In 1993, UNEP's Governing Council approved the creation of two Centres, both based in Japan. The purpose of the Centres is to promote the development and transfer of environmentally-sound technologies, with a particular emphasis on sustainable freshwater management technologies, as well as other environmentally-related technologies. At the Session of UNEP's Governing Council in 1995, governments requested that such Centres include work on developing "modalities for financing endogenous capacity-building of scientific and technology centres, in particular in developing countries and countries with economies in transition."

Biodiversity Convention

29. The first meeting of the Conference of the Parties to the Biodiversity Convention took place in Nassau (Bahamas) from 28 November to 9 December 1994. Under Article 25 of the Convention, the Conference of the Parties established a subsidiary body on scientific, technical and technological advice. The first meeting of this body will be in Paris on 4 to 8 September 1995. The provisional agenda for that meeting includes, among others, identification of ways and means to promote and facilitate access to and transfer and development of technologies as envisaged in Articles 16 and 18 of the Biodiversity Convention. The Conference

³²The last part of Article 16.3 states that measures taken under that provision have to be "consistent with paragraphs 4 and 5 below", and the last part of Article 16.4 states that Contracting Parties "shall abide by the obligations included in paragraphs 1, 2 and 3 above." Thus both Articles 16.3 and 16.4 are linked back to Article 16.2.

of the Parties has also decided to establish a clearing-house mechanism for technical and scientific cooperation under Article 18.3 of the Convention.

30. Under its medium term work programme (1995 to 1997), the Conference of the Parties to the Biodiversity Convention at its second meeting³³ may consider, *inter alia*, the following tasks: "to compile existing legislation, administrative and policy information on access to genetic resources and the equitable sharing of benefits derived from their use; to compile information provided by Governments as well as relevant reports from appropriate international organizations regarding policy, legislative, or administrative measures related to intellectual property rights as provided in Article 16 of the Convention and to access to and transfer of technology that makes use of genetic resources; to consider ways to promote and facilitate access to and transfer and development of technology, as envisaged in Articles 16 and 18 of the Convention".³⁴

31. In 1996, the third meeting of the Conference of the Parties may consider aspects including "to compile the views of Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15; [and] to consider ways to promote and facilitate access to and transfer and development of technology, as envisaged by Articles 16 and 18 of the Convention."

32. The Conference of the Parties to the Convention have established a group of experts to examine the need for and modalities of a protocol on biosafety. UNEP, UNIDO, WHO and FAO have been asked to work with the Secretariat of the Biodiversity Convention in this context. The group of experts met from 1 to 5 May 1995, and a meeting of an *ad hoc* group of experts will take place from 24 to 28 July 1995 to advise the Conference of the Parties on this issue.

Consultative Group on International Agricultural Research (CGIAR)

33. The CGIAR is a consortium of donor and development agencies that supports autonomous research Centres which aim to develop technologies and information relevant to improving the productivity and sustainability of agricultural, forestry and aquatic systems in developing countries. One of the activities of the CGIAR is *ex-situ* conservation and use of plant genetic resources. The CGIAR Centres have collected and stored seeds or other reproductive parts of their mandate crops. Each year, more than 120,000 germplasm accessions from the in-trust collections and 500,000 samples of improved material are distributed by the Centres, the large majority to developing countries. The Centres are also involved in research to improve technologies for *in-situ* conservation.

34. Under agreements signed in October 1994, the Centres of the CGIAR that maintain germplasm collections have placed these collections under the auspices of FAO. The agreements contain obligations that the material will be made available to all users, and that the Centres will not claim any property rights on these materials. These conditions will apply also to the material with the users to which it is made available, except for "the repatriation of the germplasm to the country that provided such germplasm."

³³This meeting will be held in Jakarta from 6 to 17 November 1995.

³⁴The first two tasks come under the heading "access to genetic resources" while the third task comes under "transfer of technology".

Food and Agriculture Organization (FAO)

35. In 1983, the FAO established a Global System for the Conservation and Utilization of Plant Genetic Resources for food and agriculture. The Global System is being developed and monitored by the intergovernmental Commission on Plant Genetic Resources (CPGR) within the context of the International Undertaking on Plant Genetic Resources, a non-binding agreement that was adopted by the FAO Conference in 1983.³⁵ The CPGR is an intergovernmental forum of donors and users of plants genetic resources, technology and funds.³⁶ It has negotiated a Code of Conduct for Plant Germplasm Collecting and Transfer which provides guidelines for collecting and transferring plant genetic resources to facilitate access and promote their use and development on an equitable basis³⁷; a draft Code of Conduct on Biotechnology which includes provisions on IPRs is under development. The CPGR has also provided a framework for agreements negotiated between various States and institutions, such as the International Agricultural Centres of the Consultative Group on International Agricultural Research. Moreover, in 1989 and 1991, the FAO Conference adopted resolutions on farmers' rights³⁸ and plant breeders' rights.³⁹

36. One of the CPGR's areas of interest relates to IPR over plant varieties, related technologies and farmers' germplasm. During the sessions of the Commission, discussions on these matters have been conducted among member countries since 1983, and following UNCED, further discussions are being held on access to plant genetic resources for food and agriculture, access to related technologies, and the realization of farmers' rights. Other matters being discussed by the Commission include the impact of IPRs on the environment, (especially the distinctiveness, uniformity and stability criteria for plant breeders' rights), and a revision of the International Undertaking on Plant Genetic Resources to harmonize it with the Biodiversity Convention (including negotiations on access to plant genetic resources and the realization of farmers' rights). A meeting of the Commission for the revision of the International Undertaking on Plant Genetic Resources is scheduled for 19 to 30 June 1995.

37. A report on the state of the world's plant genetic resources, and a global plan of action for plant genetic resources will be presented at the Fourth International Technical Conference on Plant Genetic Resources to be held in Germany in June 1996.

³⁵The Undertaking recognizes a principle of free access to genetic resources. It includes a provision for an international fund for the conservation and utilization of plant genetic resources. However, compensation was not necessarily to be provided directly to farmers. The fund has not yet become operational.

³⁶Currently 144 countries are formally part of the system.

³⁷This code of conduct was adopted by the FAO Conference in 1993.

³⁸The role of the farmers in developing plant varieties was recognized at the FAO Conference in 1989, which endorsed a concept of farmers' rights. It was stated that farmers have "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources [which] allow farmers, their communities, and countries in all regions, to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources, through plant breeding and other scientific methods." (FAO Resolution 5/89)

³⁹Plant breeder's right or plant variety protection is an exclusive right granted to the breeder of a new plant variety to exploit his new variety. The nature of these rights can vary depending on the system of protection adopted in this context. See for example the note in Annex 1 to this paper. For more details on plant breeder's rights, see International Union for the Protection of New Plant Varieties of Plants (1994), "UPOV National Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention", UPOV/ISB/94/1, 10 November 1994.

World Intellectual Property Organization (WIPO)

38. WIPO offers a range of assistance and services to developing countries. In respect of intellectual property and the environment, two types of assistance are of special interest to developing countries:

- (i) the provision of advice and training to governments and public and private sector organizations, and their staff, on negotiations and arrangements relating to the licensing of intellectual property and the management of such property, where such arrangements have an impact on the environment;
- (ii) the provision, with the cooperation of some industrialized countries, of technological state-of-the-art search reports covering various categories of technology, including technology relevant to the environment. Those reports, which are provided free, are prepared on the basis of information available from patent documents, of which some 30 million are in existence, held by those industrialized countries. Since the search service started, some 8,000 such search reports have been provided.

International Union for the Protection of New varieties of Plants (UPOV)

39. UPOV administers the International Convention for the Protection of New Varieties of Plants, notably the 1978 Act which is presently in force, and the 1991 Act which is yet to enter into force. A summary of the main features of these two Acts of the Convention is at Annex 1.

40. UPOV develops test guidelines for the conduct of tests for "distinctness, homogeneity and stability" of plant varieties. This is an ongoing task involving four Technical Working Parties, responsible respectively for test guidelines for individual species for agricultural crops, for fruit crops, for ornamental crops and forest trees, and for vegetables. In addition, there are two special Working Parties. One studies the application and harmonization of biochemical and molecular techniques in the field of plant variety protection, and the other focuses on the possibility of automation and the harmonization of computer programmes within UPOV with a view to promote the harmonization of the method used by member states in distinguishing between plant varieties.

41. In order to avoid duplication of tests of varieties for which applications for protection are filed with more than one member State, cooperation in technical examination has been achieved on the basis of agreements between the competent authorities of member States, under which the testing of a given species is effected for a group of members States by one member State, and the purchase by a member State on an *ad hoc* basis of the result of a test carried out by another member State. The office of UPOV maintains and updates a list of species for which offers for cooperation in examination have been made.

42. The Office of the UPOV collects national laws on plant breeders' rights and prepares translations of them into English. It also provides assistance in the development of the legal systems in different countries to take account of the criteria mentioned in the UPOV Convention.

43. The Office of the UPOV is in the process of preparing a study on the effects of the TRIPS Agreement on the protection of plant varieties.

