UNEP

CBD

CONVENTION ON
BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/COP/3/23
5 October 1996

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSIT
Third meeting
Buenos Aires, Argentina
4 to 15 November 1996
Item 14 of the provisional agenda

THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS): RELATIONSHIPS AND SYNERGIES

1. INTRODUCTION

1. In response to a request by the second meeting of the Conference of the Parties (COP), this paper reviews synergies and relationships between the Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights (TRIPs), part of the Agreements Establishing the World Trad Organisation (WTO Agreements) that were concluded in the Uruguay Round of negotiations of the General Agreement on Tariffs and Trade (GATT). This paper also includes options for the third meeting of th COP to consider in preparing a possible input to the Committee on Trade and Environment (CTE) of th WTO.

2. The relationships b tween the TRIPs Agreement and the Convention on Biological Diversity ar multifaceted and complex, as are the links between intellectual property rights (IPR) and the Convention which are described in more detail in UNEP/CBD/COP/3/22, *Intellectual Property Rights*. The COP may

wish to identify specific topics within this issue area for further work. The CTE of the WTO is discussing the relationship between the TRIPs Agreement and the sustainable development and protection of th environment, which creates a specific opportunity for exploring the relationship between the TRIPs Agreement and the Convention objectives. The COP may wish to consider providing input into the CTE deliberations from the perspective of the Convention and its objectives. Given the complexity of the issues, the COP might wish to begin by suggesting procedures for consultation.

3. In preparing this study, the Secretariat sent an earlier draft to the WTO Secretariat for its comments. The WTO Secretariat suggested a number of changes of a factual or technical nature regarding WTO activities and agreements. In addition, in support of the Secretariat preparation on this agenda item, the WTO released two of the restricted background documents prepared for the WTO Committ on Trade and Environment. The first, *Environment and TRIPs,* is available for the COP as UNEP/CBD/COP/3/Inf. 9. The second, *Factors Affecting Transfer of Environmentally-Sound Technology: Note by the Secretariat,* is available as UNEP/CBD/COP/3/Inf. 10. The WTO also released the report of one of the CTE meetings at which IPR were discussed (WTO 1995a). The contents of this paper are, however, remains the responsibility of the Executive Secretary of the Convention on Biological Diversity.

2. BACKGROUND

4. In Decision II/12 on intellectual property rights, the COP asked the Executive Secretary to, *inter alia,*

> l]iaise with the Secretariat of the World Trade Organization to inform it of the goals and th ongoing work of the Convention on Biological Diversity and to invite the Secretariat of the World Trade Organization to assist in the preparation of a paper for the Conference of the Parties that identifies the synergies and relationship between the objectives of the Convention on Biological Diversity and the TRIPs Agreement".

5. The COP noted that t]his paper could be the basis for consideration by the third meeting of th Conference of the Parties in preparing a possible input for negotiations that are taking place in th Committee on Trade and Environment of the World Trade Organization".

6. A number of other items on the provisional agenda of the third meeting of the COP are relevant to the relationship between the Convention and the TRIPs Agreement. Most important is Item 14.1, a discussion of the impact of intellectual property rights systems (IPR systems) on the objectives of th Convention. A more detailed discussion of a number of IPR issues relevant to this paper may be found in the background paper for that agenda item, UNEP/CBD/COP/3/22. Also relevant is Item 11.1, regarding the implementation of Article 8(j) concerning the knowledge, innovations and practices of indigenous and local communities, for which the Secretariat has prepared a background paper, UNEP/CBD/COP/3/19.

7. While this review is limited to the relationship between the Convention on Biological Diversity and the TRIPs Agreement, there are many other important relationships between the Convention objectives

and trade policies and institutions. Trade and trade policy significantly affect biological diversity, both directly and indirectly. For example, foreign demand for timber, agricultural and wildlife products may intensify pressures for over-exploitation and the conversion of habitat. Shipping introduces alien species into new habitats where they can threaten native species and destabilise ecosystems. Foreign direct investment — trade in capital — creates new challenges for ensuring business accountability. Trad disciplines may offer opportunities for reducing market distortions that have an impact on biological diversity, such as subsidies for agriculture or fisheries.

8. The Parties will need to consider these impacts when implementing a number of the Convention provisions, including: determining how trade policy can create incentives under Article 11; and identifying and regulating trad -related processes or activities that adversely affect biological diversity (Articles 7 (c) 8(l)). The Parties' activities in multilateral trade institutions are also relevant to Article 5. This Articl requires Parties, as far as possible and as appropriate, to cooperate, where appropriate, through competent international organisations, regarding matters of mutual interest for the conservation and sustainable use of biological diversity.

9. It is also worth noting that the elaboration of measures for implementing the Convention could create the potential for interaction with other WTO Agreements in addition to TRIPs (Downes 1995). For example, biosafety standards, whether under Article 8(g) of the Convention or under a future protocol to the Convention, could raise issues under GATT principles, including national treatment, most-favoured nation, and the rule against quantitative restrictions. Other WTO Agreements, such as the Agreement on Technical Barriers to Trade, could also be relevant (*ibid.)* These issues are, however, beyond the scope of this paper.

