



CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/WG-ABS/1/4
10 August 2001

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

First meeting

Bonn, 22-26 October 2001

Item 5 of the provisional agenda*

REPORT ON THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN THE IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING ARRANGEMENTS

Note by the Executive Secretary

I. INTRODUCTION

1. In paragraph 15 of its decision V/26 A, on access and benefit-sharing arrangements, the Conference of the Parties to the Convention on Biological Diversity:

“*Noting* that the Panel of Experts on Access and Benefit-sharing was not able to come to any conclusions about the role of intellectual property rights in the implementation of access and benefit-sharing arrangements, and that the Panel developed a list of specific issues that require further study (UNEP/CBD/COP/5/8, paras. 127-138)

(a) *Invites* Parties and relevant organizations to submit to the Executive Secretary information on these issues by 31 December 2000;

(b) *Requests* the Executive Secretary, on the basis of these submissions and other relevant material, to make available for the second meeting of the Panel, or the first meeting of the Ad Hoc Open-ended Working Group, a report on these specific issues;

(c) *Recalls* recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention, and requests the Executive Secretary to prepare his report in consultation with, *inter alia*, the Secretariat of the World Intellectual Property Organization;

(d) *Invites* relevant international organizations, including the World Intellectual Property Organization, to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for intellectual property rights, including patents;”

2. The present note was prepared by the Executive Secretary in response to that request. Section II reviews developments on issues for further consideration identified by the Panel of Experts on Access and Benefit-sharing at its first meeting:

* UNEP/CBD/WG-ABS/1/1.

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- (a) The role of intellectual property rights in prior informed consent,
- (b) Intellectual property and traditional knowledge related to genetic resources;
- (c) Intellectual property rights and access and benefit-sharing agreements; and
- (d) Scope, prior art and monitoring.

3. To avoid duplication and to provide a comprehensive overview, reference is made to relevant work carried out in the Working Group on Article 8(j) and in the World Intellectual Property Organization (WIPO). In addition, a synthesis of contributions submitted by Parties through their thematic reports ^{1/} or in response to notifications sent to national focal points is included under each of the points identified for further study.

4. Section III reviews recent developments in other international forums, which are also considering intellectual property rights, genetic resources and traditional knowledge, including WIPO, the World Trade Organization (WTO) and the Food and Agriculture Organization of the United Nations (FAO).

II. THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN ACCESS AND BENEFIT-SHARING ARRANGEMENTS

5. In order to facilitate reference to the issues for further consideration identified by the Panel of Experts during its first meeting and reflected in paragraphs 127 to 138 of its report, the relevant portions of the report are reproduced, in italics, under each heading.

A. The role of intellectual property rights in prior informed consent

6. It has been argued that intellectual property rights could encourage access and benefit-sharing, if applications for such rights required: (i) identification of the source of genetic material used in the development of subject matter which is to be protected by intellectual property rights; and (ii) proof of the prior informed consent of the competent national authority of the provider country, if the genetic resource was acquired after the entry into force of the Convention on Biological Diversity and does not fall within the scope of a possible multilateral system for plant genetic resources for food and agriculture.

7. In its first meeting, the Panel of Experts suggested that:

“Intellectual property rights application procedures could require that the applicant submit evidence of prior informed consent. Such a system may create incentives for users to effectively comply with obligations to seek prior informed consent.

“The effectiveness of such measures should be further evaluated. Other alternatives or complementary instruments such as user-country legislation or multilateral information systems, must also be explored regarding their effectiveness to promote the objectives of the Convention. In doing so, other international legal instruments need to be taken into consideration. The Conference of the Parties needs to explore this matter in greater depth.” ^{2/}

8. It is worth recalling that Article 15, paragraph 5, of the Convention on Biological Diversity provides that:

“Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party”.

9. Moreover, Article 8(j) of the Convention, on the respect, preservation and maintenance of the traditional knowledge of local and indigenous communities also recognizes that the wider application of

^{1/} Thematic reports on access and benefit-sharing received as of 13 June 2001 have been taken into account in the drafting of this note.

^{2/} Report of the first meeting of the Panel of Experts on Access and Benefit-sharing (UNEP/CBD/COP/5/8), paras. 127-129

traditional knowledge should only take place with the approval and involvement of the holders of such knowledge, innovations and practices.

10. At its first meeting, the Panel suggested that, as an incentive for users to effectively comply with obligations to seek prior informed consent, application procedures for intellectual property rights could require that the applicant submit evidence of prior informed consent. This would help to ensure that bioprospectors who use genetic resources and/or related traditional knowledge would obtain the prior informed consent of the competent national authorities and holders of this traditional knowledge before they could obtain access to genetic resources and related knowledge.

11. The Panel recognized that, in countries where legislation on access to genetic resources and human rights pertaining to indigenous peoples were implemented, the obligations of Article 8(j) of the Convention had been reinforced and extended. It also felt that requirements to consult indigenous and local communities prior to access, and obligations to seek prior informed consent for collection activities, demonstrate the need for identification and recognition of rights over traditional knowledge, innovations and practices.^{3/}

12. Access legislation in a number of countries (Philippines, Costa-Rica, the Andean Community) has recognized the rights of indigenous and local communities to decide on access to resources on their territories or lands, as well as to their knowledge, innovations and practices. Both Andean decision No. 391 of 16 August 1996 establishing the Common Regime on Access to Genetic Resource and the Biodiversity Law of Costa Rica enacted on 27 May 1998^{4/} provide that information concerning the origin of the genetic resource in question and, to some extent, proof of the prior informed consent of government authorities and holders of traditional knowledge are to be provided in patent applications.^{5/} In addition, decision 486 of the Andean Community relating to the patenting of traditional knowledge of indigenous and local communities establishes legal recourse that provide for "*hulidad absoluta*" of a patent, in cases where prior informed consent of indigenous and local communities was not granted regarding the products or processes to be patented.

13. In other countries currently in the process of developing national legislation on the issue of intellectual property rights, genetic resources and traditional knowledge, such as Panama,^{6/} India ^{7/} and New-Zealand, ^{8/} the prior informed consent of competent national authorities and affected indigenous authorities is also being considered as a condition to obtaining intellectual property rights.

14. A survey on the protection of biotechnological inventions carried out by the World Intellectual Property Organization (WIPO) in 2000 included two questions addressing the disclosure of genetic resources in patent applications. Out of the 57 responses, a majority responded that their (patent)

^{3/} Report of the first meeting of the Panel of Experts on Access and Benefit-sharing, UNEP/CBD/COP/5/8, paragraph 121.

^{4/} Article 81 of the Biodiversity Law of Costa Rica.

^{5/} Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPs Agreement: The Problem and the Solution*, Washington University Journal of Law and Policy, 2 (371), 371-401, 2000.