IV. INTER-GOVERNMENTAL AGREEMENTS ON THE ENVIRONMENT AND IPR-RELATED ASPECTS

44. This section will present a summary of the main features of several multilateral environmental agreements (other than the Biodiversity Convention and UPOV) which generally do not contain provisions referring explicitly to IPRs, but focus on generation or transfer of technology, and access to the process/result of research and development.⁴⁰

45. Since multilateral environmental agreements focus on mutual co-operation to address a specific environmental problem, most of them contain mechanisms for multilateral consultation, exchange of information, cooperation, and compliance monitoring through the multilateral institution. Some of them also contain conditional or absolute prohibition of an activity, prior informed consent or prior authorization, technical norms setting qualitative and quantitative standards, and financial and technical assistance. A recent study on international environmental law noted that "virtually all major environmental treaties in recent years have included important provisions providing financing, technical assistance, or technology transfers to developing countries. ... New approaches to technology transfer have also been explored, although no consensus has yet been reached on the best specific methods for such transfers".⁴¹ At a more general level, this trend is reflected in Agenda 21 which includes chapters on "Transfer of Environmentally Sound Technology, Cooperation and Capacity Building", "Science and Sustainable Development", and "Environmentally Sound Management of Biotechnology". Five broad objectives of the chapter on technology transfer in Agenda 21 are: to help ensure access by developing countries to scientific and technological information, including information on state-of-the-art technologies; to promote access to and transfer of environmentally sound technologies; to facilitate the maintenance and promotion of environmentally sound indigenous technologies; to support national capacity building, particularly in developing countries, so that developing countries can assess, adopt, manage and apply environmentally sound technologies;

⁴⁰For further information on multilateral environmental agreements, see L/6896, TRE/W/1 and 10/Rev.1, and PC/SCTE/W/3 and 4. The multilateral agreements reviewed for this section are: Convention on International Trade in Endangered Species of Wild Fauna and Flora (1973, amended 1979 and 1983); Convention for the Protection of the Ozone Layer (Vienna 1985); Montreal Protocol on Substances that Deplete the Ozone Layer (1987); London Adjustments to the Montreal Protocol on Substances that Deplete the Ozone Layer (1991); Copenhagen Adjustments and Amendments to the Montreal Protocol on Substances that Deplete the Ozone Layer (1992); Transfrontier Movements of Hazardous Waste (OECD Decision/Recommendation Adopted on 1 February 1984); Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989); Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa (1991); London Guidelines For the Exchange of Information on Chemicals in International Trade (amended 1989); United Nations Framework Convention on Climate Change (1992); United Nations Environment Programme: Montreal Guidelines on the Protection of the Marine Environment Against Pollution from Land-Based Sources (1985); Kuwait Regional Convention for Co-operation on the Protection of the Marine Environment from Pollution (1978); Amazon Treaty Pact (1978); Convention on Long-Range Transboundary Air Pollution (1979); 1988 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution Concerning the Emissions of Nitrogen Oxides or Their Transboundary Fluxes; Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region (1983); Protocol Concerning Specially Protected Areas and Wildlife to the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region; The Convention on Wetlands of International Importance Especially as Waterfowl Habitat (Ramsar, 1971); International Tropical Timber Agreement (1994); Convention of the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (1972); Convention for the Prevention of Pollution by Ships (1973); Convention on the Conservation of Migratory Species of Wild Animals (1980); United Nations Convention on the Law of the Sea (1982); The Convention Concerning the Protection of the World Cultural and Natural Heritage (Paris, 1972); The Convention on the Conservation of Migratory Species of Wild Animals (Bonn, 1979).

⁴¹David Hunter, Julia Sommer and Scott Vaughan (1994), *Concepts and Principles of International Environmental Law: An Introduction*, Environment and Trade Paper Number 2, United Nations Environment Programme, page 11.

and, to promote long-term technological partnerships between holders of environmentally sound technologies and potential users.⁴²

46. As in the case of the Biodiversity Convention, certain other multilateral Agreements include provisions supporting, as appropriate, cooperation in the conduct of research and scientific assessment of the specific issue covered by the Agreement⁴³, facilitation of access to technology⁴⁴, cooperation in developing technical capacity among the Parties⁴⁵, or in developing and implementing environmentally friendly technologies.⁴⁶

⁴²Furthermore, United Nations General Assembly Resolution 229 (XLIV) on International Cooperation in the Field of the Environment (1989), paragraph 14, states the need to examine effective modalities for favourable access to, and transfer of, environmentally sound technologies, in particular to developing countries, including on concessional and preferential terms, and for supporting all countries in their efforts to create and develop their endogenous technological capacities in the field of scientific research and development. More recently, Principle 9 of the Rio Declaration on Environment and Development (1992) provides that "States should cooperate ... by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies."

⁴³Convention for the Protection of the Ozone Layer (Vienna 1985), Articles 3 and 4; Montreal Protocol (1987), Article 9; Basel Convention (1989), Article 10.2; Bamako Convention (1991), Article 10.2; London Guidelines (1989), Articles 13 and 15; United Nations Framework Convention on Climate Change (1992), Article 4; United Nations Environment Programme: Montreal Guidelines on the Protection of the Marine Environment Against Pollution from Land-Based Sources (1985), Article 8; Kuwait Regional Convention (1978), Article XI; Amazon Treaty (1978), Article IX; Convention on Long- Range Transboundary Pollution (1979), Articles 3 and 7; Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region (1983), Article 13; Protocol Concerning Specially Protected Areas and Wildlife to the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region, Article 17; Convention for the Prevention of Pollution by Ships (1973), Article 17; Convention of the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (1972), Article IX; United Nations Convention on the Law of the Sea (1982), Articles 200 and 202.

⁴⁴Convention for the Protection of the Ozone Layer (Vienna 1985), Article 4; Montreal Protocol (1987), Article 5; London Adjustments to the Montreal Protocol (1991), Article 10 and 10A; Basel Convention (1989), Articles 10.2 and 14; Bamako Convention (1991), Article 10.2 and 14; United Nations Framework Convention on Climate Change (1992), Article 4; United Nations Environment Programme (1985), Article 9; Kuwait Regional Convention (1978), Article XI; Convention on Long- Range Transboundary Pollution (1979), Articles 3 and 7; International Tropical Timber Agreement (1994), Articles 27.2 and 27.3; Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region (1983), Article 13; Convention for the Prevention of Pollution by Ships (1973), Article 17; Convention of the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (1972), Article IX; United Nations Convention on the Law of the Sea (1982), Articles 202.

⁴⁵Convention for the Protection of the Ozone Layer (Vienna 1985), Article 4; Montreal Protocol (1987), Article 9; London Adjustments to the Montreal Protocol (1991), Article 10A; Basel Convention (1989), Articles 10.2 and 14; Bamako Convention (1991), Article 10.2 and 14; London Guidelines (1989), Articles 13 and 15; United Nations Framework Convention on Climate Change (1992), Article 4; United Nations Environment Programme (1985), Article 8; Kuwait Regional Convention (1978), Article XI; Convention on Long- Range Transboundary Pollution (1979), Articles 3 and 7; International Tropical Timber Agreement (1994), Articles 27.2 and 27.3; Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region (1983), Article 13; United Nations Convention on the Law of the Sea (1982), Articles 202.

⁴⁶Montreal Protocol, Article 9; London Adjustments to the Montreal Protocol, Article 10; Basel Convention, Article 10.2; Bamako Convention, Article 10.2 and 14; United Nations Framework Convention on Climate Change (1992), Article 4; United Nations Convention on the Law of the Sea, Article 202.

V. PROVISIONS OF THE TRIPS AGREEMENT RELEVANT TO MATTERS RAISED IN DISCUSSIONS IN ENVIRONMENTAL FORA

47. While the TRIPS Agreement covers all the main areas of intellectual property (copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, and undisclosed information), the intellectual property related issues that have been raised in the environmental fora concern essentially those IPRs relevant to technology, in particular patents.

48. This section attempts to present the provisions of the TRIPS Agreement that are relevant to various matters identified in Sections II to IV above where reference has been made to IPRs in discussions on environmental issues. In doing this, the relationship between the substance of the TRIPS Agreement and that of the Biodiversity Convention is discussed.⁴⁷ The following issues are considered in turn: promotion of environmentally-sound technology; access to and transfer of technology; technology that may adversely affect the environment; patentability of genetic material/life forms; and contribution of countries/communities sources of genetic material. These points are addressed without prejudice to whether they are all intellectual property related or indeed environment related but because they have been raised in environmental fora by at least some as having an IPR dimension.

(a) Promotion of environmentally-sound technologies

49. The importance of promoting environmentally-sound technology has been referred to in many discussions in environmental fora; for example, it is reflected in Agenda 21. A fundamental feature of IPR systems and of the TRIPS Agreement, particularly in the area of patents, is to provide incentives for the generation of new technology, by giving the inventor an exclusive right (subject to certain exceptions) over the use of his invention for a finite period of time (see Annex 3 for the text of the provisions in the TRIPS Agreement which relate to patents). The IPR system provides protection to the results of investment in the development of new environmentally-friendly technology, thus giving the incentive and the means to finance such research and development. A combination of a well-functioning IPR system and appropriate price signals in the market, which direct research and development effort to environmentally-sound technologies, can play a major role in developing the technologies that will respond to environmental problems. The TRIPS Agreement will help reinforce this in a wider range of countries.

50. The objective of promoting the development of new technology is referred to in Article 7 of the TRIPS Agreement which says 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".

51. With this objective in mind, the TRIPS Agreement (Article 27.1) requires that patents be available for any invention, in all fields of technology, subject to certain limited exceptions

⁴⁷As regards the legal relationship between the two Agreements, see paragraph 12 above for the provision of the Biodiversity Convention on its relationship with other international agreements.

(mainly for inventions in the area of plants and animals⁴⁸). The minimum rights that a patent must confer on its owner are set out in Article 28⁴⁹. Article 33 requires that the term of protection available must be at least 20 years from the date of filing of the patent application.

