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Item 3 of the provisional agenda*

STUDY ON THE RELATIONSHIP BETWEEN AN INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING AND OTHER INTERNATIONAL INSTRUMENTS AND FORUMS THAT GOVERN THE USE OF GENETIC RESOURCES

The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and the International Union for the Protection of New Varieties of Plants (UPOV)

1. At its ninth meeting, the Conference of the Parties, in paragraph 13 (c) of decision IX/12, on access and benefit-sharing, requested the Executive Secretary to commission a study on how an international regime on access and benefit-sharing could be in harmony and be mutually supportive of the mandates of and coexist alongside other international instruments and fora which govern the use of genetic resources, such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.
2. In order to respond to this request, the work was divided into three components examining the relationship of the international regime with the following instruments and forums, namely:
 - (a) The International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) (UNEP/CBD/WG-ABS/7/INF/3/Part.1);
 - (b) The World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the International Union for the Protection of New Varieties of Plants (UPOV), including their relevant agreements and treaties (UNEP/CBD/WG-ABS/7/INF/3/Part.2);
 - (c) The Antarctic Treaty System and the United Nations Convention on the Law of the Sea (UNCLOS) (UNEP/CBD/WG-ABS/7/INF/3/Part.3).
3. The three components of the work were carried out by three different experts/institutions, taking into account their particular area of expertise.

* UNEP/CBD/WG-ABS/7/1.

4. This document is part 2 of the study. It was carried out by Mr. Jorge Cabrera Medaglia, an independent consultant from Costa Rica, and addresses the relationship between an international regime on access and benefit-sharing and respectively, the World Trade Organization, the World Intellectual Property Organization and the International Union for the Protection of New Varieties of Plants (UPOV).

5. The views expressed are those of the author and do not necessarily reflect the views of the Secretariat of the Convention on Biological Diversity. The study is reproduced in the form and the language in which it was received by the Secretariat of the Convention.

Study on the relationship between the ABS International Regime and other international instruments which govern the use of genetic resources: The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and the International Union for the Protection of New Varieties of Plants (UPOV)

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For the Secretariat of the Convention on Biological Diversity

February 2009

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ACRONYMS

ABS: ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

CBD: CONVENTION ON BIOLOGICAL DIVERSITY

COP: CONFERENCE OF THE PARTIES TO THE CBD

GR: GENETIC RESOURCES

IGC: INTERGOVERNMENTAL COMMITTEE ON GENETIC RESOURCES AND INTELLECTUAL PROPERTY RIGHTS; TRADITIONAL KNOWLEDGE AND FOLKLORE

IT: INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE OF THE FAO

IPR: INTELLECTUAL PROPERTY RIGHTS

IR: INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

MAT: MUTUALLY AGREED TERMS

PIC: PRIOR INFORMED CONSENT

PBR: PLANT BREEDERS RIGHTS

TEG: TECHNICAL EXPERT GROUP OF THE CBD

TT: TECHNOLOGY TRANSFER

TK: TRADITIONAL KNOWLEDGE

TRIPS: WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

UPOV: THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

WGABS: WORKING GROUP ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

WIPO: WORLD INTELLECTUAL PROPERTY ORGANISATION

WTO: WORLD TRADE ORGANISATION

1. Introduction

1. In accordance with paragraph 13 (c) of COP Decision IX/12 (Access and Benefit Sharing) adopted at the last Conference of the Parties of the CBD¹, a request was made to the Secretariat to commission studies on the following topics:

“c) How an international regime on access and benefit-sharing **could be in harmony and be mutually supportive of the mandates of and coexist alongside other international instruments and forums that govern the use of genetic resources**, such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture”

2. This study examines the relationship between the IR and the following fora and instruments:

- The World Trade Organization (WTO)
- The International Convention for the Protection of New Varieties of Plants (UPOV)
- The World Intellectual Property Organization (WIPO).

3. Section 1 provides a general introduction, while section 2 gives an overview and a factual description of the three instruments and fora, as well as their provisions related to ABS and the relationships between the IR and the ABS provisions or developments identified. Section 3 seeks to address the different scenarios and options to achieve mutual supportiveness between the IR and the instruments and fora. Finally, some general remarks are presented.

2. Overview and factual description of the relevant ABS provisions and developments at the WTO, WIPO and UPOV

4. The document “Overview of recent developments at the international level relating access and Benefit Sharing” prepared for the Fifth meeting of the Ad-Hoc Open Ended Working Group on Access to Genetic Resources and Benefit Sharing, presents an overview and factual description of the relevant ABS activities and provisions developed at the WTO, WIPO and UPOV and this study should be read in conjunction with and in addition to that document². However, for the benefit of clarity some information contained in the document will be summarized and presented in this study.