^{6/} In Panama, according to a draft legislation No. 36, prior informed consent of the indigenous authorities and of the "Independent Institute of Traditional Indigenous Medicine established to guarantee the rights to benefits derived from the commercial use of traditional knowledge will be required. Intellectual property rights granted as a result of indigenous knowledge or derived from access to genetic resources require the prior informed consent of the indigenous authority and of the institute guaranteeing rights to benefits of commercial use.

^{7/} With respect to India's proposed biodiversity legislation, obtaining intellectual property rights is conditional to the prior approval of the National Biodiversity Authority (NBA).

^{8/} In New Zealand, work has been under way for some years to examine ways to modify intellectual property rights systems. A number of provisions have been included in draft legislation designed to address Maori concerns regarding the inappropriate use of Maori imagery and text as trade marks. These include a mechanism for prior informed consent, where applicants with proposed trade marks containing Maori imagery, the use or registration of which might be considered to cause offence, will be referred to the appropriate Maori authority for confirmation.

legislation did not include any special provisions to ensure the recording of contributions to inventions (such as...the source of genetic resources that originate or are employed in biotechnological inventions, the grant or prior informed consent to have access to those resources, etc.) or that they could not provide a copy of the relevant legal provisions. Of the 57 countries that responded, three countries responded positively when asked whether their country was planning to introduce legislation to ensure the recording of such contributions and whether they could provide a copy of the relevant draft provisions and the timeframe for their enactment by the relevant authorities. ^{9/}

15. At its second meeting, the Panel of Experts suggested that:

“[I]ntroducing requirements into existing intellectual property rights procedures, such as in the filing of patent applications (e.g. specification of the country of origin or source of the genetic materials and resources), may be a possible way to track compliance with prior informed consent and mutually agreed terms on the basis of which access was granted. In this regard, seeking intellectual property rights may be one indicator of commercial intent”. ^{10/}

16. Under certain circumstances, however, obtaining the prior informed consent of competent national authorities and holders of traditional knowledge may prove difficult. Such may be the case if the material is obtained from a research institution lacking knowledge of the origin of the material, or if it is a plant genetic resource for food and agriculture covered by a possible multilateral system for access and benefit-sharing on certain plant genetic resources for food and agriculture. In the latter situation, if a requirement for disclosure of the origin of genetic resources in patent applications were to be introduced, it may be assumed that the “origin” that would be listed in the case of those plant genetic resources for food and agriculture which are listed in annex 1 to the revised International Undertaking would be the “multilateral system”. Another outstanding issue is the situation where genetic resources were acquired before the Convention on Biological Diversity entered into force.

B. Intellectual property and traditional knowledge related to genetic resources

17. It has been argued that traditional intellectual property rights regimes are not appropriate for the protection of traditional knowledge. However, it has also been suggested that such regimes could be adapted to accommodate traditional knowledge. In addition, *sui generis* systems for the protection of traditional knowledge could be developed. These issues and other related matters, such as the customary use of genetic resources and traditional knowledge are addressed in this section.

18. It should be noted, as recognized by the Panel of Experts on ABS, in paragraph 78 of the report of its second meeting, that “the protection of traditional knowledge and access to genetic resources and benefit-sharing are related, and...that the issue of traditional knowledge is being addressed by the Ad Hoc Working Group on Article 8(j)”. A number of cross-references are therefore included in this section to the work of the Working Group on Article 8(j) and Related Provisions.

1. Definition of relevant terms

19. In paragraph 130 (a) of the report of its first meeting, the Panel of Experts: “...considers that, in relation to the protection of traditional knowledge, the Conference of the Parties should consider how to facilitate progress in relation to the following issues:

“(a) *How to define relevant terms including subject matter of traditional knowledge and scope of existing rights;*

“...”

^{9/} The results of the survey are included in document WIPO/GRTKF/IC/1/6 prepared for the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

^{10/} Par. 77(a) of the report of the second meeting of the Panel of Experts on Access and Benefit-sharing (UNEP/CBD/WG-ABS/1/2).

20. The elaboration of key terms of Article 8(j) was considered in a note by the Executive Secretary prepared for the Workshop on Traditional Knowledge and Biological Diversity, held in Spain, in November 1997. ^{11/}

21. In this note, “traditional knowledge” is defined as:

“A term used to describe a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use.

“In the context of knowledge, innovation is a feature of indigenous and local communities whereby tradition acts as a filter through which innovation occurs. In this context, it is traditional methods of research and application and not always particular pieces of knowledge that persist. Practices should therefore be seen as the manifestations of knowledge and innovation.”

22. Task 12 of the work programme on the implementation of Article 8(j), annexed to decision V/16 of the Conference of the Parties, provides that the Working Group on Article 8(j) is to develop guidelines that will assist Parties and Governments in the development of definitions of relevant key terms and concepts in Article 8(j) and related provisions that recognize, safeguard and fully guarantee the rights of indigenous and local communities over their traditional knowledge, innovations and practices, within the context of the Convention. This element of the work programme is to be addressed after the sixth meeting of the Conference of the Parties.

23. In the overview document prepared by WIPO (WIPO/GRTKF/IC/1/3) for the first meeting of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the need for a more rigorous use of terminology is recognised and Annex 3 sets out the prevalent use of relevant terms in international discussions regarding traditional knowledge. It also contains a section on “terminological and conceptual issues” in the main body of the document. The task of clarifying terminological issues and the scope of subject matter referred to by the term “traditional knowledge” has been taken up by the Committee. ^{12/}

24. A number of Parties have recognised that agreed definitions are essential before entering into further discussion. ^{13/} In their thematic reports on access and benefit-sharing, several countries (i.e., the Central African Republic, Panama, India, Namibia) have submitted their national definitions of the terms found in article 8(j).

2. *The use of intellectual property rights to protect traditional knowledge*

25. The Panel of Experts, in paragraph 130 (b) of the report of its first meeting, felt that further consideration should be given to: “*Determining whether existing intellectual property rights regimes can be used to protect traditional knowledge*”.

26. Legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity were considered at the first meeting of the Working Group on Article 8(j) and Related Provisions. ^{14/}

27. A number of Governments (India, Turkey, Namibia, Ecuador) have expressed the view that intellectual property rights systems and more particularly patent systems are inappropriate for the protection of traditional knowledge, innovation and practices. Such knowledge associated with biological

^{11/} UNEP/CBD/TKBD/1/2, pp. 17-23.

^{12/} See document WIPO/GRTKF/IC/1/3, paragraph 155.

^{13/} Thematic report on access and benefit-sharing by Austria, Switzerland, Norway.