52. A number of other provisions of the TRIPS Agreement are also of relevance to the promotion of technological innovation. One is Article 39 on the protection of undisclosed information (see Annex 3 for the text of this Article). This requires Members to give natural or legal persons the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices. To be eligible for such protection under the TRIPS Agreement, the information in question must be secret, have commercial value because it is secret and have been subject to reasonable steps to keep it secret.⁵⁰ Another section of the TRIPS Agreement that is particularly relevant to the promotion of technological innovation which can be of benefit to the environment is that on the protection of the layout-designs (topographies) of integrated circuits (Articles 35 to 38).

(b) Access to and transfer of technology

53. This issue is addressed in the Biodiversity Convention, in Agenda 21 and in a number of other agreements on environmental matters. As indicated in paragraph 50 above, it is an objective of the TRIPS Agreement to promote not only technological innovation, but also "the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

54. The objectives of promoting technological innovation and the transfer of technology are usually mutually consistent since right holders are generally more willing to transfer technology voluntarily where a country's IPR system provides effective protection. In addition, the disclosure requirements of the patent system and exceptions to patent rights for experimental use are designed to maximize the degree to which knowledge of new technology becomes publicly available and can be the basis for further technological development. Moreover, the TRIPS Agreement contains some specific requirements on developed country Members to provide incentives for technology transfer to least-developed country Members. These aspects are discussed in paragraphs 57 to 60 below.

55. In the event that there is tension between the objectives of promoting technological innovation and the transfer of technology, and with the aim of securing the objectives of Article 7, the TRIPS Agreement contains a number of provisions, in particular on compulsory licensing and control of anti-competitive practices, to establish an appropriate balance between these two objectives, and thus between the interests of producers and users of technological knowledge, conducive to social and economic welfare. These provisions are discussed in paragraphs 61 to 65 below.

⁴⁸These are discussed in paragraphs 70 to 75 below.

⁴⁹These are subject to a number of exceptions, some of which are discussed in paragraphs 59 and 61 to 65 below.

⁵⁰The protection does not establish an exclusive right; it only operates against disclosure, acquisition and use "in a manner contrary to honest commercial practices" and, unlike a patent, does not provide any rights in respect of the same information that has been independently developed or reverse engineered.

56. Before discussing the particular provisions of the TRIPS Agreement on these matters, a number of introductory observations may be useful:

- Most technology is in the public domain, either because protection was never sought in the first place⁵¹ or because any term of protection granted has expired;
- When technology, whether patented or not, is in the control of a government, that government is of course free to transfer it on concessional terms if it so wishes;
- There is nothing in the TRIPS Agreement that would prevent a government or an international financial mechanism from providing financial assistance to enable the voluntary transfer of privately-held proprietary technology on concessional terms;
- The obligations of the TRIPS Agreement only have to start applying at the expiry of transition periods (Articles 65 and 66) - generally one year for developed countries, five years for developing countries and countries in transition facing special problems in structural reform of the intellectual property systems, and eleven years (with a possibility of extension) for least-developed countries. In the situation where a developing country does not presently give product patent protection in a particular area of technology, the introduction of such protection can be delayed for up to ten years. In respect of pharmaceutical and agricultural chemical products, there are special additional transition provisions that take account of the regulatory delay before such products are approved for marketing (Articles 70.8 and 70.9).

(i) Disclosure

57. One of the purposes of the patent system is to encourage inventors to disclose new technology rather than attempt to keep it secret, so that new technology can become part of the common pool of knowledge of mankind. Article 29 establishes an obligation on Members to require that patent applicants disclose the invention⁵². This means that, at the end of the patent term, the technology will fall into the public domain. In many jurisdictions, the practice is to publish patent applications 18 months after they have been filed. The resulting information, which is stored and classified in patent documentation, is accessible to anyone⁵³, including to those in

⁵¹ In order to benefit from patent protection, it is necessary to obtain a separate patent in each jurisdiction and that patent is only valid in that jurisdiction. The extent to which patents are taken out varies greatly from country to country. WIPO figures for 1991 show that, while over 90,000 patents were granted in the US and more than 30,000 in each of Japan, Germany, France and the UK, the largest number granted in a developing country was 2,419 (Brazil). In four other developing countries it was more than 1,000, in 21 between 100 and 1,000, and in the rest of those listed less than 100.

⁵²Article 29 reads as follows:

"1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

"2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

⁵³See Section III for the assistance provided by WIPO in this regard.

countries where a patent has not been sought, and "constitutes the single most valuable and comprehensive source of technology available in the world today".⁵⁴

58. The obligation to disclose has a number of important consequences for the transfer of and access to technology.

- For the duration of the term of protection, information is readily available about from whom the technology can be obtained;
- At the end of the patent term, the disclosed invention falls into the public domain and is freely available to all;
- Further research and development is facilitated - see next heading.

(ii) Experimental use

59. Article 30 allows Members to make "limited exceptions" to the rights conferred by a patent, subject to certain conditions⁵⁵. It is clear from the drafting history of this provision that one of the "limited exceptions" that was intended to be covered was acts done for experimental purposes. This type of provision is to be found in most, if not all, patent laws. The combination of this provision with the disclosure requirement reflects an underlying objective of the patent system - to promote, and not be an impediment to, the further advance of science and technology.

(iii) Incentives to transfer of technology

60. As mentioned earlier, the TRIPS Agreement does not stand in the way of governments providing incentives for the transfer of technology. Indeed, Article 66.2 of the TRIPS Agreement requires developed country Members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".

(iv) Compulsory licences⁵⁶

61. The TRIPS Agreement contains a provision allowing a compulsory licence (i.e. a licence granted without the agreement of the patent owner) to be granted to an applicant to use a patented invention where the right holder has not been willing to grant a voluntary licence on reasonable commercial terms and conditions within a reasonable period of time, subject to a number of conditions aimed at protecting the legitimate interest of the patent owner.⁵⁷ The relevant

⁵⁴WIPO, Background Reading Material on Intellectual Property, WIPO, 1988.

⁵⁵The full text of Article 30 is as follows:

"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."

⁵⁶Also sometimes referred to as "non-voluntary licences."

⁵⁷In cases of national emergency or other circumstances of extreme urgency and in cases of public non-commercial use, a Member may waive the requirement to first seek a voluntary licence.

provisions of the TRIPS Agreement are Article 31⁵⁸, the last sentence of Article 27.1 and Article 5A of the Paris Convention (incorporated by virtue of Article 2.1 of the TRIPS Agreement). The text of these provisions can be found at Annex 3.

62. Except in the particular area of semi-conductor technology (Article 31(c)), these provisions do not limit the grounds on which a compulsory licence can be granted: Members are not called upon to justify the reason for granting a compulsory licence, provided that the various conditions listed are respected. These include the requirements that each grant of a compulsory licence must be considered on its individual merits, that the compulsory licensing system not discriminate between areas of technology, that the right holder be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the licence, and that the legal validity of the decision to grant a compulsory licence and the decision on remuneration of the right holder be subject to judicial or other independent review. Certain of these requirements are relaxed where a compulsory licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

(v) Anti-competitive practices

63. Article 8.2 of the TRIPS Agreement recognizes 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."

64. The TRIPS Agreement contains a Section (Section 8 of Part II) which provides for international cooperation in the control of anti-competitive practices in contractual licences. This Section recognizes that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology" (Article 40.1) and that nothing in the TRIPS Agreement "shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market" (Article 40.2). It recognizes the right of Members to "adopt, consistently with other provisions of the Agreement, appropriate measures to prevent or control such practices" (Article 40.2). A number of specific examples of practices against which Members may wish to take action in particular cases are cited; these are exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing. The Section then introduces a procedure for consultation and exchange of information among Members to facilitate the control of anti-competitive practices in contractual licences. The full text of Section 8 of Part II can be found at Annex 3.

65. Among the measures that a Member may take to remedy abusive anti-competitive practices is the grant of a compulsory licence. Where a compulsory licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, Article 31(h) relaxes several of the conditions normally applicable to the compulsory licensing of patents. In such a case, there is no longer a requirement to seek first a voluntary licence on reasonable commercial

⁵⁸Article 31 does not talk of "compulsory licences" or "non-voluntary licences", but of "other use without the authorization of the right holder". This is because the Article covers, in a single set of rules, both compulsory licensing and so-called government use, i.e. use by the government or by a contractor working for the government. Compulsory licensing and government use are both types of use without the authorization of the right holder.

terms and conditions, the goods produced under the licence need not be predominantly for the supply of the domestic market of the Member granting the compulsory licence, and the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration of the right holder.

(c) Technology that may adversely affect the environment

66. A concern highlighted in various discussions on environmental matters is the need to curb the adverse effect of certain technology on the environment. In the work on the Biodiversity Convention, in FAO and elsewhere, the issue of control of the release of new biotechnological products into the environment has been prominent. In discussions on plant variety protection and "farmer's rights", concern about the possible effect of uniform new varieties displacing the biodiversity provided by traditional varieties has been expressed by some. Similarly, a long-standing subject of attention in most countries has been the environmental effects of agricultural chemicals, which are generally subject to a testing and approval procedure before being authorized for marketing.

67. As far as the TRIPS Agreement is concerned, the main point is that it does not affect the right of governments to restrict research or development or the use of technology on the grounds of protecting the environment. A patent gives the right to the patent owner to prevent others from using the protected invention (subject to certain exceptions), but does not guarantee the patent owner the right to exploit the technology in question. In this regard, the provisions of Article 8.1 of the TRIPS Agreement should be noted:

"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

68. Although, as stated above, the possibility for a government to restrict the use of technology on environmental grounds is not affected by the grant of a patent, it should also be noted that Article 27.2 of the TRIPS Agreement enables a Member to exclude from patentability inventions whose use would seriously prejudice the environment. This provision is discussed in paragraph 3 above.