3. INTELLECTUAL PRO ERTY RIGHTS-RELATED MEASURES IN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRI s AGREEMENT

10. Intellectual property rights are th subject of the TRIPs Agreement, and they also figure prominently in the Convention on Biological Diversity. This section provides basic information on the IPR-related provisions of the Convention on Biological Diversity and the TRIPs Agreement. It does not purport to define authoritative interpretations of these agreements, which must be developed by the respectiv governing body of each agreement. Only the COP of the Convention on Biological Diversity can interpret the terms of the Convention, as a number of governments pointed out during discussions in the WTO CTE (WTO 1995a). Article 23 of the Convention provides that the COP shall keep under review th implementation of the Convention, considering and taking whatever actions are needed for achieving th Convention purposes in light of the experience gained in its operation.

11. The TRIPs Agreement may only be authoritatively interpreted by the Ministerial Conference or th General Council, acting on the basis of a recommendation by the Council for TRIPs (Marrakesh Agreement Establishing the WTO, 1994, Article IX). These three bodies are composed of representatives of all WTO members. In addition, interpretations of the TRIPs Agreement may be addressed in the cours of dispute settlement under the Understanding on Rules and Procedures Governing the Settlement of

Disputes (Annex 2 to the Marrakesh Agreement, 1994).

3.1 Intellectual Property Rights and the Convention on Biological Diversity

12. The objectives of the Convention on Biological Diversity are: the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the use of genetic resources (Article 1). The sharing of the benefits from the use of genetic resources is defined to include, *inter alia,* the "appropriate transfer of relevant technologies, taking into account all rights ... to technologies" (Article 1). The reference to rights can be understood to include IPR. Thus, technology transfer is highlighted as a method for achieving one of the Convention's three principal objectives, and IPR are identified as a significant aspect of technology transfer.

13. The treatment of IPR was a contentious issue in the negotiations on the Convention. Many developing countries argued that the application of existing IPR systems hinders the transfer of technology to the developing world, and unfairly disregards the contributions of generations of farmers to the world's plant genetic resources, which underpin global food security. These countries objected to the expansion of IPR over new crop varieties and other products based on genetic resources, and proposed that th Convention provide for, or authorise, restrictions on IPR. For their part, some developed countries argued that strong universal protection of IPR would stimulate technology transfer and investment in research and development in developing countries, indirectly increasing the incentives to conserve biological diversity. The language on which negotiators eventually agr ed does not entirely resolve these differing perspectives on the role of IPR in achieving the Convention's objectives (see UNEP/CBD/COP/3/22 for furthe discussion.)

14. Article 16(1) requires each Party to provide and/or facilitate access and transfer to other Parties of technologies, including biotechnologies, that are relevant for conservation and sustainable use or that mak use of genetic resources and are not significantly damaging to the environment. Each Party shall tak measures "ith 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 thos resources, on mutually agreed terms including technology protected by patents and other intellectual property rights" (Article 16(3)). The provisions of paragraphs 2 and 5 concerning IPR appear in this context.

15. Article 16(2), on the one hand, provides that technology transfer must be carried out "n terms which recognize and are consistent with the adequate and effective protection of intellectual property rights". The phras "dequate and effective" is not defined. Article 16(5), on the other hand, provides that parties, "ecognizing that patents and other intellectual property rights may have an influence on th 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".

16. Several of the Convention's provisions relating to access to and the sharing of benefits fro genetic resources are also relevant to IPR. Article 15 recognises that Parties have sovereign rights over

their genetic resources and confirms that they have the authority to determine access through national legislation. Parties shall "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention". Access "shall be on mutually agreed terms," and shall be "subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party".

17. Where a Party provides genetic resources to another Party, the receiving Party "shall endeavour to develop and carry out scientific research based on [those] genetic resources ... with the full participation of, and where possible in, [the providing Party]" (Article 15(6)). Similarly, Article 19(1) provides that Parties shall take appropriate measures to provide for the effective participation in biotechnological research by Parties, especially developing countries, that provide the genetic resources for such research, in such Parties where feasible. In general, each Party shall take measures "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 th[Party] providing such resources" (Article 15 (7)). Such sharing shall be upon mutually agreed terms (*ibid.*) Article 19(2) requires parties to "take all practicabl measures to promote and advance priority access on a fair and equitable basis" for Parties providing genetic resources, especially developing countries "the results and benefits arising from biotechnologies based upon [those] genetic resources ... on mutually agreed terms". The implementation of these provisions could involve the development of information that could be subject to patents or trade secrets. A number of other provisions involving technology, research and sharing of information could relate to IPR, such as Articles 12(c), 17, and 18 (see UNEP/CBD/COP/3/22).

18. The emphasis of Article 8(j) on knowledge and innovations makes it potentially relevant to IPR. It requires each Party — as far as possible, as appropriate, and subject to its national legislation — to: "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 the benefits arising from the utilization of such knowledge, innovations and practices". Indeed, much discussion among the Parties has concerned th relationship between IPR and the knowledge and innovations of local and indigenous communities within the terms of Article 8(j).

19. Intellectual property rights are also relevant to the implementation of Article 10, which, *inter alia,* requires Parties, as far as possible and as appropriate, to integrate considerations of the conservation and sustainable use of biological resources into national decision-making, and to adopt measures relating to th use of biological resources to avoid or minimise effects on biological diversity. These provisions may b implicated to the extent that IPR has an impact on the use of biological resources; for example, through th application of patents to living modified organisms.

20. Article 14(b) requires the Parties, as far as possible and as appropriate, to introduce appropriat arrangements to ensure that they duly take into account the environmental consequences of their

programmes and policies that are likely to have significant adverse effects on biological diversity. Effectiv implementation would likely involve a preliminary review of IPR policies to determine whether they ar likely to have significant adverse impacts, and a further assessment if the answer to the preliminary inquiry is positive.