2.1 Factual overview of relevant provisions/developments/processes at the WTO Agreement on Trade-related Aspects of Intellectual Property Rights

5. Since the entry into force of the TRIPS Agreement, there have been calls, mainly by developing countries, to explore the relationship between the CBD and intellectual property rights (IPRs). In parallel, CBD COP decisions have stressed the need to gather information on the impact of IPRs on achieving the objectives of the CBD, and to explore the relationship between the Convention and the TRIPS Agreement^{3 4}.

¹ Decision IX/12 par 13(c).

² See UNEP/CBD/WG-ABS/5/4/add.1

³ Nnadozie, Kent, Lasen, Carolina and Herve, Dominique, *Synergetic implementation: coordinated national implementation of access and benefit sharing issues – CBD, Biosafety Protocol, ITPGRA and relevant IPR instruments*, unpublished manuscript on the file of the author.

⁴ Decision III/15, paragraph 8; Decision V/26 B, paragraphs 1-4; Decision VI/24 D, paragraph 10; Decision VI/24/C 1; Decision VIII/4 d.

6. As early as COP 3⁵, the CBD Secretariat was requested to co-operate with the WTO through the Committee on Trade and Environment (CTE) to explore the extent to which there may be linkages between Article 15 on ABS and relevant provisions of the TRIPS Agreement. In the WTO context, the TRIPS Council has included the relationship between TRIPS and the CBD on numerous occasions in its discussions.⁶ Some of the debates about the links between the CBD and WTO took place in the context of the TRIPS review of Article 27.3(b), which was started by the TRIPS Council during 1999, four years after the entry into force of the Agreement.

7. There have also been similar discussions regarding the TRIPS Agreement under the CTE including protection of Traditional Knowledge; the transfer of environmentally sound technology; ethical concerns associated with the patenting of living organisms; and compatibility between TRIPS and the CBD.⁷

8. The TRIPS Council has also discussed what the implications of IPRs are for access to and transfer of technology. One view has been that IPRs in respect of genetic resources could impede access to and raise the cost of technology in this area, by virtue of the exclusive rights given to rights-holders to prevent others from using the protected technology. In response, it has been argued that full implementation of the TRIPS Agreement in developing countries would stimulate investment in those countries and, therefore, facilitated technology transfer form part or the basis of benefit sharing as envisaged under the CBD⁸. Technology transfer is also a relevant issue addressed by the CBD. Article 16 of the CBD on access to and transfer to technology contains numerous references to IPRs. COP 7 adopted a program of work on technology transfer and technological and scientific cooperation, which required the CBD Secretariat to prepare, in collaboration with UNCTAD, WIPO and other relevant international organizations, technical studies⁹ to explore and analyze the role of IPRs in technology transfer, in the context of the CBD, and identify potential options to increase synergy and overcome barriers to technology transfer and cooperation.¹⁰

9. Later, in 2001, the Doha Declaration, which launched the current round of trade negotiations (paragraph 19), specifically instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other new and relevant developments pointed out by the Members. In particular, it shall take this into account in conducting the examination provided for in paragraph 3 (b) of article 27; the examination of the application of the TRIPS Agreement provided for in paragraph 1 of article 71; and in its work in compliance with paragraph 12 of the Declaration. In carrying out this work, the TRIPS Council shall be governed by the objectives and principles stated in articles 7 and 8 of the TRIPS Agreement and shall fully consider the dimension of development.

10. This debate was originally wide-ranging¹¹, it now focuses on how the TRIPS agreement relates to the CBD and particularly whether the agreement should be amended to require disclosure in IPR

⁵ Decision III/15, paragraph 8.

⁶ See document IP/C/W/368/rev 1, 8 February 2006, *Summary of issues raised and points made with regard the relationship between the TRIPS Agreement and the CBD*.

⁷ See Doha Declaration paragraph 32 (ii).

⁸ Nnadozie et al , *op cit*.

⁹ The Study was prepared and can be found in <https://www.cbd.int/doc/meetings/cop/cop-09/information/cop-09-inf-07-en.pdf>.

¹⁰ CBD Decision VII/29, Annex, Program Element 3.