69. Also of relevance to controls on the use of environmentally-prejudicial technology are the provisions of Article 39.3 on the protection of undisclosed test or other data submitted in order to obtain marketing approval for pharmaceutical and agricultural chemical products which utilize new chemical entities. These provisions provide protection to the very considerable investment that frequently has to be made in testing such products to ensure their usefulness and safety, notably for the environment in the case of agricultural chemicals. While one of the forms of protection that should be granted is against disclosure of the information, this does not apply where disclosure is necessary to protect the public or where steps are taken to ensure that the data is protected against unfair commercial use.

(d) Patentability of genetic material/life forms

70. The extent to which genetic material and life forms should be patentable is an active issue in many contexts - in the judicial, legislative and executive branches of many governments, in commercial circles, and in public opinion. Environmental groups have participated actively in this debate. Concerns that they have raised include the issue of the environmental safety of

biotechnological inventions and the possible effect on biodiversity of the uniformization of productive varieties/races. The way in which the TRIPS Agreement relates to these issues has already been indicated in paragraphs 67 and 68 above. Ethical questions about the patenting of life forms have also been raised as well as economic questions about the effects on users and the distribution of benefits with the suppliers of the underlying genetic material.

71. The first point to note is that Article 1.1 of the TRIPS Agreement makes it clear that there is no expectation that countries will have identical patent laws: the obligation is to meet the minimum standards of the TRIPS Agreement while being free to grant more extensive protection than is required by the Agreement. The implication of this is that the fact that patents may be granted in response to certain applications in some countries does not necessarily mean that this would be an obligation under the TRIPS Agreement.

72. Article 27.1 of the TRIPS Agreement establishes the basic criteria for patentability. The relevant part of this provision reads as follows:

"...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

For this provision of the TRIPS Agreement the term "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with "non-obvious" and "useful" respectively.

73. Thus, the TRIPS Agreement allows each Member to refuse to grant a patent for any claimed invention which does not meet any one of the following criteria: it must be new; it must involve an inventive step or be non-obvious; it must be capable of industrial application or useful (and it must have been adequately disclosed). A country would remain free to refuse a patent for biological or genetic material which has been merely discovered or where the use of it claimed as the subject of the invention was already known.

74. Even if an application meets the basic tests of patentability, Article 27.3(b) of the TRIPS Agreement allows Members to exclude from patentability certain plant and animal inventions. The relevant portion of Article 27.3(b) reads as follows:

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

75. Even if an invention meets the basic criteria for patentability of Article 27.1 and does not fall within the exceptions allowed under Article 27.3(b), a patent may still be refused under Article 27.2 if the invention is offensive to *ordre public* or morality, including to human, animal or plant life or health or to avoid serious prejudice to the environment. As was indicated in Section I, the main condition attached to the use of this exception to patentability is that the prevention of the commercial exploitation of the invention is necessary to protect *ordre public* or morality, including to avoid serious prejudice to the environment.

(e) Contribution of countries/communities sources of genetic material

76. In discussions in fora concerned with environmental matters, such as in the negotiation of the Biodiversity Convention and in the FAO Commission on Plant Genetic Resources, the issue of recognizing the contribution of indigenous peoples and local communities through the provision of traditional knowledge and informal innovation practices has been raised. In the FAO, the concept of "farmer's rights" has been defined as "rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity" (FAO Resolution 5/89). Attention is also given in the Biodiversity Convention to the question of the participation of countries sources of genetic resources in research activities using such resources and, on mutually agreed terms, in the results and benefits arising from biotechnologies using such genetic resources.

77. This matter has two aspects. One is the question of the recognition of the intellectual contribution made by indigenous peoples/local communities. The strengthened protection of IPRs worldwide that should flow from the TRIPS Agreement will help indigenous and local communities benefit from their contributions where the conditions for protection of patents, plant varieties, trade secrets, industrial designs, geographical indications, copyright and performers' rights (e.g. in respect of expressions of traditional culture) are met. The question of new forms of protection adapted to the particular circumstances of such peoples/local communities was not raised during the TRIPS negotiations.

78. The second aspect concerns the contribution of countries/communities through the conservation and provision of genetic resources in their natural state. The TRIPS Agreement is silent on the question of the participation of countries/communities in the benefits arising from the use of technology based on genetic resources originating in their territories. There is also nothing in the TRIPS Agreement that stands in the way of contractual arrangements between countries and companies seeking to use genetic resources from those countries, public transfers of funds or any other mechanism compatible with its provisions.

VI. NEGOTIATING HISTORY OF THE RELEVANT PROVISIONS OF THE TRIPS AGREEMENT

79. This Section provides a brief overview of the TRIPS negotiations and then discusses more specifically the drafting history of the provisions on patentable subject matter, compulsory licensing and the control of anti-competitive practices in contractual licences.

(i) General summary of the TRIPS negotiations

80. The negotiations were launched with a section of the Ministerial Declaration of Punta del Este (20 September 1986) on "Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods". Much of the first two years was taken up with the identification of what were the trade problems arising in the field of intellectual property rights that should be the subject of negotiation in the Negotiating Group. There were marked differences of view, particularly on the question of whether the negotiations should address the substantive standards for the scope, availability and use of intellectual property rights. Agreement on the agenda for the negotiations was reached in the Mid-Term Review which took place between December 1988 and April 1989. The text that was adopted provided for negotiations on all the major aspects raised by delegations, including substantive standards, enforcement, dispute settlement, basic principles and transitional arrangements, and that the underlying public policy

objectives of national IPR systems would be taken into account, that strengthened disciplines on the multilateral settlement of disputes would be reached and that the issue of the institutional framework for the implementation of the results of the negotiations would be left open.⁵⁹

81. Following this agreement, suggestions from a large number of countries on the different aspects of the agenda were examined in the Negotiating Group. The negotiations properly speaking began in the second quarter of 1990 with the tabling of five draft legal texts, by the EC, the United States, 12 developing countries, Switzerland and Japan.⁶⁰ These texts were combined into a single "composite draft text", using square brackets and alternatives to indicate differences. This text was the subject of detailed consultations which led to the tabling of a Chairman's text in July 1990 (see Annex 4 for the provisions relating to patents contained in this text).⁶¹ Successive revisions of this text, as the result of further consultations, were produced leading to the text that was sent to the Brussels Ministerial Meeting as part of MTN.TNC/W/35/Rev.1. By the time of the Brussels meeting, in addition to the question of the institutional framework for the implementation of the results of the TRIPS negotiations, the outstanding differences had been reduced to some 20 key issues, a large proportion of which were in the area of patents. Useful discussions took place in Brussels and work resumed intensively in the last quarter of 1991. This led to the tabling of the text that formed part of the Draft Final Act in December 1991. As a result of subsequent discussion, the text adopted at Marrakesh contains only two relatively small changes of substance compared to that in the Draft Final Act (the addition of language on semi-conductor technology in Article 31(c) and the addition of paragraphs 2 and 3 of Article 64 on dispute settlement).

(ii) Patentable subject matter

82. A key issue in the TRIPS negotiations as a whole was the provision on patentable subject matter (Article 27). On this matter, the basic criteria for patentability (novelty, inventive step and industrial applicability) were generally accepted from the outset and were the subject of relatively little discussion (Article 27.1). The major area for negotiation was what, if any, exceptions should be made to the general rule that inventions which meet these criteria should be patentable, in particular what exceptions beyond the normal exception for inventions contrary to public order and morality might be permitted.

83. One aspect concerned permissible exceptions for inventions in the area of plants and animals. In this regard, three main positions were evident in the texts tabled in 1990:

- one was that there should be no permissible exception in this regard;
- the second was along the lines of the language found in Article 53(b) of the European Patent Convention, namely that plant and animal varieties and essentially biological processes for the production of plants or animals, other than microbiological processes or the products thereof, could be excluded from patentability. Plant varieties, however, would have to be protected either by patents and/or by an effective *sui generis* system;

⁵⁹Document MTN.TNC/9

⁶⁰Documents MTN.GNG/NG11/W/68, 70, 71, 73 and 74.

⁶¹Document MTN.GNG/NG11/W/76

- the third was a broader exception which would cover any plant or animal or processes for the production of plants or animals and would also allow further limitations as regards biotechnological inventions.

84. A second aspect concerned the patentability of pharmaceuticals, agricultural chemicals and foodstuffs. In this regard, there were two main positions. One was that such products should, where they meet the normal conditions for patentability, be patentable, without discrimination as to area of technology. The other was that Members should be allowed to exclude products and processes for their manufacture on grounds of public interest, national security, and public health or nutrition.

85. The situation was still essentially the same as late as early December 1991, the main development being that the countries advocating the first position concerning inventions in the area of plants and animals appeared to have come to accept that the TRIPS Agreement would not match their national legislation on this point and to be willing to join the countries advocating the second position, on condition that the provision would be reviewed a certain period after the entry into force of the Agreement. In the final phase of the negotiations in 1991, the so-called patent complex of issues was considered as a package. This included the above issues of patentability, together with issues relating to the scope of patent rights, including safeguards against abuse, for example in respect of compulsory licensing, anti-competitive practices, and parallel imports, and issues relating to timing such as the transitional arrangements addressed in Articles 65 and 70 of the present Agreement. As a result of this negotiation, the text of Article 27, as it appears in the Agreement, was formulated. The eventual outcome of the negotiations on patentability of inventions in the area of plants and animals combines elements of the second and third positions outlined above.