21. While IPR figure prominently in the Convention on Biological Diversity, the Convention provisions relating to IPR are framed in general terms. For example, Article 16(5) states that the Parties generally must cooperate to ensure that IPR promote and do not run counter to the Convention objectives, suggesting that the Parties have a general obligation to begin a process of consultation on the issue. At th national level, the Convention language would encompass a variety of approaches to the treatment of IPR within frameworks for controlling both the access to and the benefit-sharing of genetic resources under th Convention, as long as these approaches are consistent with the counterpoised provisions of paragraphs 2 and 5 of Article 16. One approach, for instance, could be to provide for mutually agreed-upon terms for acc ss to genetic resources that allocated IPR under TRIPs-compatible systems among the Parties. A Party could make access to its genetic resources conditional to the access-seeker agreeing to relinquish some or all IPR over products derived from the genetic resources.[1] Similarly, a Party might require access-seekers to agree to carry out joint research with sourc -country nationals, or to carry out research in the sourc country as a condition of access. This would likely be consistent with both the Convention and the IPR standards of the TRIPs Agreement (UNEP/CBD/COP/3/Inf.9, paragraph 78).

3.2 Intellectual Property Rights in the TRIPs Agreement

22. The Ministerial Declaration of Punta del Este launching the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade included provisions on trad -related aspects of IPR.[2] Negotiations continued until the development of the Draft Final Act in December 1991, which was th basis, with relatively minor changes, for the final text of the Agreements Establishing the WTO — including the TRIPs Agreement — adopted at Marrakesh in April 1994. Some of the most important issues in negotiations concerned patents. The basic definition of patents — novelty, inventive step and industrial applicability — was never in question. There was, however, considerable disagreement over whether countries should be permitted to make generic exclusions from patentability. One controversial issue was concerned with whether there should be an obligation to make living organisms, particularly plants and animals, patentable. Another was concerned with whether countries should be able to exclude certain products and processes from patenting, in particular pharmaceuticals, agricultural chemicals and foodstuffs, on the grounds of public interest, national security, public health or nutrition.

23. The TRIPs Agreement that resulted from these negotiations is based in part on a recognition of th dual need to romote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" (Preamble, paragraph 1). The Agreement requires all parties to meet certain minimu standards for protecting IPR, defined as including copyrights, patents, plant variety protection (PVP), industrial designs, geographic designations, the layout-design of integrated circuits, and trade secrets. Th Agreement also requires parties to provide fair, effective judicial proc dures and remedies for rights-

holders claiming infringement (Articles 42-49). It provides developing countries with a fiv -year grace period to phase in most of the Agreement requirements (Article 65). The least developed countries have an eleven-year grace period for implementing most obligations (Article 66).

24. The TRIPs Agreement requires WTO members to observe the principles of national treatment and most-favoured nation with respect to IPR (Articles 3-4). For example, a country could not recognis patents on inventions by its nationals (its citizens and corporations) without doing the same for similar inventions by foreign nationals, neither could it discriminate among inventions by nationals of different foreign countries.

25. Of the types of IPR covered by the TRIPs Agreement, patents and PVP are those most likely to have an impact on the objectives of the Convention, although trade secrets and geographic indications may also have some effect. (Further discussion of categories of IPR may be found in UNEP/CBD/COP/3/22.) The TRIPs Agreement includes a definition of the basic characteristics of patents — novelty, involving an inventive step or non-obviousness, and capable of industrial application or being seful" (Article 27). Article 29 provides that WTO members must require patent applicants to disclose the invention such that a person skilled in the art could reproduce it. Article 31 sets out a number of conditions limiting th circumstances in which a government may authorise use of a patent against the will of the patent owner, subject to appropriate compensation (compulsory licensing).

26. The TRIPs Agreement requires countries to recognise patents on most products and processes, including pharmaceuticals, modified microorganisms, and icrobiological processes" (Article 27.3(b)). Furthermore, countries must protect plant varieties either through patents or an ffective *sui generis* system" or both (*ibid.*) The TRIPs Agreement leaves to each country discretion whether to recognis patents on plants or animals, or ssentially biological [but not microbiological] processes for th production of plants or animals" (*ibid.*). The provisions of Article 27.3(b) will be reviewed in 1999, four years after the entry into force of the Agreements Establishing the WTO (*ibid.*)

27. WTO members may exclude products or processes from patenting wher he prevention within [national] territory of [their] commercial exploitation ... is necessary to protect *ordre public* [public order] or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to th environment" (Article 27.2). However, such an exclusion shall not be mad erely because the exploitation is prohibited by domestic law" (*ibid.*) This language is intended to make clear that products cannot b excluded from patentability merely because they have not yet been approved under normal health and safety regulatory procedures (UNEP/CBD/COP/3/Inf.9, paragraph 88).

28. In addition countries ay 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 legitimat interests of third parties" (Article 30). This provision was intended to allow for exceptions to exclusiv rights, such as the use of the invention for experimental purposes (UNEP/CBD/COP/3/Inf.9, p. 19).

29. The provisions of Article 27.3(b) on plant varieties appear to give WTO members considerabl

flexibility in designing *sui generis* systems for PVP. Provisions of the TRIPs Agreement on several other types of IPR in effect incorporate other existing international agreements by reference. Article 9 on copyrights, for instance, provides that WTO members shall comply with provisions of the Bern Convention. Article 27.3(b), in contrast, does not refer to either of the two versions of the principal international agreement concerning PVP, the International Union for the Protection of New Varieties of Plants (UPOV Convention). □ountries have thus been left greater flexibility in meeting their obligations in this area than would have been entailed by a specific reference to UPOV" (Otten 1994).