^{14/} UNEP/CBD/WG8J/1/2, Part II, par. 5-12, addresses legal forms of protection for traditional biodiversity-related knowledge.

resources may not meet all the conditions required for the granting of certain intellectual property rights under existing regimes, such as the conditions of novelty, inventive step and industrial applicability, which are required for the granting of patents. The following arguments are put forward as evidence of the inadequacy of intellectual property rights for the protection of traditional knowledge:

- (a) IPRs are based on the protection of individual property rights whereas traditional knowledge is generally created, improved and transmitted collectively;
- (b) Traditional knowledge is generally developed over a period of time and either codified in texts or retained in oral traditions over generations. The conditions of novelty and innovative steps necessary for the granting of patents may therefore be questionable;
- (c) Knowledge is often held by different independent communities;
- (d) Patents grant protection for a limited period of time whereas traditional knowledge is passed on from generation to generation.

28. However, genetic resources and traditional knowledge may contribute to the obtaining of patents by the biotechnology industry, which has based certain of its inventions on these resources and/or their related knowledge. It has been suggested^{15/} that possible means may exist to ensure that intellectual property rights, in particular patents, provide for an equitable sharing of benefits arising from genetic resources, including the protection of traditional knowledge. In this regard, existing intellectual property rights regimes could be flexible enough or adapted to accommodate such knowledge. Suggested approaches include:

- (a) The introduction of a requirement in intellectual property rights applications that relevant provisions of the Convention on Biological Diversity have been followed with respect to prior informed consent and mutually agreed terms;
- (b) A requirement in intellectual property rights applications to disclose the origin of genetic resources and/or the traditional knowledge used for products/processes that are the subject of intellectual property rights.

29. It is argued that incentives such as the introduction of lower intellectual property rights fees could be considered or sanctions by increasing such fees if the origin of the resource is not disclosed in the intellectual property rights application. By providing for disclosure of the origin of genetic material including proof of prior informed consent between the country of origin and receiving country (or private company), intellectual property rights would contribute to the implementation of relevant obligations of the Convention.

30. In decision V/26 A, paragraph 15 (d), the Conference of the Parties invited: “relevant organizations, including the World Intellectual Property Organization, to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for intellectual property rights, including patents”. The issue of providing information on the origin of genetic resources in relevant patent applications has been discussed extensively at WIPO since 1999 and is the subject of ongoing discussions, as set out in paragraphs 92-99 below.

31. As noted in a document prepared by the Secretariat for the third meeting of the Conference of the Parties,^{16/} a number of observers have argued that Parties should encourage or require such disclosure in their patent procedures. The disclosure could also include the certification of prior consent for the use by the source country or community.

^{15/} Input by Norway.

^{16/} “The Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights (TRIPs): Relationships and Synergies” (UNEP/CBD/COP/3/23).

32. The document also refers to a study that reviewed over five hundred patent applications in which the invention involved the use of biological materials, such as materials derived from plants or animals. In the section of patent applications entitled “Background of the Invention”, the patent applicant normally sets out any existing problems or difficulties which the invention overcomes. Previous solutions to the problem are described, preferably in a manner which clearly sets out the differences between the present and previous solutions. According to this review, in many cases this description contains a description of the origin of genetic resources and/or traditional knowledge related to the claimed invention. Most of the patent applications reviewed were in the pharmaceutical field, while others were in fields such as cosmetics and pesticides. The applications originated from a number of jurisdictions, including France, Germany, the United Kingdom, Spain, the United States of America and the European Patent Office. Of the applications involving plants, the country of origin was invariably mentioned unless the plant was widely distributed or well known (such as the lemon or rosemary). A number of applications also mentioned indigenous or traditional uses as prior art. ^{17/}

33. In addition, as noted in UNEP/CBD/WG8J/1/2, paragraph 8, disclosure of the use of traditional biodiversity-related knowledge may provide grounds for not granting a patent. Since the patenting process normally requires the description of the invention and the background knowledge it is based on, patent examiners could reject a patent application if it were found that previous knowledge in this area showed that the invention was not novel. This point was also noted by the Panel of Experts. ^{18/}

34. It is interesting to note that the Preamble of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, adopted in July 1998, provides that if an invention is based on biological material of plant or animal origin, or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known. However, to provide such information is not, presently, an obligation under Community law. Hence, the failure to provide such information does not have, as such, any legal consequence for the processing of patent applications, or on the validity of rights arising from granted patents.

35. Task 11 of the work programme on Article 8(j) addresses this issue. It provides that: *“The Working Group is to assess existing subnational, as appropriate, national and international instruments, particularly intellectual property instruments, that may have implications on the protection of the knowledge, innovations and practices of indigenous and local communities with a view to identifying synergies between these instruments and the objectives of article 8(j).”*

36. At its second meeting, the Panel of Experts referred to the need for further work on the protection of traditional knowledge by means of intellectual property rights, *sui generis* systems and other approaches, taking into account work carried out by the Working Group on Article 8(j) and WIPO. ^{19/}

3. *Sui generis protection of traditional knowledge rights*

37. In paragraph 130 (c) of the report of its first meeting, the Panel of Experts suggested the consideration of *“options for the development of sui generis protection of traditional knowledge rights”*.

38. In decision V/26 B, paragraph 1, the Conference of the Parties reaffirmed “the importance of systems such as *sui generis* and others for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention, taking into account the ongoing work on Article 8(j) and related provisions”.

^{17/} Information document UNEP/CBD/COP/4/Inf.30 submitted by Spain at the fourth meeting of the Conference of the Parties contains examples of patents using biological source material and mention of the country of origin in patents using biological source material.

^{18/} UNEP/CBD/WG-ABS/1/2, para. 77(c).

^{19/} Report of the second meeting of the Panel of Experts on Access and Benefit-sharing, para. 77(b)

39. In addition, in decision V/16, paragraph 14, on Article 8 (j) and related provisions, the Conference of the Parties recognized ‘the potential importance of *sui generis* and other appropriate systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits from its use to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions,.....’

40. A number of Governments are of the view that there is a need to develop *sui generis* systems for the protection of traditional knowledge and that therefore options for their development are to be considered. Possible elements of *sui generis* legislation, annexed to the report of the first meeting of the Panel of Experts on Access and Benefit-sharing, 20/ include:

- (a) Recognition of ancestral community rights over knowledge, innovations and practices related to genetic resources.
- (b) Recognition that such rights exist even where information may be in the “public domain”.
- (c) Establishment of the principle that such rights may be collective in nature.
- (d) Distinction between the rights over genetic resources (where vested in the State) and rights over knowledge associated with such resources (vested in local and indigenous custodians).
- (e) Presumption that use of genetic resources implies use of associated knowledge, innovations and practices.
- (f) Establishment of administrative and judicial review processes to resolve disputes regarding the granting of access on the basis of potential environmental, economic, cultural or social impacts.
- (g) Creation of benefit-sharing mechanisms/obligations to ensure equitable distribution of benefits among custodians, whether parties to access agreements or not.
- (h) Establishment of local and centralized registers of traditional knowledge, innovations and practices of local and indigenous communities.
- (i) Creation of programmes and processes for the strengthening of traditional knowledge systems.
- (j) They should be developed in close collaboration with indigenous and local communities through a broad-based consultative process that reflects a country’s cultural diversity.