86. Proposals that explicit provision should be made for the Members to be able to exclude from patentability "scientific theories, mathematic methods, discoveries and materials or substances [already existing] [in the same form found] in nature" were deleted from the text in October 1990 because it was accepted that these matters were already addressed by the basic criteria for patentability in Article 27.1.

87. A proposal to allow a specific exclusion from patentability for inventions relating to nuclear or fissionable material was not retained in Article 27.3 because it was accepted that this matter was adequately covered by Article 73 of the TRIPS Agreement ("Security Exceptions").

88. The notion that there should be provisions allowing inventions to be excluded from patentability on grounds of *ordre public* or morality commanded wide support from the outset. The negotiations that took place on this matter concerned the fine tuning of the language and the conditions to be attached. Article 27.2 did not contain any reference to "environment" until almost the end of 1991. In November 1991, an earlier suggestion to include a reference to the environment was further considered. Two possible options for including some text referring to the environment were discussed, namely "to protect the environment" and "to avoid serious prejudice to the environment". It was decided to include the latter option. The last phrase of Article 27.2, "provided that such exclusion is not made merely because the exploitation is prohibited by their law", was added at the same time. The reason was that concerns had been expressed that the paragraph as it stood without this phrase could leave open the interpretation that inventions of some products could be excluded from patentability on the grounds that the prevention of their exploitation was necessary to protect life and health pending the completion of the normal testing procedures necessary to establish their effectiveness and safety prior to the

grant of marketing approval. This language was also designed to meet a legal concern about a possible conflict between Article 27.2 and Article 4*quater* of the Paris Convention.⁶²

(iii) Compulsory licensing

89. Two of the main underlying issues in the negotiation of the provisions in the TRIPS Agreement on compulsory licensing (Article 31, the last sentence of Article 27.1 and the incorporation by reference of Article 5A of the Paris Convention) were whether the grounds for the grant of compulsory licences should be limited as well as certain conditions imposed aimed at protecting the legitimate interests of the right holder, and whether equivalent rules should apply to compulsory licensing and government use - the use by a government of an invention for its own purposes or by a contractor working on its behalf.

90. On the first issue, some of the draft legal texts presented in the spring of 1990 would have limited the grounds on which compulsory licences could be granted; for example, in one of them compulsory licences would only be allowed to remedy an adjudicated violation of competition laws or to address, only during its existence, a declared national emergency. Under this approach, certain conditions would also have been specified. The other draft legal texts envisaged an approach which would not attempt to constrain the grounds on which a compulsory licence could be granted but would require certain conditions to be respected. Within this approach, there were those who supported more far-reaching and numerous conditions and those who advocated keeping the conditions to one or two basic requirements, primarily relating to remuneration of the right holder. The latter also put emphasis on the control of anti-competitive practices in contractual licences. The draft texts that formed the basis of the work from the middle of November 1990 onwards reflected only the approach that would put conditions on the grant of compulsory licences without constraining the underlying grounds for their grant. The subsequent negotiations focused on the details of what these conditions should be and led to the text that was finally adopted.

91. One of the conditions that was proposed by some delegations was that laws, regulations and requirements relating to the grant of a compulsory licence should not discriminate between fields of technology. This led to a counter-proposal that the right to discriminate between fields of technology should be explicitly recognized, *inter alia* in areas of public health, nutrition or environmental protection. The subsequent negotiations on this point led to the inclusion of the concept of non-discrimination between fields of technology in the enjoyment of patent rights in the last sentence of Article 27.1.

92. The second main underlying issue in the negotiation of Article 31 was whether government use practices should be subject to the same disciplines as compulsory licensing. This led to a set of conditions common to both compulsory licensing and government use, in texts from the middle of November 1990 onwards. For this reason, from this time, the texts did not refer to compulsory licensing (or non-voluntary licensing) and government use as such, but, in more generic terms, to "other use without the authorization of the right holder".

⁶²Article 4*quater* of the Paris Convention reads as follows:

The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.

(iv) Control of anti-competitive practices and contractual licences

93. This issue was addressed in only one of the draft legal texts tabled in the spring of 1990 - the one tabled by 12 developing countries. That text sought a recognition of the right of Members to specify in their national legislation practices deemed to constitute an abuse of intellectual property rights or to have an adverse effect on competition and to adopt appropriate measures to prevent or control such practices. It also would commit each Member to consult and cooperate with any other Member with a view to ensuring that the IPR owners of the first Member complied with the national legislation in this respect of the second Member.

94. The subsequent negotiations focused on a number of themes:

- one was whether it should be recognized that practices may be deemed *per se* anti-competitive or whether the text should be based on the notion of a case-by-case or rule-of-reason approach;
- a second related issue concerned a subsequent proposal to specify some 14 practices which could be deemed anti-competitive or abusive;
- a third issue concerned whether this section of the text should refer to practices or conditions which were anti-competitive and abusive or whether it should cover such measures or practices when they were either anti-competitive or abusive;
- another element in the negotiations was whether the measures to remedy such practices would have to be consistent with the other provisions of the TRIPS Agreement;
- in regard to the nature of the cooperation, there was concern that the proposal as initially formulated might imply having to accept that the national legislation of Members had extra-territorial effect;
- the negotiations subsequently focused on provisions for consultation and exchange of information. In this regard, the question of whether provision should be made for the exchange of confidential as well as non-confidential information was a particular issue.

95. The outcome of these negotiations is the text that is contained in Section 8 of Part III of the TRIPS Agreement.

VII. Article XX OF GATT 1994 AND THE TRIPS AGREEMENT

96. Article XX of GATT 1994 specifies certain conditions under which a Member is exempted from obligations under other provisions of GATT 1994. Similarly, the TRIPS Agreement has provisions which exempt Members from certain obligations imposed by other provisions of the TRIPS Agreement. For example, Articles 27.2 and 27.3 permit exemption from patenting in specified circumstances or for specified inventions. Article 30 permits certain exemptions to the rights conferred by patents, and Article 31 permits the use of patented technology without authorization of the right holder provided certain conditions are met. Details on these provisions have already been provided above.

97. In the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement"), there are provisions that regulate conflict between the WTO Agreement and the multilateral trade agreements in its Annexes⁶³, between GATT 1994 and other Agreements in Annex 1A⁶⁴, and between certain Agreements in Annex 1A (such as Agreement on Technical Barriers to Trade and Agreement on the Application of Sanitary and Phytosanitary Measures⁶⁵). There is no provision regulating conflict between Agreements in Annex 1A and Agreements in Annexes 1B or 1C to the WTO Agreement.

⁶³See Article XVI.3 of the WTO Agreement.

⁶⁴See, for example, the general interpretative note to Annex 1A.

⁶⁵See Article 1.5 of the Agreement on Technical Barriers to Trade.

ANNEX 1

A Note on UPOV

98. UPOV is the commonly used acronym for the International Union for the Protection of New Varieties of Plants, an intergovernmental organization with headquarters in Geneva. The acronym UPOV is derived from the French name of the organization, which is "Union internationale pour la Protection des Obtentions Végétales". UPOV was established by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"), which was signed in Paris in 1961. The Convention entered into force in 1968. It was revised in Geneva in 1972, 1978 and 1991 (henceforth "1972 Act", "1978 Act" and "1991 Act", respectively). Currently, the 1978 Act is in effect.⁶⁶

99. The 1991 Act is not yet in force. It will come into force one month after five States have deposited their instruments of adherence, provided that at least three such instruments are deposited by existing member States.⁶⁷ When it comes into force it will only bind States which have deposited the instruments for becoming a member. After the date of entry into force of the 1991 Act, the 1978 Act will be closed for further accessions, except for developing countries. The 1978 Act will remain open for accession by developing countries until 31 December 1995.

100. States adhering to the UPOV Convention undertake to create a system of granting plant breeders' rights (PBRs) within their domestic laws, in accordance with the UPOV Convention. The right is granted in each member State for its own territory and not on an international basis.⁶⁸ Both the 1978 Act and 1991 Act set out a minimum scope of protection that States must grant and offer member States the possibility of taking their national circumstances into account in their legislation. This note provide a summary of the main features of 1978 Act and 1991 Act in terms of the minimum rights that member States have to grant under the UPOV Convention, and does not address the different possible situations that could arise if a member State decides to grant more extensive rights.⁶⁹

⁶⁶On 3 May 1995, UPOV had 27 members: Argentina, Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Norway, Poland, Slovakia, South Africa, Spain, Sweden, Switzerland, United Kingdom, the United States, and Uruguay.

⁶⁷Article 34(1)(b) of the 1991 Act provides for possible membership by an intergovernmental organization. This provision was designed to open the possibility of membership by the EC in particular, after the adoption of the Council Regulation (EEC) on Community plant variety rights. This Regulation was adopted as Council Regulation (EC) No 2100/94 of 24 July 1994 on Community plant variety rights, and was implemented on 27 April 1995.

⁶⁸Under the system set up by the Junta of the Cartagena Agreement under Decision 345, Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties, the right granted by one member State (Bolivia, Colombia, Ecuador, Peru or Venezuela) will be recognized by the other member States.

⁶⁹This note provides a summary of the provisions in the 1978 Act and 1991 Act. For more detail, see Barry Greengrass (1991), "The 1991 Act of the UPOV Convention", *European Intellectual Property Review*, Volume 13, Issue 12; B. Greengrass (1991), "The UPOV Convention - The Scope of Protection and its General Provisions", and "The interface between plant breeders' rights and other forms of intellectual property protection and the future", both papers presented at a seminar organized by UPOV on the nature of and rationale for the protection of plant varieties under the UPOV Convention, Buenos Aires, 26 and 27 November 1991.