¹¹ See the minutes of the meetings of the TRIPS Council (IP/C/M) which can be found on the WTO website (www.wto.org) There are several issues that were discussed by the delegations at the TRIPS Council, which are relevant to the CBD: such as the “patentability of life”, removal of references to patenting of microorganisms from article 27; inclusion of the TK protection on the concept of sui generis systems found in article 27.3(b); the scope and extension of the exemptions of article 27.3 (b); among others. See document UNEP/CBD/COP/8/Inf/37 “The Relationship between the TRIPS Agreement and the Convention on Biological Diversity - Summary of Issues Raised and Points Made - Submission by the WTO Secretariat”.

applications, which has been discussed in the WTO based on the mandate established in Doha, or whether alternative approaches including contractual based systems or databases of genetic resources and traditional knowledge could be more effective in ensuring mutual supportiveness between the TRIPS and the CBD.

11. One of the first measures suggested in order to achieve mutual supportiveness between the CBD and intellectual property systems (in particular, the WTO TRIPS) was the disclosure of the origin of genetic resources or associated traditional knowledge in intellectual property rights applications, particularly in patents. It has been suggested by developing countries mostly that the TRIPS Agreement should be amended so as to require that patent applicants disclose, as a condition to patentability one or more of the following: the source and origin of any genetic material used in a claimed invention; and/or any related traditional knowledge used in the invention; evidence of prior informed consent from the competent authority in the country of origin of the genetic material; and evidence of fair and equitable benefit sharing. Proponents of disclosure requirements argue that this stipulation would help to support compliance with the CBD provisions on access to genetic resources and benefit-sharing. In response, it has been expressed that such a modification is not necessary to implement the CBD requirements as they should be implemented through corresponding contracts at the national level and that the TRIPS Agreement is not the appropriate instrument to regulate ABS.

12. The Declaration adopted at the Ministerial Summit in 2005 in Hong Kong provides (in paragraph 44) that note be taken of the work carried out by the TRIPS Council, in accordance with paragraph 19 of the Doha Declaration, and agrees that work will continue based on this paragraph and on the progress made to date. In addition, in accordance with paragraph 39 concerning implementation, it was decided to address the relationship between the TRIPS Agreement and the CBD through a consultation process on different aspects of implementation (paragraph 12 of the Doha Declaration). This consultation is being carried out with the intervention of the Deputy Director General of the WTO.

13. In May 2006, six countries, including India, Brazil and Peru, submitted a proposal to the TRIPS Council suggesting concrete changes to the TRIPS Agreement in order to support disclosure of origin. The Communication¹² aims to incorporate a new article 29 bis into the TRIPS Agreement. It proposes an amendment to the TRIPS Agreement to incorporate requirements for disclosure of the origin of genetic resources¹³ and associated traditional knowledge in patent applications along with evidence of prior informed consent and benefit-sharing.¹⁴

14. At the Mini-Ministerial Conference held in July 2008¹⁵, as far as TRIPS is concerned, it appears that the result of the Mini-Ministerial leaves the matter more or less at the state they entered. This means, consistent with the Ministerial Decision at the Hong Kong Ministerial Summit, that a determination regarding the proposed amendment to the TRIPS Agreement to incorporate the disclosure of origin remains to be made at the WTO. A draft modality text on IP was presented including negotiations on disclosure. The draft called¹⁶ for text based negotiations on the IP issues

¹² WT/GC/W/564, 31st May 2006. Norway has also submitted an alternative proposal for disclosure of origin (IP/C/W473). See also paragraph 37 on Switzerland proposals and note 37 on the EC proposal.

¹³ The language of the proposal is broader and makes reference to “biological resources”.

¹⁴ For further details see documents WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2, IP/C/W/474 and WT/GC/W/564/Rev.2/Add.2, TN/C/W/41/Rev.2/Add.2, IP/C/W/474/Add.2.

¹⁵ See WT/GC/W/591TN/C/W/50 dated, 9 June 2008 “Issues related to the extension of the protection of geographical indications provided for in article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity” which summarized the different positions on this issue before the Mini-Ministerial.

¹⁶ Draft Modality text as contained in document TN/C/W/52 have been cosponsored by 110 Members which request the inclusion of the TRIPS related issues as part of the horizontal process for the negotiations. The Draft speaks of country providing/source of genetic resources not of origin.

(including disclosure)¹⁷. This draft modalities proposal for negotiating the IP issues at the Ministerial level have gathered the support of the majority of developing country Members and some developed countries as well. A large coalition of more than a hundred developing and developed countries led by Brazil, the EU, India, and Switzerland, were pushing for the three TRIPS issues to be moved forward as a single undertaking in the Round, but the proposal was strongly rebuffed by some country Members who contended that the intellectual property issues should not be discussed in tandem with the Doha negotiations on liberalising trade in agricultural and industrial goods.