41. In accordance with decision 391 of the Andean Community, Bolivia, Ecuador, and Colombia have initiated participatory processes with a view to the development of indigenous proposals on the recognition and protection of their knowledge, innovations and practices. In Peru, draft legislation on the protection of indigenous knowledge has already been the subject of wide discussion, and processes are under way to bring it to consideration by stakeholders at the national level.

42. A number of models for *sui generis* protection of traditional biodiversity-related knowledge have been developed and are cited in document UNEP/CBD/WG8J/1/2 21/ prepared for the first meeting of the Working Group on Article 8(j). The first *sui generis* model for the protection of traditional knowledge-related subject matter was developed jointly by the United Nations Educational, Cultural and Scientific Organization (UNESCO) and WIPO in 1982 and is embodied in the UNESCO-WIPO Model Provisions for National Laws on the Protection of Folklore from Illicit Exploitation and Other Prejudicial Actions.

43. Based on these models, the same document suggests that *sui generis* systems should have among their basic objectives:

- (a) The encouragement of the sustainable use of biodiversity;

20/ UNEP/CBD/COP/5/8, annex VI.

21/ UNEP/CBD/WG8J/1/2, paras. 14 (a) to (f).

- (b) The promotion of social justice and equity;
- (c) The effective protection of traditional biodiversity-related knowledge and resources against unauthorized collection, use, documentation and exploitation – in part this would require a provision on prior informed consent; and
- (d) The recognition and reinforcement of customary laws and practices, and traditional resource-management systems that are effective in conserving biological diversity;

44. In this regard, the development of guidelines to assist Parties in the development of legislation and other mechanisms, such as *sui generis* systems, is under consideration under task 12 of the work programme on Article 8(j), to be carried out after the sixth meeting of the Conference of the Parties.

45. Developments reported by Parties to the Convention on Biological Diversity in their thematic reports which are relevant to the development of *sui generis* systems include the following:

- While certain countries are still considering options for the development of *sui generis* systems, such as the documentation of traditional knowledge, registration and innovative patent systems, or the development of legal frameworks outside the existing patent system, others have already established national systems for the protection of traditional knowledge. In India, a National Innovation Foundation (NIF) has been established to build a national register of innovations.
- In Namibia, a draft policy on the regulation of access to genetic resources and the protection of associated traditional knowledge and draft legislation on Access to genetic resources have been developed. It constitutes a *sui generis* system that aims at ensuring compatibility between the WTO/TRIPs Agreement and the Convention on Biological Diversity at the national level.
- It has been suggested ^{22/} that the development of national *sui generis* systems may not provide adequate protection for traditional knowledge in situations/cases where the same knowledge is found in more than one country (regional traditional knowledge). The *sui generis* system could then be circumvented by using the same traditional knowledge from another country with no *sui generis* system of protection. A multilateral framework may therefore be necessary to ensure the protection of traditional knowledge and to ensure protection of all stakeholders involved.

4. Other related matters

The relationship between customary laws and the formal intellectual property system

46. In paragraph 131 (a) of the report of its first meeting, the Panel of Experts recognized: “A need to study the relationship between customary laws governing custodianship, use and transmission of traditional knowledge, on the one hand, and the formal intellectual property system, on the other”.

47. This issue is also being addressed by the Working Group on Article 8(j). ^{23/} The issue of the recognition of customary law as a mechanism for the protection of traditional knowledge, innovation and

^{22/} Submission by Switzerland. The issue of regional traditional knowledge is also addressed by WIPO in document WIPO/GRTK/IC/1/3.

^{23/} UNEP/CBD/TKBD/1/2, paragraphs 58-60.

practices is considered an important rights issue dealt with in many indigenous and local community declarations, statements and charters generated as standard-setting documents.^{24/}

48. Therefore, in addition to attempting to use or modify existing intellectual property rights regimes as a means of regulating access to and control over knowledge, Parties to the Convention on Biological Diversity might consider that traditional knowledge should be acquired and used in conformity with the customary laws of the indigenous and local communities concerned. However, there would be a need to accommodate customary-law systems, or at least those elements of them relevant to the Convention on Biological Diversity, within national statutory and common-law legal systems, in those countries where this is not already the case.^{25/}

49. The recognition of indigenous and local community customary laws in national legislation may be an important facet of the implementation of both Articles 8(j) and 10(c) of the Convention on Biological Diversity.

50. WIPO has identified a need to further study the relationship between customary protection of traditional knowledge and the intellectual property system and has included this issue as part of the work programme of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, for 2000-2001.^{26/}

51. One example of an attempt to accommodate indigenous and local community customary laws is the Philippines Access Regime (Philippines Executive Order No. 247 (1995)) which provides that prospecting for genetic resources shall be allowed “within the ancestral lands and domains of indigenous cultural communities only with the prior informed consent of such communities, obtained in accordance with the customary laws of the community concerned.”

52. Thematic reports on access and benefit-sharing have provided interesting illustrations of country experiences, such as the following:

(a) In New-Zealand, the customary Maori system contrasts sharply with the formal IP system. The Maori have raised concern over the inadequate and inappropriate protection afforded to their traditional knowledge under the current intellectual property regime. These concerns are the subject of a claim to the Waigani Tribunal – Wai 262. A review of intellectual property legislation has been undertaken by the Government of New-Zealand with a view to providing better protection for the traditional knowledge of the Maori;^{27/}

(b) In Namibia, customary rules and traditional lifestyles are being eroded by the forces of modernization and commercialization. There is a need to integrate customary law into modern policy/legislation. The Namibian intellectual property rights and formal legal system do not recognise customary systems. Colonial and apartheid policies severely undermined customary systems. Also in Africa, transmission of traditional knowledge from one generation to another has largely proceeded in an oral fashion, not through documentation of knowledge. Therefore it is difficult for the conventional intellectual property rights systems to capture the essence of traditional knowledge. A system of community register is being developed.^{28/} The scope of the Namibian draft access legislation excludes

^{24/} The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, the Julayinbul Statement, and the “Heart of the Peoples Declaration”. The draft American Declaration of the Rights of the Indigenous Peoples, approved by the Inter-American Commission on Human Rights at its 95th regular session on 26 February 1997, provides, in its Article XVI, for the recognition of indigenous law. Likewise, Article 8 of the International Labour Organization (ILO) Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries also provides impetus for the recognition of customary-law systems. For further reference, see UNEP/CBD/WG8J/1/2, paras 30-31.