The 1978 Act

101. The 1978 Act requires five criteria to be met by a plant variety in order to qualify for PBRs: distinctness, homogeneity (or uniformity)⁷⁰, stability⁷¹, commercial novelty⁷², and the submission of an acceptable denomination (or generic designation) for the plant variety. Also, the breeder must competently maintain his variety if he wishes to retain the benefit of protection. Under Article 2 of the 1978 Act, a state may provide protection to plant varieties either in the form of PBRs or a patent, but once it has opted for protecting a plant specie by PBRs it must not subsequently protect varieties of that same specie by a patent. Under Article 3 of the 1978 Act, national treatment has to be provided to nationals and residents of other member States with regard to recognition and protection of their varieties, but reciprocity may be required on a species-by-species basis.

102. Under the 1978 Act, member States must provide breeders of a new plant variety certain exclusive rights, namely, authorization from the breeders is required for the production for purposes of commercial marketing of the reproductive or vegetative propagating material of the new plant variety; the offering for sale of the propagating material; the marketing of such material; the repeated use of the new plant variety for the commercial production of another variety; and the commercial use of ornamental plants or parts thereof as propagating material in the production of ornamental plants or cut flowers. States have to grant PBR protection for a minimum period of 18 years for vines, forest trees, food trees and ornamental trees, and 15 years in the case of all other species. However, the 1978 Act does not require member States to protect all botanical genera and species; it requires them to apply the Convention to a minimum of five genera when first acceding to the UPOV Convention and then progressively apply the Convention to a greater number of species, with a minimum of 24 genera or species being covered after eight years.⁷³ Member States can, under their own laws, grant more extensive rights to breeders of a particular genus or species, including the possibility of extending their rights to the marketed product of the variety. In practice, few States have availed themselves of this right.

103. The 1978 Act limits the breeders' rights to production and sale of reproductive or vegetative propagating material, i.e. they do not extend to the harvested product (for example the fruit from a protected variety of fruit tree). Since the exclusive right applies to production for commercial marketing, it does not extend to production of propagating material that is not for commercial marketing. Production of seed, for instance, by a farmer for subsequent sowing on his own farm, falls outside the breeder's protection ("farmer's privilege").

⁷⁰This criterion requires that variations from a standard description are within reasonable limits.

⁷¹Stability means that the variety should retain its distinguishing features from one generation to the next.

⁷²The variety must not, prior to the date of application, have been offered for sale or marketed with the agreement of the breeder in the territory of the state where the application for PBR is filed. However, in this regard, States have a choice to permit varieties to be marketed or offered for sale in their own territories for a maximum of one year prior to the date of application (The 1991 Act requires all member states to make provision in their laws for this one year grace period, i.e. it is no longer optional under that Act). An additional aspect of commercial novelty is that the variety must not have been offered for sale or marketed with the agreement of the breeder in the territory of any other State for longer than six years in the case of certain woody species, and for four years in the case of all other plants.

⁷³Most member States protect all species of economic importance in their countries and a number of them protect the entire plant kingdom.

104. Another important aspect is that authorization of the breeder is not required for use of the protected variety as an initial source of variation for creating other new varieties ("breeder's exemption"). Accordingly, protection under the 1978 Act does not give the plant breeder any rights with regard to genes, the underlying genetic resource, which is contained in his variety. The only permitted exception to this is when repeated use of the variety is necessary for the commercial production of another variety.⁷⁴

105. The exclusive right of the breeder can be restricted for reasons of public interest but when restrictions for this reason are imposed, the member State involved must take all necessary measures to ensure that the breeder receives equitable remuneration.

The 1991 Act

106. Under the 1991 Act, Parties are free to protect plant varieties by PBRs or by other types of IPRs such as patents, and are allowed to grant simultaneous protection to the same plant variety by more than one type of IPR (e.g. PBRs and patents). The 1991 Act requires existing member States of the UPOV Convention to protect all plant genera and species five years after becoming bound by the Act, and requires new member States to protect all plant genera and species ten years after they become bound by the Act. The duration of the breeders' rights has been extended to 25 years for vines, forest trees, fruit trees and ornamental trees, and to 20 years for all other species.

107. The 1991 Act contains more detailed provisions for defining the scope of the breeder's rights concerning the propagating material. The authorization of the breeder is thus required for production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting and importing, stocking for any other purposes. Such acts relate to two classes of material: (i) the propagating material, and (ii) the harvested material (including whole plants and parts of plants), provided such material has been obtained through the unauthorized use of propagating material and that the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.⁷⁵ The 1991 Act extends the breeders' rights to all production and reproduction of his variety (Article 14(1)), but permits member States on a discretionary (or optional) basis to exempt from breeders' rights any seed saved and retained on the farm by the farmer (Article 15(2)).

108. The 1991 Act establishes three compulsory exceptions to the defined breeder's right: acts done privately and for non-commercial purposes; acts done for experimental purposes; acts done for the purpose of breeding and exploiting other varieties (provided such other varieties are not essentially derived varieties). The 1991 Act provides that varieties that are "essentially derived" from a protected variety can be protected but cannot be exploited without the permission of the

⁷⁴This limited exception relates basically to the use of an inbred line in the commercial production of a hybrid.

⁷⁵Article 14(3) of the 1991 Act provides for further extension of the breeders' rights to products made directly from harvested material. However, adherence to this provision is optional, i.e. it is not part of the mandatory minimum scope of protection.

breeder of the protected variety from which they were derived.⁷⁶ Article 14(5) of the 1991 Act provides a non-exhaustive list of examples of acts that may result in essential derivation.

⁷⁶Typical examples include insertion of a single gene by genetic engineering or selection of a colour mutant from an ornamental variety. In general, a variety is deemed to be essentially derived from another variety when it is predominantly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety; it is clearly distinguishable from the initial variety; and except for the difference which results from the act of derivation, it conforms to the initial variety in the expression of the initial characteristics that result from the genotype or combination of genotypes of the initial varieties.

ANNEX 2Countries that have signed or ratified the Convention on Biological Diversity

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
Afghanistan	X	
Albania		X (Ac)
Algeria	X	
Angola	X	
Antigua and Barbuda	X	X (R)
Argentina	X	X (R)
Armenia	X	X (R)
Australia	X	X (R)
Austria	X	X (R)
Azerbaijan	X	
Bahamas	X	X (R)
Bahrain	X	
Bangladesh	X	X (R)
Barbados	X	X (R)
Belarus	X	X (R)
Belgium	X	
Belize	X	X (R)
Benin	X	X (R)
Bhutan	X	
Bolivia	X	X (R)
Botswana	X	
Brazil	X	X (R)
Bulgaria	X	
Burkina Faso	X	X (R)
Burundi	X	
Cambodia		X (Ac)
Cameroon	X	X (R)
Canada	X	X (R)
Cape Verde	X	X (R)

(Cont' d)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
Central African Republic	X	X (R)
Chad	X	X (R)
Chile	X	X (R)
China	X	X (R)
Colombia	X	X (R)
Comoros Islands	X	X (R)
Congo	X	
Cook Islands	X	X (R)
Costa Rica	X	X (R)
Côte d'Ivoire	X	X (R)
Croatia	X	
Cuba	X	X (R)
Cyprus	X	
Czech Republic	X	X (Ap)
Democratic People's Republic of Korea	X	X (R)
Denmark	X	X (R)
Djibouti	X	X (R)
Dominica		X (Ac)
Dominican Republic	X	
Ecuador	X	X (R)
Egypt	X	X (R)
El Salvador	X	X (R)
Equatorial Guinea		X (Ac)
Estonia	X	X (R)
Ethiopia	X	X
European Community	X	X (Ap)
Fiji	X	X (R)
Finland	X	X (At)
France	X	X (R)
Gabon	X	
Gambia	X	X (R)
Georgia		X (Ac)
Germany	X	X (R)
Ghana	X	X (R)

(Cont'd)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
Greece	X	X (R)
Grenada	X	X (R)
Guatemala	X	
Guinea	X	X (R)
Guinea-Bissau	X	
Guyana	X	X (R)
Haiti	X	
Honduras	X	
Hungary	X	X (R)
Iceland	X	X (R)
India	X	X (R)
Indonesia	X	
Iran	X	X (R)
Ireland	X	
Israel	X	
Italy	X	X (R)
Jamaica	X	X (R)
Japan	X	X (At)
Jordan	X	X (R)
Kazakhstan	X	X (R)
Kenya	X	X (R)
Kiribati		X (Ac)
Kuwait	X	
Latvia	X	
Lebanon	X	X (R)
Lesotho	X	X
Liberia	X	
Libyan Arab Jamahiriya	X	
Liechtenstein	X	
Lithuania	X	
Luxembourg	X	X (R)
Madagascar	X	
Malawi	X	X (R)
Malaysia	X	X (R)

(Cont' d)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
Maldives	X	X (R)
Mali	X	X (R)
Malta	X	
Marshall Islands	X	X (R)
Mauritania	X	
Mauritius	X	X (R)
Mexico	X	X (R)
Micronesia (Federated States of)	X	X (R)
Monaco	X	X (R)
Mongolia	X	X (R)
Morocco	X	
Mozambique	X	
Myanmar	X	X (R)
Namibia	X	
Nauru	X	X (R)
Nepal	X	X (R)
Netherlands	X	X (At)
New Zealand	X	X (R)
Nicaragua	X	
Niger	X	
Nigeria	X	X (R)
Norway	X	X (R)
Oman	X	X (R)
Pakistan	X	X (R)
Panama	X	X (R)
Papua New Guinea	X	X (R)
Paraguay	X	X (R)
Peru	X	X (R)
Philippines	X	X (R)
Poland	X	
Portugal	X	X (R)
Qatar	X	
Republic of Korea	X	X (R)
Republic of Moldova	X	