30. The Council for Trad -Related Aspects of Intellectual Property Rights (the TRIPs Council) is established under Article 68 to monitor the operation of the Agreement, monitor WTO Members' compliance with its terms, and provide a forum for consultations on trad -related aspects of IPR. In 1999, the TRIPs Council will review Article 27.3(b) of the TRIPs Agreement, which, as mentioned above, allows countries to exclude from patenting modified plants and animals and biological processes, and allows *sui generis* plant variety protection systems, either as an alternative or as an addition to plant patent protection.

31. The TRIPs Agreement provides that each Member shall notify the TRIPs Council of laws and regulations, and final judicial decisions and administrative rulings of general application pertaining to th subject matter of the Agreement (Article 63). If consultations with WIPO succeed in establishing a common register containing countries' laws and regulations, then the Council may waive the notification requirement in favour of using the register as a depository for such national measures (*ibid*.)

32. In sum, the TRIPs Agreement, while it establishes relatively detailed legal standards to b implemented at the national level, nevertheless permits flexibility in sever al relevant respects by allowing:

(a) variation in the details of patent procedure;

(b) exceptions from patenting where preventing commercial exploitation is necessary to avoid serious prejudice to the environment;

(c) *sui generis* systems of plant variety protection;

(d) choice as to whether to issue patents for modified plants or animals other than microorganisms; and

(e) variation in levels of IPR protection by setting minimum, but not maximum, standards.

33. Nothing in the TRIPs Agreement appears either to prevent or to promote the development of additional measures that provide for the sharing of benefits with countries and communities providing genetic resources or traditional knowledge, as long as those measures do not violate TRIPs minimu standards (UNEP/CBD/COP/3/Inf.9, paragraphs 77 and 78). The TRIPs negotiations did not address th question of whether new forms of protection are needed for indigenous and local communities that go beyond conventional IPR concepts (*ibid.*). Thus, intellectual property rights-like measures that provided control over knowledge that is non-novel or that does not involve an inventive step within the terms of patent law would likely be considered outside the scope of the requirements of the TRIPs Agreement. As a result, while any WTO member would be free to elaborate such measures that would apply within its jurisdiction, other WTO members would have no obligation to provide similar protection within their territories.

4. RELATIONSHIPS BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRI s AGREEMENT

34. Intellectual property rights are important under both the Convention on Biological Diversity and the TRIPs Agreement, but the two agreements approach them from very different perspectives. A large and growing number of countries are both Parties to the Convention and members of the WTO (156 Parties to the Convention on Biological Diversity as of 4 November 1996; 125 members of the WTO as of 23 October 1996). This creates a powerful motivation to develop a mutually supportive relationship and to avoid conflicts. Both the COP and the WTO are beginning to explore the complex interrelationships between IPR and biological diversity. At this stage, the most critical issue for the relationship between th Convention on Biological Diversity and the TRIPs Agreement appears to be whether and how to establish procedures for consultation and cooperation between the bodies associated with the two agreements.

35. Both the Convention on Biological Diversity and the TRIPs Agreement allow a significant degr of flexibility in national implementation. This suggests that there is potential for complementary and perhaps synergistic implementation. Because both agreements entered into force recently and discussions of the relationships between IPR and biological diversity are preliminary, specific legal or policy mechanisms that would create synergies between the two agreements or their implementing measures have yet to b identified. Nevertheless, some general areas for complementarity hav been noted.

36. For example, mutually agreed-upon terms for access to genetic resources could allocate IPR as part of the benefits to be shared among parties to an agreement on genetic resources, as noted previously (see paragraph 21 above). Such IPR could be defined under TRIPs-compatible IPR systems.

37. Another possibility is for the Convention and the TRIPs Agreement to develop procedures for exchanging relevant information. Article 16 of the Convention on Biological Diversity, and possibly others as well, prescribes IPR obligations for the Parties. The implementation of these obligations would likely fall within the scope of the notification requirement found in Article 63 of the TRIPs Agreement (see paragraph 31 above). Countries implementing measures that implicate both agreements — such as rules requiring patent applications to disclose the country of origin of biological material — might report them to th TRIPs Council while at the same time disclosing the same information to the clearing-house mechanism for scientific and technical cooperation established under Article 18(3) of the Convention, or including information regarding the measures in the national reports required under Article 26 of the Convention. It may be useful to note that the WTO and the World Intellectual Property Organization (WIPO) recently concluded an agreement formalising arrangements for the exchange information, in particular copies of IPR laws and regulations received by the two organisations (WIPO/WTO 1995).

38. Other policy and legal proposals involving interrelated implementation of both the Convention on Biological Diversity and the TRIPs Agreement may warrant further examination. One proposal, for example, is to require or encourage disclosure in patent applications of the country and community of origin for genetic resources and informal knowledge used to develop the invention. This has been proposed by a number of commentators (e.g., Gadgil and Devasia 1995; Hendrickx et al. 1994; Gollin 1993). Some evidence suggests that such disclosures are already common practice in filing patent applications. Possibl elements of such a requirement, which could help to encourage the implementation of both Article 15 and Article 8(j), are outlined in the Executive Secretary background paper on Article 8(j) (UNEP/CBD/COP/3/19). More information concerning this proposal, including examples of patent applications, is included as Annex I to this paper.