^{25/} UNEP/CBD/WG8J/1/2 on the accommodation of indigenous and local community customary-law systems within national legal systems, paragraphs 30 to 34.

^{26/} WIPO/GRTKF/IC/1/3, par.68, p.22.

^{27/} Thematic report provided by New-Zealand.

^{28/} Thematic report provided by Namibia.

customary use in order not to put controls on customary practices and traditional knowledge but rather to control access to such practices and knowledge for their better protection.

53. In paragraph 131 (c) of its report, the Panel of Experts pointed out the need *‘to ensure that granting intellectual property rights does not preclude continued customary use of genetic resources and related knowledge’*.

54. It has been suggested that it is the responsibility of the State to ensure the continued customary use of genetic resources and traditional knowledge. In the case of New Zealand, nothing in the national system would prevent continued customary use of a particular resource should the resource feature in a new patent application. This issue is being further considered in the current revision of the Patents Act.

55. Article 7.5 of the draft guidelines on access and benefit-sharing for the utilization of genetic resources, submitted by Switzerland, provides that access to genetic resources and related activities should not impede the continuation of traditional use of genetic resources.

Pilot projects for testing purposes

56. Paragraph 131 (b) of the report of its first meeting, the Panel of Experts expressed: *“A need for pilot projects by means of which holders of traditional knowledge, including indigenous peoples, may test means of protection of traditional knowledge based on existing intellectual property rights, sui generis possibilities, and customary laws”*.

57. A number of case-studies submitted to the Secretariat on the implementation of Article 8(j) and related provisions, are available in documents UNEP/CBD/TKBD/1/Inf.1 and UNEP/CBD/WG8J/1/INF/2.

58. The case-studies, provided through submissions of Governments and local and indigenous communities cover the following issues:

(a) Interactions between traditional and other forms of knowledge relating to the conservation and sustainable use of biological diversity;

(b) The influence of international instruments, intellectual property rights, current laws and policies on knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;

(c) The extent to which traditional knowledge of indigenous and local communities has been incorporated into development and resource management decision-making processes;

(d) Documented examples and related information on ethical guidance for the conduct of research in indigenous and local communities about the knowledge they hold; and

(e) Matters of prior informed consent, fair and equitable sharing of benefits and *in situ* conservation in lands and territories used by indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

59. In decision V/16, paragraph 13, the Conference of the Parties emphasized “once again the need for case-studies developed in conjunction with indigenous and local communities requested in paragraphs 10(b) and 15 of its decision IV/9, to enable a meaningful assessment of the effectiveness of existing legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities”. As suggested by the Conference of the Parties, the next step is to determine how effective these instruments have been. Pilot projects could be carried out for this purpose. There is a need to flesh out more specifically what should be included in these pilot projects and invite Parties to demonstrate their interest in carrying them out.

C. Intellectual property rights and access and benefit-sharing agreements

60. It has been argued that intellectual property rights may be a means to ensure benefit-sharing. This could be achieved through different mechanisms such as: joint ownership, sharing of royalties arising from the exploitation of patents and others.

61. In paragraphs 132 to 135 of the report of its first meeting, the Panel of Experts:

“[A]cknowledges that intellectual property rights may have an influence on the implementation of access and benefit-sharing agreements. The Panel considers that when entering into such agreements, it must be on mutually agreed terms. It also has to be taken into account that contractual arrangements must be consistent with national and international law.

In particular, the following issues could be considered as guiding parameters for contractual agreements:

(a) Regulating the use of resources in order to take into account ethical concerns;

(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;

(c) Provision for the exploitation and use of intellectual property rights include joint research, obligation to work any right on inventions obtained or provide licenses;

(d) Taking into account the possibility of joint ownership of intellectual property rights.

Traditional knowledge may be protected as a trade secret or as a form of know-how as appropriate and may be subject to licensing.

Potential parties to an access and benefit-sharing agreement may consider the usefulness of licenses to secure continued control by providers over genetic resources.”

62. A number of thematic reports on access and benefit-sharing submitted by Parties illustrate how these guiding parameters are being implemented nationally:

Ethical concerns

63. With respect to ethical concerns, New Zealand has reported that traditional Maori knowledge about biodiversity is respected and informs biodiversity management. Two methods have been used to address ethical concerns in New Zealand. The Government has asserted ownership of the resources in order to allow their management to be undertaken in a way that reflects the public views and/or that allows the Government to protect the particular ethical concerns of Maori. One illustration of this is the Government ownership of marine mammals and their management through legislation requiring their full protection. In addition, Government legislation ensures that private property interests are not used in ways that are contrary to widely accepted ethical standards, (e.g. legislation on animal welfare issues).

64. It has been suggested that a participatory approach and consultation involving all stakeholders may assist in addressing ethical concerns. ^{29/}

65. In the survey carried out by WIPO in 2000 on biotechnological inventions and referred to in paragraph 14 above, countries were asked whether there was any basis in their law that precluded the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed (for example, ethical or moral concerns). Twenty-eight countries out of the 57 who responded provided a positive response.

Customary use

66. Illustration has also been provided of measures for the continued customary use of genetic resources. The Mataranga Maori project in New Zealand is an initiative that encourages the continued customary use of genetic resources. It is part of the national biodiversity strategy and provides for Iwi

^{29/} Submission by Santa Lucia.

and Hapu participation in managing biodiversity in ways that are consistent with customary knowledge remaining the property of the Iwi and Hapu.

Exploitation and use of intellectual property rights

67. With respect to the exploitation and use of intellectual property rights, including joint research, obligation to work any right on inventions obtained or to provide licenses, various national approaches have been adopted:

68. As suggested by Switzerland, measures have to be taken to encourage joint research, such as the availability of adequate protection of the results of the joint research by intellectual property rights in the country where this joint research is taking place.

69. Licences may be considered in order to secure continued use by providers of genetic resources. As suggested, holders of intellectual property rights can be expected to have an interest in licensing their protected goods, as the earned royalties will create a return on their investment. Thus, licenses will generally be made available on a voluntary basis. Some forms of intellectual property rights can, under certain circumstances, be subjected to compulsory licenses.^{30/}

Joint ownership of intellectual property rights

70. Finally, contributions received also addressed the possibility of joint ownership of intellectual property rights:

71. As Switzerland mentioned in its thematic report, existing intellectual property rights can be held jointly by several owners. If, for example, several persons are jointly responsible for an invention, they can be granted joint ownership of the patent protecting this invention. Existing intellectual property rights therefore already adequately take into account the possibility of joint ownership.

72. India's proposed biodiversity legislation provides that while granting access to biological resources and associated traditional knowledge, the National Biodiversity Authority (NBA) will impose terms and conditions to secure equitable sharing of benefits, including the granting of joint ownership of intellectual property rights to the NBA, or where benefits claimers are identified, to such benefit claimers.