(Cont' d)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
Romania	X	X (R)
Russian Federation	X	X (R)
Rwanda	X	
Saint Kitts and Nevis	X	X (R)
Saint Lucia		X (Ac)
Samoa	X	X (R)
San Marino	X	X
Sao Tome and Principe	X	
Senegal	X	X (R)
Seychelles	X	X (R)
Sierra Leone		X (Ac)
Singapore	X	
Slovakia	X	X (Ap)
Slovenia	X	
Solomon Islands	X	
South Africa	X	
Spain	X	X (R)
Sri Lanka	X	X (R)
Sudan	X	
Suriname	X	
Swaziland	X	X (R)
Sweden	X	X (R)
Switzerland	X	X (R)
Syrian Arab Republic	X	
Thailand	X	
Togo	X	
Trinidad and Tobago	X	
Tunisia	X	X (R)
Turkey	X	
Tuvalu	X	
Uganda	X	X (R)
Ukraine	X	X (R)
United Arab Emirates	X	
United Kingdom of Great Britain and Northern Ireland	X	X (R)

(Cont'd)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

PARTY	SIGNATURE	RATIFICATION, ACCESSION, ACCEPTANCE OR APPROVAL
United Republic of Tanzania	X	
United States of America	X	
Uruguay	X	X (R)
Vanuatu	X	X (R)
Venezuela	X	X (R)
Viet Nam	X	X (R)
Yemen	X	
Yugoslavia	X	
Zaire	X	X (R)
Zambia	X	X (R)
Zimbabwe	X	X (R)

(R) Ratification

(At) Acceptance

(Ac) Accession

(Ap) Approval

ANNEX 3

Selected Provisions of the TRIPS Agreement

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

⁵For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Article 28

Rights Conferred

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: making, using, offering for sale, selling, or importing⁶ for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

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.

⁶This 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.

*Article 31**Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

⁷"Other use" refers to use other than that allowed under Article 30.

- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.⁸

⁸It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

- (a) if the product obtained by the patented process is new;
- (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

Article 35

Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36

Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:⁹ importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

⁹The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

Article 37

Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.
2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38

Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.
2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.
3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices¹⁰ so long as such information:

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- (b) has commercial value because it is secret; and
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity

¹⁰For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

ANNEX 4

Relevant Provisions on Patents Compiled by the Chairman of the Negotiating Group on the Basis of Discussions of Different Proposals (Extract from MTN.GNG/NG11/W/76)

Note: The symbol "A" in front of the numbers of the Articles denotes that the proposal was from those who favoured an overall agreement on TRIPS and counterfeit and piracy, and "B" denotes that the proposal was from those who favoured two separate agreements of TRIPS and counterfeit and piracy.

1. Patentable Subject Matter

- 1.1 Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.
- 1.4 The following [shall] [may] be excluded from patentability:
 - 1.4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].
 - 1.4.2 Scientific theories, mathematical methods, discoveries and materials or substances [already existing] [in the same form found] in nature.
 - 1.4.3 Methods of [medical] treatment for humans [or animals].
 - 1.4.4 [Any] plant or animal [including micro-organisms] [varieties] or [essentially biological] processes for the production of plants or animals; [this does not apply to microbiological processes or the products thereof]. [As regards biotechnological inventions, further limitations should be allowed under national law].
 - 1.4.5 [Production, application and use of] nuclear and fissionable material, [and substances manufactured through nuclear transformation].
- 1.5B PARTIES may exclude from patentability certain kinds of products, or processes for the manufacture of those products on grounds of public interest, national security, public health or nutrition.
- 1.6A PARTIES shall provide for the protection of plant varieties by patents and/or by an effective sui generis system.

2.2 Exceptions to Rights Conferred

2.2 [Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:

2.2.1 Rights based on prior use.

2.2.2 Acts done privately and for non-commercial purposes.

2.2.3 Acts done for experimental purposes.

2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.

2.2.5A Acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant.

2.2.6B Acts done by government for purposes merely of its own use.

3. Obligations of Patent Owners

The owner of the patent shall have the following obligations:

3.1 to disclose prior to grant the invention in a clear and complete manner to permit a person versed in the technical field to put the invention into practice [and in particular to indicate the best mode for carrying out the invention];
(See also point 1.3 above)

3.2 to give information concerning corresponding foreign applications and grants;

3.3B to work the patented invention in the territory of the Party granting it within the time limits fixed by national legislation;

3.4B in respect of licence contracts and contracts assigning patents, to refrain from engaging in abusive or anticompetitive practices adversely affecting the transfer of technology, subject to the sanctions provided for in Sections 8 and 9 below.

5. Compulsory Licences/Licences of Right/Use for Government Purposes

5A.1 The term "compulsory licence" shall be understood to cover licences of right [and government use without the authorization of the patent owner]. PARTIES shall minimise the grant of compulsory licences in order not to impede adequate protection of patent rights.

5A.2 A compulsory licence may [only] be granted for the following purposes:

5A.2.1 To remedy an adjudicated violation of competition laws.

- 5A.2.2a To address, only during its existence, a [declared] national emergency.
- 5A.2.2b On the grounds of the public interest concerning national security, or critical peril to life of the general public or body thereof.
- 5A.2.2c Where the exploitation of the patented invention is required by reason of an overriding public interest, the possibility of exploitation of the patented invention by the government, or by third persons authorized by it.
- 5A.2.3 Where the invention claimed in a later patent cannot be exploited without infringing an earlier patent, a compulsory licence may be given to the extent necessary to avoid infringement of the patent, provided that the invention claimed in the later patent involves an important technical advance in relation to the invention claimed in the earlier patent or serves an entirely different purpose.
- 5A.2.4 In the event [of failure to exploit the patented invention or that its exploitation] [that the acts of manufacturing, selling or importing of the patented product or using of the patented process and the performance of any of these acts regarding the product obtained by the process] does not satisfy the [basic] needs of the local market before the expiration of a period of four years from the date of the patent application, or three years from the date of the grant of the patent, whichever period expires last, [unless legitimate reasons as viewed from Government's regulation or normal commercial practices exist].
- 5A.3 Where the law of a PARTY allows for the grant of compulsory licences, [such licences shall be granted in a manner which minimises distortions of trade[. To this end] [and]] the following provisions shall be respected:
- 5A.3.1 A compulsory licence may only be granted after unsuccessful efforts have been made by the applicant to negotiate a voluntary licence in line with normal commercial practices with the right holder, [except in the case of a manifest national emergency].
- 5A.3.2 Compulsory licences for non-working or insufficiency of working on the territory of the granting authority shall not be granted if the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons.
- 5A.3.3 The scope of a compulsory licence shall be limited to the precise extent necessary for the purpose for which it was granted.
- 5A.3.4 Compulsory licences shall be non-exclusive [and non-assignable except with that part of the enterprise or goodwill which exploits such licence].
- 5A.3.5 Compulsory licences shall be granted to permit manufacture for the local market only.
- 5A.3.6 Each case involving the possible grant of a compulsory licence shall be considered on its individual merits.

- 5A.3.7 Compulsory licences shall not require the transfer of know-how related to the exploitation of the invention.
- 5A.3.8 Any compulsory licence shall be revoked when the circumstances which led to its granting cease to exist and are unlikely to recur, subject to adequate protection of the legitimate interests of the right holder and of the licensee. The continued existence of these circumstances shall be reviewed upon request of the right holder.
- 5A.3.9 The payment of [an equitable remuneration to the right holder corresponding to the economic value of the licence] [remuneration to the right holder adequate to compensate the right holder fully for the licence] [reasonable compensation to the patentee] shall be required [, except for compulsory licences to remedy adjudicated violations of competition law].
(See also point 2.1B(c))
- 5A.3.10 Any decision relating to the grant and continuation of compulsory licences and the compensation provided therefor shall be subject to [judicial review] [review by a distinct higher authority].
- 5B Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (i) for the working or use of a patent for governmental purposes; or (ii) where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines.
(See also point 2.1B(c) above and Section 8 below)

ANNEX 5

Declarations made at the time of signature, adoption or ratification
of the Convention on Biological Diversity

Argentina

Declaration:

The Argentine Government considers that this Convention represents a step forward in that it establishes among its objectives the sustainable use of biological diversity. Likewise, the definitions contained in Article 2 and other provisions of the Convention indicate that the terms "genetic resources", "biological resources" and "biological material" do not include the human genome. In accordance with the commitments entered into in the Convention, the Argentine Nation will pass legislation on the conditions of access to biological resources and the ownership of future rights and benefits from them. The Convention is fully consistent with the principles established in the "Agreement on trade-related aspects of intellectual property rights", including trade in counterfeit goods, contained in the Final Act of the Uruguay Round of GATT.

Chile

Declaration:

The Delegation of Chile wishes to state that its agreement to Article 22, on the relationship with other international conventions, was based on a desire not to block the existing consensus, although it would have preferred that the Article did not appear in this Convention. The Government of Chile hopes that the content and scope of this Article will be thoroughly studied within the framework of the Conference of the Parties.

Colombia

Declaration:

A thorough review of the text we are adopting today by a consensus to which Colombia was party reveals areas on which we must confirm and specify our position, with a view to strengthening the Convention in the near future and making it more useful with respect to the concerns of developing countries such as our own.