39. In spite of the flexibility of the Convention and the TRIPs Agreement, and th potential for synergies, there is still a possibility that conflicts could arise (Downes 1995). For example, national measures to promote technology transfer under Article 16 might raise most-favoured nation issues if Convention Parties and non-Parties were treated differently, might raise national-treatment issues if foreign nationals received less favourable treatment, and might raise TRIPs issues if owners of proprietary technology were compelled to license technologies on grounds other than those prescribed in the TRIPs Agreement.

40. Looking to the provisions of the agreements regarding conflicts, Article 22(1) of the Convention provides that its provisions hall not affect [a Party's] rights and obligations ... deriving from any existing international agreement, except where the exercise of those rights and obligations would caus

a serious damage or threat to biological diversity". It is not clear how this Article would apply in the cas of conflicts with the TRIPs Agreement. The TRIPs Agreement contains no explicit reference to its relationship to the Convention on Biological Diversity or any other environmental agreement.

41. If WTO members cannot resolve disagreements regarding the implementation of the TRIPs Agreement through consultations, one member may bring a complaint against another for failure to meet its obligations, using the dispute resolution procedures generally applicable for WTO members (Article 64). In certain circumstances, a member prevailing in a dispute may be authorised to take measures for compensation and suspension of concessions. While decisions in such disput -resolution proceedings do not establish legal precedents, as a practical matter members may look to them when interpreting terms of th Agreement in the future. To date, there have been five cases in which the disput -settlement mechanism has been initiated regarding TRIPs matters; none of these cases has reached the panel stage as yet.

42. If Parties to the Convention have a dispute about its interpretation or application, they may seek solution by negotiation, by the mediation of a third party, by conciliation, or (if they agree to be bound by such a means of dispute settlement) by arbitration or submission of the dispute to the International Court of Justice (Article 27). These procedures have not yet been invoked by a Convention Party. Like the WTO procedures, dispute-resolution procedures for the Convention emphasise avoidance of direct conflict by requiring other steps, such as negotiation.

43. There are several possible scenarios for conflict. A dispute might arise between countries that ar both Convention Parties and WTO members; or between a country that is a Convention Party and a WTO member, and a country that is either a WTO member or a Convention Party. A conflict concerning the two agreements would presumably involve a claim, in a forum associated with one of the instruments, that a country had violated its obligations, countered by a defence that the alleged violation constituted implementation of the other instrument, and was obligated or authorised by it. In such disputes, it is likely that a forum associated with one instrument would need an interpretation of the other agreement. In such a case, it is unclear how a disput -resolution proceeding would reach such a determination; neither instrument provides for such an eventuality. The absence of a clear mechansim for reconciling perceived differences further emphasises the value of cooperation to avoid such differences.

5. THE WORLD TRADE ORGANIZATION COMMITTEE ON TRADE AND ENVIRONMENT

44. The WTO was established as a result of the agreement forged in the Uruguay Round of GATT negotiations. It is the administering body for the set of international trade agreements, the WTO Agreements, signed at the close of the Uruguay Round at the Ministerial Conference in April 1994. Th TRIPs Agreement is one such agreement administered by the WTO. The WTO primary forum for considering trade and environment is the Committee on Trade and Environment (CTE). The CTE agenda specifically includes the environmental aspects of the TRIPs Agreement and the relationship between provisions of the multilateral trading system and trade measures pursuant to multilateral environmental agreements. Thus, this discussion highlights the CTE as the most appropriate WTO organ for considering

relationships between the TRIPs Agreement and the Convention.

45. The CTE is a ministerial committee of the Trade and Environment Division of the World Trad Organization (WTO). It was created by the Marrakesh Decision on Trade and Environment of 15 April 1994, adopted by the Ministers of the WTO (WTO 1995b:469). The CTE will report on its progress to th first biennial meeting of the WTO Ministerial Conference, to be held in Singapore in December 1996.

46. A predecessor body to the CTE was the Group on Environmental Measures and International Trade (EMIT), which was constituted under the precursor instrument to the WTO, the General Agreement on Tariffs and Trade (GATT). EMIT, a stand-by GATT mechanism established in 1971 in response to concerns that pollution controls might create new barriers to trade, remained inactive for over twenty years. Finally activated in October 1991, EMIT held some preliminary discussions of issues, such as th relationship between GATT and multilateral environmental agreements, before its existence ended in April 1994.

47. At that time, the Marrakesh Ministerial Decision on Trade and Environment provided for th formal establishment of the CTE at the first General Council of the WTO. In the interim prior to the General Council, the Sub-Committee on Trade and Environment of the Preparatory Committee of the WTO was authorised by the Marrakesh decision to carry out the responsibilities of the CTE. The Sub-Committ met five times from May to November 1994. The CTE itself convened its first meeting in February 1995. It has subsequently met twelve times, approximately every one to two months.

48. The CTE mandate (established by the Marrakesh Decision) is to oordinate the policies in the field of trade and environment" in light of the principle that ther hould not ... nor need be any policy contradiction between promotion of the multilateral trading system", protection of the environment, and th promotion of sustainable development. In particular, the CTE is to:

> dentify the relationship between trade measures and environmental measures, in order to promot sustainable development; [and]
>
> make appropriate recommendations on whether any modifications of the provisions of the multilateral trading system are required [such as] ...
>
> (a) rules to enhance positive interaction between trade and environmental measures, for the promotion of sustainable development, with special consideration to the needs of developing countries, in particular those of the least developed among them
>
> (b) [means to avoid protectionist measures]

(c) effective multilateral disciplines to ensure responsiveness of the multilateral trading system to environmental objectives set forth in Agenda 21 and the Rio Declaration [and]

(d) surveillance of trade measures used for environmental purposes, of trade related aspects of environmental measures which have significant trade effects, and of effectiv implementation of the multilateral disciplines governing those measures".