73. In Namibia, it is possible for two or more partners to create a legal entity and to jointly file patent applications on products or processes that are novel, involve an inventive step and are industrially applicable. A more common option would be for one of the partners to apply for the patent and to pay royalties to the other partners, on the basis of a contractual agreement. However, little experience has been acquired in Namibia regarding the joint ownership of intellectual property rights.

74. In addition to the guiding parameters identified by the Panel of Experts during its first meeting, the note by the Executive Secretary prepared for the Working Group on Article 8(j),^{31/} refers to a series of principles/elements, which should guide contractual agreements in order to protect indigenous and local community collective traditional biodiversity-related knowledge. They are the following:

(a) The collective nature of the knowledge, both within and among generations of indigenous and local communities, should be recognized;

(b) Control of the use of knowledge should remain firmly in the hands of the indigenous and local communities of origin, even where such information is found within the "public domain";

(c) The exercise of rights by any community, or group of communities, should not infringe the rights of other communities to use, dispose of, or otherwise control the use of, their resources;

^{30/} Submission by Switzerland.

^{31/} UNEP/CBD/WG8J/1/2, para. 21-29, on contractual agreements as other forms of legal protection of traditional knowledge.

(d) The creation of monopolistic rights over knowledge should be avoided, and the possibility of acquiring monopolistic rights over knowledge or the associated biological resources prevented;

(e) Equitable benefit-sharing within and among communities should be ensured;

(f) Assistance in the re-evaluation of traditional and biodiversity-related knowledge should be provided, its use promoted and adverse impacts on resources and cultures minimized; and

(g) A presumption should be established that use of resources over which there exists knowledge, in particular regarding medicinal plants, implies use of that knowledge.

75. At all stages, there must be broad consultations with the relevant indigenous and local communities, and any developmental, resource-use and conservation measures must be compatible with and build upon their cultures.

76. In its second meeting, the Panel of Experts recognised that contractual agreements were the main legal mechanism to facilitate access and benefit-sharing arrangements and that intellectual property rights clauses play a fundamental role in these agreements. In this context, it was suggested that WIPO could provide assistance in the development of up-to-date model intellectual property rights clauses.^{32/}

77. WIPO document WIPO/GRTKF/IC/1/3 provides illustrations of intellectual property rights provisions included in material transfer agreements, such as: utilization allowed for research purposes only; obligation not to file patent applications; provisions to share intellectual property rights; provisions to share royalties from intellectual property rights; progeny and derivative material; grant-back licenses; and obligation to defer publication.

78. At the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held from 30 April to 3 May 2001, WIPO Member States agreed to a work programme that includes considering the development of “best contractual practices”, guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources and different transfers within different sectors of genetic resources policy.

D. Scope, prior art and monitoring

79. In paragraphs 136 to 138 of the report of its first meeting, the Panel of Experts indicated that:

“Some Panel members expressed concerns regarding the obtaining of intellectual property rights where there is potential misapplication of the formal requirements for protection.

“Some Panel members expressed concerns that the scope of protection under intellectual property rights regimes may prejudice the legitimate interests of indigenous and local communities in respect of their knowledge, innovations and practices.

“Panel members agreed that the development of registers of traditional knowledge could promote the identification and accessibility of prior art.”

80. By decision V/16, the Conference of the Parties requested “Parties to support the development of registers of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity through participatory programmes and consultations with indigenous and local communities, taking into account strengthening legislation, customary practices and traditional systems of resource management, such as the protection of traditional knowledge against unauthorized used”.

81. Registries of knowledge are ordered collections or repositories of information and have typically taken the form of databases. They have been developed by indigenous people and local communities in

^{32/} UNEP/CBD/WG-ABS/1/2, para. 77 (d).

order to promote and protect traditional knowledge. They are generally compiled by communities or community groups for their benefit. They have been found useful for organizing knowledge in view of allowing protection and improved management of the community resources. ^{33/}

82. In its second meeting, the Panel of Experts acknowledged that traditional knowledge registers could provide protection which could be used to avoid the inappropriate granting of intellectual property rights. ^{34/}

83. In addition to protection against inappropriate granting of intellectual property rights, these registries may serve a number of other purposes, including: ^{35/}

(a) Raising awareness of communities with respect to the value of indigenous and local knowledge;

(b) Encouraging the long-term conservation and promotion of natural resources and their related knowledge;

(c) Providing information to interested parties who may be interested in obtaining information available in the registry, in exchange of a fee;

(d) Serving as part of a legislative system for the assertion of intellectual property rights over traditional knowledge (e.g. a national *sui generis* intellectual property right law to protect indigenous and local knowledge ^{36/}). The possibility of establishing a *sui generis* regime for the protection of traditional knowledge databases has already been mentioned in WIPO. ^{37/}

84. It has been argued that one of the major problems patent granting authorities have been facing, when determining the novelty and inventive step of an invention that might include traditional knowledge related to genetic resources, is the inaccessibility of prior art regarding this knowledge. This is due to the fact that traditional knowledge, which is generally transmitted orally, is often not documented in a written form.

85. The creation of an international database or a global registry has been suggested to address this difficulty. Such a database could assist patent authorities when considering patent applications that raise the issue of prior art regarding the use of traditional knowledge.

86. Some of the suggested characteristics of the database include the following: ^{38/}

(a) It should be established at the international level to facilitate its access by all patent and relevant judicial authorities;

^{33/} David R. Downes and Sarah A. Laird, *Community Registers of Biodiversity-Related Knowledge: The Role of Intellectual Property in Managing Access and Benefit*, 1999.

^{34/} Ibid, paragraph 77 (c).

^{35/} Volume Two, Seeding Solutions: Options for National Laws Governing Control over Genetic Resources and Biological Innovations (Final, edited pre-publication version, April 2001).

^{36/} Namibia has reported that a mechanism for a community register is included in Namibia's draft *sui generis* legislation (article 29 vi).

^{37/} Document WIPO/GRTKF/IC/1/5 submitted by the Group of Latin American and Caribbean States (GRULAC) at the first meeting of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, April 30-May 3 2001. Statement by Brazil to the "WIPO Meeting in Intellectual Property and Genetic Resources", held April 17-18 2000.

^{38/} Switzerland has proposed the establishment of an international database in the TRIPs Council meetings of October 1999 and April 2001. Such a proposal was reiterated in a communication from the Permanent Mission of Switzerland in Geneva and circulated at the meeting of the Council for Trade-Related Aspects of Intellectual Property Rights, as an unrestricted Council document IP/C/W/284, dated 15 June 2001

(b) In order to be as cost efficient as possible, the international database could take the form of a gateway to existing local, national and regional databases and assist in the development of an international network;

(c) The recording of traditional knowledge would be voluntary, would not constitute a prerequisite for the existence of any rights regarding traditional knowledge and should be organised in a standardized classification.