First, with respect to the principle laid down in the third Article of the Convention, our country shares its spirit but interprets the text to mean that no country shall be responsible for activities carried out beyond the control of its Government, within its national jurisdiction, which cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Secondly, our country welcomes the full recognition within the Convention of the knowledge, innovations and practices of indigenous communities, but considers that such communities must be fully guaranteed participation in the benefits arising from the use of such knowledge, innovations and practices and not only that such participation should be encouraged,

as the text of Convention rather weakly states. We therefore believe a future instrument under the Convention should endeavour to improve on this point.

Furthermore, Colombia questions the inclusion in the Convention of an Article laying down the relationship with other international treaties, since this matter falls under the Vienna Convention on the Law of Treaties and also because the Article refers to another legal instrument that has still not entered into force.

Denmark, Finland, Sweden and Norway

Declaration:

The Nordic countries stress that concept and idea of national action plans for the conservation and sustainable use of biological diversity is an important implementation tool to fulfil the obligations under the Convention. Without strong national commitments, the Convention will not achieve its objectives.

The Nordic countries would also like to stress the special obligations of developed countries to contribute financially and technologically to enable developing countries to fulfil their obligations under the Convention. The highly different socio-economic conditions and the enormous differences in the amount of biological diversity found in various countries, must be taken into account. A fair international burden sharing according to each country's means and needs is therefore absolutely crucial for the ultimate achievement of the objectives of the Convention.

The Nordic countries will continue full participation in and contribution to the work for conservation and sustainable use of biological diversity worldwide. The Nordic countries urge all countries of the world to sign the Convention in Rio de Janeiro and to ratify it as soon as possible.

European Community

Declaration:

Within their respective competence, the European Community and its Member States wish to reaffirm the importance they attach to transfers of technology and to biotechnology in order to ensure the conservation and sustainable use of biological diversity. The compliance with intellectual property rights constitutes an essential element for the implementation of policies for technology transfer and co-investment.

For the European Community and its member States, transfers of technology and access to biotechnology, as defined in the text of the Convention on Biological Diversity; will be carried out in accordance with Article 16 of the said Convention and in compliance with the principles and rules of protection of intellectual property, in particular multilateral and bilateral agreements signed or negotiated by the Contracting Parties to this Convention.

The European Community and its Member States will encourage the use of the financial mechanism established by the Convention to promote the voluntary transfer of intellectual property rights held by European operators, in particular as regards the granting of licences,

through normal commercial mechanisms and decisions, while ensuring adequate and effective protection of property rights.

France

Upon ratification:

Declaration:

With reference to Article 3, that it interprets that Article as a guiding principle to be taken into account in the implementation of the Convention;

The French Republic reaffirms its belief in the importance of the transfer of technology and biotechnology in guaranteeing the protection and long-term utilization of biological diversity. Respect for intellectual property rights is an essential element of the implementation of policies for technology transfer and co-investment.

The French Republic affirms that the transfer of technology and access to biotechnology, as defined in the Convention on Biological Diversity, will be implemented according to Article 16 of that Convention and with respect for the principles and rules concerning the protection of intellectual property, including multilateral agreements signed or negotiated by the Contracting Parties to the present Convention.

The French Republic will encourage recourse to the financial mechanism established by the Convention for the purpose of promoting the voluntary transfer of intellectual property rights under French ownership, *inter alia*, as regards the granting of licences, by traditional commercial decisions and mechanisms while ensuring the appropriate and effective protection of property rights.

With reference to Article 21, paragraph 1, the French Republic considers that the decision taken periodically by the Conference of the Parties concerns the "amount of resources needed" and that no provision of the Convention authorizes the Conference of the Parties to take decisions concerning the amount, nature or frequency of the contributions from Parties to the Convention.

India

Declaration:

The Government of India is of the view that the issue of liability and compensation for damage to biological diversity, referred to in Article 14, paragraph 2, of the Convention, is not a priority area of work to be addressed by the Conference of the Parties. There is lack of clarity as regards the subject matter and the scope of the studies referred to in that Article. It also believes that the focus of the studies referred to and relating to liability and compensation should be on subjects such as biotechnology products, the environmental impacts or effects of genetically modified organisms, and acid rain.

As regards Article 22, paragraph 1, of the Convention, it is the clear understanding of the Government of India that the reference to "any existing international agreement" means "any existing international agreement compatible with the conservation and sustainable use of biological diversity".

It is also the understanding of the Government of India that the "institutional structure" referred to in Article 39 of the Convention and the "mechanism" referred to in Article 21 are identical. Moreover, the phrase "Provided that it has been fully restructured in accordance with the requirements of Article 21" implies that for the Global Environment Facility to be the interim institutional structure as per Article 39 would require that it shall (a) function under the authority and guidance of, and be accountable to, the Conference of the Parties; (b) operate within a democratic and transparent system of governance; and (c) have universal membership.

Malawi

Declaration:

Malawi will sign the convention on Biological Diversity because she strongly believes that this instrument will save the ever-declining conservation and sustainable utilization of biological diversity, especially in the developing countries. We feel that the mechanisms that have been developed in the various articles of this Convention, namely, access to and transfer of relevant technologies, provision of new and additional financial resources to developing countries, and fair and equitable sharing of the benefits arising out of the utilization of genetic resources will achieve the underlying aims of the Convention.

Malawi attaches great importance to the protection and sustainable use of all forms of biological resources. We agree with the policy of involving the public in the protection of the country's biological resources, especially those communities living near protected areas (national parks and forest reserves) where a number of conservation economic activities have been initiated.

Malawi endorses the sovereign right of each State to exploit its own biological resources in accordance with its policies, but each Contracting Party as a State has a responsibility for the conservation and sustainable use of its biological resources.

Malaysia

Declaration:

My delegation wishes to state that the terms of transfer of technology referred to in Article 16, paragraph 2, do not fully reflect the position of my country which requires that such transfer should be specifically on concessional and preferential terms.

Our reservation on Article 39, on financial interim arrangements, are recorded in the draft report of the sixth plenary meeting in document UNEP/Bio.Div/N7-INC.5/L.1/Add.3 and reads as follows:

"The Malaysian delegation always maintained that we do not see any role for the GEF in this Convention. It has always been our clear position that the Convention should have its own specific funds, called the Biological Diversity Fund. In view of that, we wish to express our reservations in the strongest terms that the GEF has been accepted into the draft Convention, even on an interim basis. As we all know, in spite of our best efforts and intentions, these interim measures have the habit of becoming permanent features."

While concurring with the consensus on Article 19 of the Convention dealing with handling of biotechnology and distribution of its benefits, the delegation of Malaysia understands the term "living modified organisms" to mean "genetically modified organisms".

Switzerland

Upon signature:

Declaration:

The Swiss Government wishes to emphasize particularly the progress made in establishing standard terms for cooperation between States in a very important field: research activities and activities for the transfer of technology relevant to resources from third countries.

The important provisions in question create a platform for even closer cooperation with public research bodies or institutions in Switzerland and for the transfer of technologies available to governmental or public bodies, particularly universities and various publicly-funded research and development centres.

It is our understanding that genetic resources acquired under the procedure specified in Article 15 and developed by private research institutions will be the subject of programmes of cooperation, joint research and the transfer of technology which will respect the principles and rules for the protection of intellectual property.

These principles and rules are essential for research and private investment, in particular in the latest technologies, such as modern biotechnology which requires substantial financial outlays. On the basis of this interpretation, the Swiss Government wishes to indicate that it is ready, at the opportune time, to take the appropriate general policy measures, particularly under Articles 16 and 19, with a view to promoting and encouraging cooperation, on a contractual basis, between Swiss firms and the private firms and governmental bodies of other Contracting Parties.

With regard to financial cooperation, Switzerland interprets the provisions of Articles 20 and 21 as follows: the resources to be committed and the management system will have regard, in an equitable manner, to the needs and interests of the developing countries and to the possibilities and interests of the developed countries.

Upon ratification:

Declaration:

Switzerland wishes to reaffirm the importance it attaches to transfers of technology and to biotechnology in order to ensure the conservation and sustainable use of biological diversity. The compliance with intellectual property rights constitutes an essential element for the implementation of policies for technology transfer and co-investment.

For Switzerland, transfers of technology and access to biotechnology, as defined in the text of the Convention on Biological Diversity, will be carried out in accordance with Article 16 of the said Convention and in compliance with the principles and rules of protection of intellectual property, in particular multilateral and bilateral agreements signed or negotiated by the Contracting Parties to this Convention.

Switzerland will encourage the use of the financial mechanism established by the Convention to promote the voluntary transfer of intellectual property rights held by Swiss operators, in particular as regards the granting of licences, through normal commercial mechanisms and decisions, while ensuring adequate and effective protection of property rights.

United States of America

Declaration:

In signing the Final Act, the United States recognizes that this negotiation has drawn to a close.

The United States strongly supports the conservation of biodiversity and, as is known, was an original proponent of a convention on this important subject. We continue to view international cooperation in this area as extremely desirable.

It is deeply regrettable to us that -- whether because of the haste with which we have completed our work or the result of substantive disagreement -- a number of issues of serious concern in the United States have not been adequately addressed in the course of this negotiation. As a result, in our view, the text is seriously flawed in a number of important respects.

As a matter of substance, we find particularly unsatisfactory the text's treatment of intellectual property rights; finances, including, importantly, the role of the Global Environment Facility (GEF); technology transfer and biotechnology.

In addition, we are disappointed with the development of issues related to environmental impact assessments, the legal relationship between this Convention and other international agreements, and the scope of obligations with respect to the marine environment.

Procedurally, we believe that the hasty and disjointed approach to the preparation of this Convention has deprived delegations of the ability to consider the text as a whole before adoption. Further, it has not resulted in a text that reflects well on the international treaty-making process in the environmental field.