49. The CTE agenda includes ten items. Of these, several are particularly relevant to the subject of this paper. Most important is item 8, r]elevant provisions of the Agreement on Trad -Related Aspects of Intellectual Property Rights". Also significant is item 1, t]he relationship between provisions of th multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements". Potentially relevant is item 2, t]he relationship between environmental policies relevant to trade and environmental measures with significant trade effects and th provisions of the multilateral trading system".

50. All of the WTO members may participate in the CTE, just as all Parties to the Convention on Biological Diversity may participate in the COP and its subsidiary bodies. (WTO members totalled 125 as of 23 September 1996.) Intergovernmental organisations (IGOs) may participate as observers, as in th COP of the Convention on Biological Diversity. Fourteen IGOs currently attend meetings of the CTE, including the U.N. Commission on Sustainable Development, the Food and Agriculture Organization of th U.N., the International Standards Organization (for ecolabelling issues only), OECD, the International Monetary Fund, the U.N. Environment Programme, and the World Bank. Non-WTO-member States in the process of acceding to the WTO may also observe, and thirty-seven governments did so as of July 1996.

51. Observer status in the General Council and its subsidiary bodies is granted to non-member governments in response to an application that expresses the intent to initiate negotiations to accede to th WTO within five years and that includes a description of the current economic and trade policies of the applicant nation and any planned reforms of these policies (WTO 1996a). Observer-governments ar permitted to observe both informal and formal sessions. Representatives of observer-governments may b invited to speak at meetings, but this right does not include the right to make proposals unless specifically invited to do so, or to participate in decision-making (*ibid.*)

52. IGOs that have competence or a direct interest in trade matters may be admitted as observers on a case-by-case basis by each WTO body to which a request is made, based upon the nature of the work of the organisation, the number of WTO Members in it, reciprocity with respect to access to documents and other benefits of observer status, and whether the organisation has been associated in the past with the work of the Contracting Parties to the GATT 1947 (*ibid.*) IGOs may attend formal meetings, but (unlike non-member States) are barred from informal

meetings. Representatives of IGOs may be invited to speak, but may not make proposals or circulate papers unless specifically invited to do so, and may not participate in decision-making. No organ or body of the Convention on Biological Diversity currently has observer status at the WTO.

53. Non-governmental organisations (NGOs) may not participate as observers or in any fashion whatsoever in any proceedings of the CTE or any other organ of the WTO. This reflects a WTO General Council decision that recognised the role of NGOs, especially at the national level, that asked th Secretariat to pursue closer relations with NGOs, and that provided that NGOs shall not attend any meetings of the WTO (WTO 1996b).

54. The CTE has completed at least two rounds of analysis on each of its ten agenda items. Th relationship of the TRIPs Agreement to the environment, including biological diversity and sustainable use, has been a major item on the agenda in four CTE meetings (21-22 June 1995; 25-26 March 1996; 28-29 May 1996; and 24-25 July 1996) and the topic of two Committee reports. Some delegations hav tabled non-papers on the issues. Discussions to date have been preliminary in nature, and have focused on ideas put forward by some delegations on the following issue areas:

(a) the protection of rights to biological resources and measures to ensure the equitabl sharing of benefits from patentable products derived from these resources. This has included considerable discussion of protecting the interests of indigenous peoples and enhancing their ability to protect and preserve biological diversity;

(b) methods (such as patent restrictions) for discouraging the development and exploitation of environmentally harmful products. One area of concern has been IPR as to genetically modified organisms, as an ethical as well as an environmental issue; and

(c) the appropriate level of IPR protection, in light of the impact of such protection, on th development of environmentally sound technology (EST), and on access to it and transfer of it. On the one hand, some developing-country delegates have called for reforms to TRIPs to facilitate th transfer of EST, while some developed-country representatives have argued that IPR are in fact essential to the development of EST and, therefore, to environmental protection. There has also been discussion of the impact of IPR — on both developing countries and the environment — as applied to technologies that are restricted or otherwise affected by measures pursuant to multilateral environmental agreements.

55. In these discussions, a number of WTO members have highlighted th importance of reconciling TRIPs and its IPR objectives with the CBD objectives of equitable sharing and sustainability. Other delegations do not see any irreconcilability between the two agreements. Some delegations would prefer to limit discussion of the second issue, relating to environmentally harmful products, anticipating that th negotiation of a biosafety protocol to the Convention on Biological Diversity may address many relevant concerns.

56. Both the agenda and mandate of the CTE are to be reviewed in light of the recommendations of th

CTE at the WTO Ministerial Conference in December 1996. The outcome of that review is yet to b decided. In general, CTE delegations appear to recognise that much more work remains to be done under the CTE agenda and mandate. This suggests that major changes in the CTE overall agenda or mandat are unlikely.

57. As discussed above, the TRIPs Council will review Article 27.3(b) of the TRIPs — which addresses the exclusion from patentability of plants and animals, the protection of plant varieties, and th right of countries to develop their own system to protect plant varieties — in 1999. It is possible that th CTE might study this issue in preparation for the 1999 review.