87. It has also been suggested that this international database should be established and administered by WIPO. In response to these suggestions, WIPO has created a Traditional Knowledge Task Force to study a draft Traditional Knowledge Resource Classification (TKRC) and its proper relationship to the International Patent Classification (IPC). The draft TKRC was developed by India and will be considered by the Committee of Experts of the Special Union for the IPC. Furthermore, a progress report on the status of traditional knowledge as prior art ^{39/} will be considered by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The progress report contains a detailed section on traditional knowledge databases and digital libraries ^{40/} and identifies as a possible activity to be undertaken by the Intergovernmental Committee a study on the “feasibility of electronic exchange of public domain traditional knowledge documentation data, including through the establishment of international online traditional knowledge databases and digital libraries”. ^{41/}

88. India reported a number of initiatives that have been undertaken to document knowledge, innovations and practices and develop mechanisms to ensure that their use is protected and the benefits of their exploitation returned to the local and/or indigenous communities, such as the National Innovation Foundation ^{42/}, the Peoples’ Biodiversity Registers ^{43/} and the Traditional Knowledge Digital Library (TKDL). ^{44/}

89. It has been suggested that the degree to which and the conditions under which traditional knowledge containing technological information could be regarded as Prior Art should be further explored. ^{45/} Concrete measures to achieve an improved recognition of traditional knowledge as prior art could include the following options: (i) compiling an inventory of existing traditional knowledge-related periodicals and newsletters with a view to their possible integration into the *Journal of Patent-Associated*

^{39/} Document WIPO/GRTKF/IC/2/6.

^{40/} Ibid., Section V.A.5, “Traditional knowledge databases and digital libraries (TKDL),” paragraphs 89-97.

^{41/} Ibid., paragraph 97.

^{42/} The National Innovation Foundation, launched in October 2000, was constituted by the Department of Science and Technology of the Government of India to respect, recognise and reward creativity and innovation at the grassroots level by enabling innovators to build linkages with science and technology experts, forging linkages with entrepreneurs and pursuing their intellectual property rights protection. The purpose is to build a national register of grassroots inventions and innovations, based on entries solicited about technological grassroots innovations attempted by individuals engaged in small and cottage industries, farming, craft, fishing and livestock rearing, herbal medicines and other uses. (Paper presented by R.H. Khwaja on Access to Genetic Resources and Benefit Sharing – India’s experiences at the second meeting of the Panel of Experts on ABS). For further information consult: www.nifindia.org.

^{43/} People’s Biodiversity Registers have been undertaken in a few States in India to document knowledge, innovations and practices regarding the use and management of biological diversity. They are meant to monitor a variety of biodiversity resources in the country and assist in the development of locally rooted, adaptive strategies for the conservation of these resources. (Paper presented by R.H. Khwaja on Access to Genetic Resources and Benefit Sharing – India’s experiences at the second meeting of the Panel of Experts on ABS)

^{44/} This database is to prevent patenting of the traditional uses of medicinal plants. It is to be sent to patent offices in other countries to enable them to search and examine any prevalent use/prior art, and thereby prevent biopiracy. The proposal was approved in January 2001 (Paper presented by R.H. Khwaja on Access to Genetic Resources and Benefit Sharing – India’s experiences at the second meeting of the Panel of Experts on Access and Benefit-sharing).

^{45/} Submission by Norway.

Literature;^{46/} (ii) taking into account the status of traditional knowledge as prior art in future amendments of existing guidelines for search and examination of patent applications; (iii) examining the applicability of existing intellectual property documentation standards to traditional knowledge-related subject matter; (iv) providing assistance to traditional knowledge documentation initiatives to manage the intellectual property implications during the documentation process. These options are being explored by WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore as practical measures to improve the availability, searchability and exchangeability of traditional knowledge documentation data as prior art.^{47/}

90. It is interesting to note that in certain countries the fact that traditional knowledge is not documented has contributed to the erosion of traditional knowledge systems (e.g. Namibia).

III. RELEVANT DEVELOPMENTS IN INTERNATIONAL FORUMS

91. As requested by the Conference of the Parties, the Executive Secretary transmitted decisions V/26 A-C on access to genetic resources to the secretariats of the World Trade Organization and the World Intellectual Property Organization and endeavoured to further cooperate and consult with these organizations. Recent developments in these organizations are reviewed below.

A. *World Intellectual Property Organization*

92. In paragraph 15 (d) of its decision V/26 A, the Conference of the Parties invited relevant international organizations, including the World Intellectual Property Organization, to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for intellectual property rights, including patents.

93. In the same decision, it also requested "relevant international organizations, for example, the World Intellectual Property Organization and the International Union for the Protection of New Varieties of Plants, in their work on intellectual property rights issues, to take due account of relevant provisions of the Convention on Biological Diversity, including the impact of intellectual property rights on the conservation and sustainable use of biological diversity, and in particular the value of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity".

94. Since 1998, WIPO has been addressing issues of relevance to the Convention on Biological Diversity in the context of its work programme on global intellectual property issues, which contains a sub-programme on biological diversity and biotechnology.

95. In 1999, the disclosure of the origin of genetic resources in patent applications was discussed by in the WIPO Standing Committee on the Law of Patents (SCP). The SCP requested the International Bureau of WIPO to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The SCP further invited the International Bureau to take steps to convene a separate meeting early in 2000 to consider that issue.^{48/}

96. In response to the invitation in decision V/26 A, WIPO organized a meeting on intellectual property and genetic resources in April 2000. The Meeting addressed issues that generally are raised in

^{46/} The *Journal of Patent-Associated Literature* (JOPAL) was established in 1981 with the objective of developing a centralized database of classified bibliographic data to be used as a search aid by Intellectual Property Offices for prior art searching of technical and scientific non-patent literature. The JOPAL is based on the minimum documentation list of the Patent Cooperation Treaty and is published through an international cooperation among national and regional patent-granting authorities. Originally published in paper form, the database, which is updated monthly, is now provided as a searchable database accessible via the Internet from the WIPO Intellectual Property Digital Libraries (IPDL) website.

^{47/} See document WIPO/GRTKF/IC/2/6.

^{48/} See document SCP/3/11, para. 208.

the context of access to, and *in situ* preservation of, genetic resources in their direct or indirect relationship with intellectual property, including the disclosure of the country of origin in patent applications.

97. Before the Diplomatic Conference for the Adoption of the Patent Law Treaty in May 2000, the Director General of WIPO conducted informal consultations concerning formalities in relation to the question of genetic resources. As result of these consultations, a statement was agreed stating that:

“Member State discussions concerning genetic resources will continue at WIPO. A the Twenty-Sixth Session of the WIPO General Assembly in September 2000, the Member States decided to establish an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, to facilitate such discussions.”