6. OPTIONS FOR FUTURE WORK

58. In light of the synergies and relationships discussed above, the COP might wish to consider th following options relating to a possible input to the CTE:

(a) Forwarding to the CTE relevant decisions and discussions of the COP contained in the chair report, as well as this and other relevant papers prepared by the Executive Secretary. Relevant papers might include this study, as well as *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits From Its Use: A Preliminary Study* (UNEP/CBD/COP/3/22), and/or *Knowledge, Innovations and Practices of Indigenous and Local Communities: Implementation of Article 8(j)* (UNEP/CBD/COP/3/19).

(b) Commending the CTE and WTO Secretariat for de-restricting and transmitting documents relating to the work of the CTE, inviting the WTO to continue to transmit future relevant documents as they are produced, and requesting the Convention Secretariat to reciprocate by transmitting similar documents to the CTE in the future.

(c) Seeking a role in the deliberations of the CTE, possibly by applying to participate in th CTE as an observer.

(d) Suggesting that Parties that are also WTO members notify the TRIPs Council (pursuant to the notification requir ment of Article 63 of the TRIPs Agreement) of those laws and regulations implementing the provisions relating to IPR of Article 16 of the Convention on Biological Diversity. The COP might also wish to suggest that those Parties simultaneously notify th Secretariat of the Convention so that such measures can be communicated through the clearing-house mechanism.

(e) Exploring additional ways to cooperate with the WTO on exchanging information.

(f) Continuing its exploration of issues relating to IPR by dev loping informational inputs for the CTE regarding the impact of patenting of genetically modified organisms, including animals and plants and essentially biological processes, in preparation for the 1999 review by the TRIPs

Council of Article 27.3(b) of the TRIPs Agreement.

(g) Sending a statement to the WTO CTE. The statement might refer to one or more of th following points:

(i) the large number of countries that are both Parties to the Convention on Biological Diversity and members of the WTO;

(ii) the important interrelationships between the CBD and the WTO agreements, including the TRIPs Agreement; noting that the interrelationships extend beyond TRIPs, although TRIPs is the focus of this statement;

(iii) the international and national processes of implementation now underway for both agreements;

(iv) the significant potential for complementarities in implementing the two agreements, as reflected in the Executive Secretary report;

(v) the important roles of both institutions in the area of IPR and biological diversity, in cooperation with other relevant international institutions and instruments;

(vi) an invitation to the CTE to present questions to the COP regarding the relationship of IPR and the obligations of the TRIPs Agreement and the Convention objectives.

(h) The COP might wish to continue exploring the relationships between trade and trade la and policy and the achievement of the objectives of the Convention, possibly with particular attention to Articles of the Convention that appear most c losely linked to these relationships, such as articles 5, 7(c), 8(l), or 11. The COP might wish to draw the attention of the CTE to any plans for such work.

References

Cameron, J. and Z. Makuch. 1995. *The UN Biodiversity Convention and the WTO TRIPS Agreement.* Gland, Switzerland: WWF International. WWF International Discussion Paper.

Chandler, M. 1993. he Biodiversity Convention: Selected Issues of Interest to the International Lawyer". *Colorado Journal of International Environmental Law and Policy* 4:141-175.

Downes, D. 1995. he Convention on Biological Diversity and the GATT". Pages 197-251 in Housman, R., et al., eds. *The Use of Trade Measures In Select Multilateral Environmental Agreements*. [Nairobi]: United Nations Environment Programme.

Gadgil, M. and P. Devasia. 1995. ntellectual Property Rights and Biological Resources: Specifying

Geographical Origins and Prior Knowledge of Uses". *Current Science* 69(8).

Glowka, L., et al.. 1993. *A Guide to The Convention on Biological Diversity.* Gland, Switzerland: IUCN. IUCN Environmental Law and Policy Series.

Gollin, M. A. 1993. "An Intellectual Property Rights Framework for Biodiversity Prospecting". In W.V. Reid, et al., eds. *Biodiversity Prospecting: using genetic resources for sustainable development.* [Washington, D.C.]: WRI, INBio, Rainforest Alliance and ACTS.

Hendrickx, F., V. Koester and C. Prip. "Access to genetic resources: A legal analysis". In V. Sánchez and C. Juma, eds. *Biodiplomacy: genetic resources and international relations.* Nairobi: ACTS Press.

Otten, A. 1994. "The Uruguay Round TRIPs Agreement: Implications for the Protection of Plant Varieties". Presentation at Workshop on IPRs in Relation to Agricultural and Microbial Biotechnology, Madras, India.

Philippines, Republic of. 1995. Executive Order No. 247 Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for Other Purposes. Manila: Republic of the Philippines.

Philippines, Republic of. 1996. Department of Environment and Natural Resources. Department Administrative Order No. 96-20. Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources. Manila: Philippines Department of Environment and Natural Resources.

Sukhwani, A. 1996. *Intellectual Property and Biological Diversity: Issues Related to Country of Origin.* Paper prepared for the Secretariat for the Convention on Biological Diversity.

WIPO (World Intellectual Property Organization) and WTO (World Trade Organization). 1995. Agreement Between WIPO and WTO. Geneva: n.p. (Concluded in Geneva Dec. 22, 1995 and entered into force Jan. 1, 1996.)

WTO (World Trade Organization). Committee on Trade and Environment. 1995a. *Report of the Meeting Held on 21-22 June 1995: Note by the Secretariat.* Geneva: WTO. Doc. No. WT/CTE/M/3.