98. The most recent development of direct relevance is the establishment of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The first session of this Committee was held from 30 April to 3 May 2001. It was attended by 102 States members of WIPO or the Paris Union for the Protection of Industrial Property, 18 intergovernmental organisations and secretariats, and 15 accredited non-governmental organisations. The Convention Secretariat participated in the session as an observer. WIPO member States expressed support for a work programme, the following components of which are relevant to access and benefit-sharing:

(a) *With respect to genetic resources.* Considering the development of “best contractual practices”, guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources and different transfers within different sectors of genetic resources policy;

(b) *With respect to traditional knowledge:*

- (i) Determining the scope of “traditional knowledge” in order to discuss the type of protection which can be awarded by intellectual property rights.
- (ii) Compiling, comparing and assessing information on the availability and scope of intellectual property protection for traditional knowledge
- (iii) Considering the revision of existing criteria and developing new criteria, which would allow the effective integration of traditional knowledge documentation into searchable prior art.
- (iv) Considering ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.

99. The second session of the Intergovernmental Committee will be held in Geneva from 10 to 14 December 2001.

B. World Trade Organization

100. In paragraph 2 of its decision V/26 B, the Conference of the Parties invited the World Trade Organization to acknowledge relevant provisions of the Convention on Biological Diversity and to take into account the fact that the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) and the Convention are interrelated and to further explore this relationship.

101. The compatibility of the TRIPs Agreement and the Convention on Biological Diversity is being considered in the context of discussions in the TRIPs Council regarding the revision of the TRIPs Agreement. While a number of countries are of the opinion that both agreements are compatible, others are of the view that the TRIPs Agreement, and more particularly Article 27.3(b), should be modified in order to meet the objectives of the Convention on Biological Diversity. For instance, it has been suggested that the TRIPs Agreement should require that patent applications include a certificate of the

source and origin of the genetic material and the traditional knowledge used, evidence of fair and equitable benefit-sharing and evidence of prior informed consent from government and local communities for the exploitation of the subject matter of the patent. It has also been suggested that the scope of the TRIPs Agreement, which covers micro-organisms, should be reviewed. Others have argued that the review of Article 27.3(b) should not lead to the lowering of patent protection of inventions.

102. In decision V/26 B, the Conference of the Parties renewed its request to the Executive Secretary to apply for observer status on the TRIPs Council and requested him to report back to the Conference of the Parties. On July 4, 2000, the Executive Secretary officially transmitted the text of decision V/26 B to the Director-General of the WTO and reiterated the request regarding the granting of observer status on the TRIPs Council to the Convention Secretariat. By letter dated 30 March 2001, the Secretary to the WTO Committee on Trade and Environment confirmed that the Executive Secretary's communication had been forwarded to the chairs of the WTO Committee on Trade and Environment (CTE) and of the TRIPs Council. However, the Convention Secretariat has still not been granted observer status on the TRIPs Council.

103. At the meeting of the Committee on Trade and Environment on 28-29 June 2001, the representative of the Convention Secretariat recalled the lack of positive response regarding the request for observer status on the TRIPs Council, although the relationship between the TRIPs Agreement and the Convention on Biological Diversity had been addressed at the last meeting of the TRIPs Council in June 2001. The Chair of the Committee noted the request and undertook to bring the issue, again, to the attention of the General Council and the Council for TRIPs.

C. Food and Agriculture Organization of the United Nations

104. The Commission on Genetic Resources for Food and Agriculture completed its work to revise the International Undertaking on Plant Genetic Resources for Food and Agriculture, in harmony with the Convention on Biological Diversity, at the sixth extraordinary session of the Commission, held in Rome from 25 to 30 June 2001. The process of revising the International Undertaking to harmonize it with the Convention on Biological Diversity had been under way since 1993. The text of the Undertaking, as prepared by the Commission, will be forwarded by the Director-General to the FAO Conference in November 2001 for finalization and adoption.

105. However, several issues are still pending. They include:

- (a) Whether or not limits to the Intellectual Property Rights that can be claimed on material received from the multilateral system extends to "parts and components",
- (b) The list of crops to be covered under the new regime established by the Undertaking; and
- (c) The relationship of the International Undertaking to existing international agreements (i.e., in particular, to the WTO Agreements).

106. A synthesis of the main components of the agreed text of the Undertaking and pending issues is included in annex II of the note by the Executive Secretary on elements for consideration in the development of draft guidelines on access and benefit-sharing (UNEP/CBD/WG-ABS/1/3).

107. A number of considerations were taken into account during the negotiations of the International Undertaking regarding intellectual property rights as potential restrictions to access to plant genetic resources for food and agriculture, which may be of relevance in the context of this report.

108. The Undertaking addresses three aspects of intellectual property rights:

- (a) Firstly, existing intellectual property rights should be respected, and this is included under the conditions of access in Article 13. Accordingly:
 - (i) Paragraph 2 (f) states that: "Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws"; and

(ii) Paragraph 2 (e) states that: “Access to plant genetic resources for food and agriculture under development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development”;

(b) Secondly, recipients are limited in the way they can take out intellectual property rights on material received from multilateral system. It is agreed that intellectual property rights cannot be claimed on the material in the form received from the multilateral systems, but there is disagreement as to whether or not such limits should extend to the “parts or components” of such material. Paragraph 2 (d) of Article 13 currently reads:

“[Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, [or their genetic parts or components,] [in the form] received from the Multilateral System]”

(c) Thirdly, intellectual property rights are referred to implicitly in Article 14 (d) (ii) on benefit-sharing in the case of commercialization. There is a mandatory provision for benefit-sharing but only in cases when use of the product for further research and breeding is limited, as in the case of patents and trade secrets. This aspect of intellectual property rights was discussed many times during the negotiations. The industry association ASSINSEL proposed that “since access to patented germplasm is restricted, a compensation should be collected from patent holders, through modalities to be defined”.^{49/} Thus patents and other intellectual property rights that restrict access became a “trigger” for mandatory benefit-sharing, although the reference to intellectual property rights in the final text is not explicit. Article 14 (d) (ii) states that “a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 20.3f, an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment”.

IV. CONCLUSION

109. In its consideration of these matters, the Working Group may wish to take into consideration the work being carried out in other forums, particularly developments in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

110. The Working Group may also wish to take into account the complementarity of, and the possible overlap with, elements of the work programme on Article 8(j) and related provisions contained in decision V/16, which have a direct bearing on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements.

^{49/} FIS/ASSINSEL, recommendations by the seed industry of developing countries on the revision of the International Undertaking, adopted in June 1998 (www.worldseed.org/pvde.htm).