WTO (World Trade Organization). 1995b. *The Results of the Uruguay Round of Multilateral Trade Negotiations: The legal texts.* Geneva: WTO.

WTO (World Trade Organization). 1996a. *WTO Rules of Procedure.* Geneva: WTO. Doc. No. WT/L/161.

WTO (World Trade Organization). 1996b. *Guidelines for Arrangements on Relations With Non-Governmental Organizations.* Geneva: WTO. Doc. No. WT/L/162.

Annex I

DISCLOSURES OF BIOLOGICAL MATERIALS IN PATENT APPLICATIONS: EXAMPLES OF EXISTING PRACTICE

1. One specific proposal that involves the interrelated implementation of both the Convention on Biological Diversity and the TRIPs Agreement is to require or encourage disclosure in patent applications of the country and community of origin for genetic resources and informal knowledge used to develop invention. A number of commentators have argued that Parties should encourage or require such disclosur in their patent procedures (e.g., Gadgil and Devasia 1995), possibly also including the certification of prior approval of the use by the source country or community (e.g., Gollin 1993; Hendrickx et al. 1994).

2. This could help implement Article 8(j) by promoting respect for indigenous and local traditional knowledge. Possible elements of such a mechanism are outlined in the background paper on Article 8(j), UNEP/CBD/COP/3/19. It is worth noting, however, that such disclosure may implicate other provisions of the Convention in some cases. For example, the publication of information on the location or habits of species or populations that are vulnerable to over-exploitation could stimulate increased exploitation that puts the species further at risk.

3. There is evidence sugg sting that such a step would in large part involve simply regularising a practice that is already common in filing patent applications. One recent study reviewed over five hundred patent applications in which the invention involved the use of biological materials, such as materials derived from plants or animals; most were in the pharmaceutical field, with some in other fields such as cosmetics and pesticides (Sukhwani 1996 and pers. comm.). The applications reviewed came from a number of jurisdictions, including France, Germany, the UK, Spain, the USA, 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). Additional discussion of this proposal may be found in the paper on impacts of IPR on the objectives of th Convention on Biological Diversity, UNEP/CBD/COP/3/22.

1. EXAMPLES OF DISCLOSURES OF INFORMATION REGARDING ORIGIN NEEDED TO CARRY OUT INVENTION

4. While important patent treaties such as the EPC do not formally require mention of the country or region that the biological material originates from, Article 83 of the European Patent Convention, for example, provides 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.

5. **European Patent No. 0513671.** □he present invention relates to new therapeutical applications of extracts, fractions and single active ingredients prepared fro *Cammiphora mukul:* the invention further relates to processes for the preparation of the total steroidal fraction which is present in the exudate of th above plant. Th *Commiphora mukul* (Hook ex Stocks) Engl. (syn. *Balsamodendron mukul* Hook) is a small tree of the Berseraceae family, endemic in the Indian peninsula, growing spontaneously in the dry and semidry Rajasthan, Gujarat and Madhya Pradesh districts in India and in Baluchistan district in Pakistan".

6. **U.S. Patent No. 3743722.** Patent US 3743722 refers to the anti-coagulant properties of two pit vipers: □hese species are found in different parts of the world, predominantly in Southeast Asia (*Agkistrodon rhodostoma*) and South America (*Bothrops atrox*)".

7. **U.S. Patent No. 5204101.** It has been discovered that if an HIV infected patient with AIDS is administered a compound mixture of constituents found in two naturally occurring plants, i.e., *Rumex acatasella* and *Phytolacca americana,* and a naturally occurring fruit, i.e., *Citrus limonia,* a substantial improvement is seen in the condition of the patient. The three plants are identified as:

COMMON NAME: Sheep Sorrel
FAMILY: Polygonaceac (Buckwheat)
GENUS: Rumex
SPECIES: *acetosella*

COMMON NAME: Pokeweed or pokeberry
FAMILY: Phytolaccaccea
GENUS: Phytolacca
SPECIES: *americana*

COMMON NAME: Lemon
GENUS: Citrus
FAMILY: Rutaceae
SPECIES: *limonia*

2. EXAMPLE OF DISCLOSURES OF PRIOR ART

8. The "background art" that typically must be disclosed in patent applications usually includes references to traditional uses of the biological material and its properties in its country or region of origin. Rule 27.1(b) of the European Patent Convention, for instance, requires that the content of the description of the patent should "indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art". Thus, in the case of the previously cited European patent, No. EP 0513671, reference is made to traditional uses of the biological material used: "In the ancient Sanskrit, this gum resin is called *guggulu* and is a product which is still used in Indian popular medicine for the treatment of obesity and some arthritic forms".

9. Source of examples: Sukhwani, A. 1996. *Intellectual Property and Biological Diversity: Issues Related to Country of Origin.* Paper prepared for the Secretariat for the Convention on Biological Diversity (as cited in UNEP/CBD/COP/3/Inf.25)

Notes

1. Indeed, the Philippines have implemented Article 15 of the Convention through regulations providing, *inter alia,* that when a foreign research or commercial institution gains access to genetic resources within that country's jurisdiction, it must agree, as a condition of access, that if it develops technology using genetic or biological resources from a species endemic to the Philippines, it will permit commercial use of that technology by a "designated Philippine institution," unless a different arrangement is "appropriate" (Philippines 1995: Section 5(l), Philippines 1996: Section 8.1[13]).

2. Much of this discussion is based on paragraphs 80-95, *TRIPs and the Environment,* WT/CTE/W/8, included as UNEP/CBD/COP/3/Inf. 9.