15. The issue of disclosure was also raised at the last TRIPS Council Meeting (October 29, 2008) with similar results. In essence, countries largely reiterated known positions on the relationship between the TRIPS Agreement and the Convention on Biological Diversity. Meanwhile, informal consultations on how to move the issue forward are ongoing.

16. However, like all issues discussed at the July Mini-Ministerial Conference, the future of the TRIPS issues depend upon the future of the negotiations.

2.1.1 Relationship between the IR and WTO

17. As presented in the previous section, discussions on the relationship between the CBD and the WTO provisions have addressed a range of issues and several proposals have been presented. However, the current debate has focused on the disclosure of origin in patent applications or whether alternative approaches including contractual based systems or databases of genetic resources and traditional knowledge could be more effective in ensuring mutual supportiveness between TRIPS and the CBD. In addition, technology transfer (TT) is another relevant issue connecting the IR and the WTO.

18. There are other issues connecting the WTO and the potential IR, but they just can be briefly mentioned here such as: the applicability of the WTO investment provisions to the ABS activities; and the relationships between the Principle of Non Discrimination (the Most Favoured Nation and National Treatment Principles) and ABS legislation and practices; among others.¹⁸

- **Disclosure of origin**

19. The Annex of Decision IX/12 has identified five components for the IR. These include: access; fair and equitable benefit sharing; compliance measures; traditional knowledge and capacity building. Under the Compliance component one of the measures for “further consideration”¹⁹ is the disclosure requirements. Decision VIII/4/D is clearer about disclosure in the context of the CBD IR negotiations.

- **Certificate of Origin/Source/ Legal Provenance/ Compliance**

20. With regard to the compliance component of the IR, the Annex of Decision IX/12 identified as an area for “further elaboration” the “Development of tools to monitor compliance: ... b) (an) internationally recognized certificate issued by a domestic competent authority”.

21. One element that would make it possible to respond to the call for user country measures and also contribute to the monitoring and traceability of genetic resources is what is known as the certificate of

¹⁷ The three current intellectual property issues: the relationship between the TRIPS Agreement and the CBD; the extension of the protection of geographical indications provided for under Article 23 to products other than wines and spirits; and the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits.

¹⁸ See Cabrera Medaglia, Jorge, *Trade (in particular free trade agreements) and access to genetic resources and benefit sharing: exploring some the linkages*, in *Asian Biotechnology and Development Review*, Vol. 10, No. 3, July 2008, India.

¹⁹ The Annex in accordance to Decision IX/12.1 shall be the basis for the negotiations. The Components have been divided in two different categories: “Components to be further elaborated with the aim of incorporating them in the IR” and “Components for Further Consideration”.

origin / source / legal provenance/compliance. It appears to have some degree of support, at least regarding an analysis of this proposal to determine whether it should be included in the Regime and, if so, how this should be accomplished. The certificate could be required in patent applications to provide evidence of compliance with national legislation on ABS, including prior informed consent and benefit sharing, thus fulfilling a role in supporting the disclosure of origin requirement.

22. COP Decision VIII/4C established an Expert Group (EG) on an internationally recognised certificate of origin/source/legal provenance. The Group agreed that the basic role of any certificate system would be to provide evidence of compliance with national ABS legislation. This could be achieved by a system of national certificates with standard features to allow for their international recognition.

23. The Group²⁰ identified a number of points common for all proposals of a certificate, including that it could be required for presentation at specific checkpoints in the user countries, *inter alia* patent and in general IP applications²¹. Indeed, the certificate of origin could perhaps be integrated into the existing system of requirements for disclosure of information in the patent system. A majority of certificates proposals envisage a system of checkpoints at which disclosure of the certificate of origin would be required for the purposes of processing IP applications, among other things. Compliance with disclosure requirements would be facilitated where an internationally recognized certificate could act as evidence of conformance with national and international law²².

24. However, the certificate, depending on its design, may raise other international trade issues. Some rules of the trade system might apply to it, especially those related to technical barriers to trade. In this regard, considering that the certificate could be a document attached to the transfers/export (international trade) of genetic resources it also should be analyzed in the context of the relevant rules of the WTO regarding non discrimination (the Most Favoured Nation Principle and the National Treatment Principle) as well as the appropriate measures contained in the Agreement on Technical Barriers to Trade (TBT) which governs, the elaboration and use of technical regulations, standards and conformity assessment procedures in a way that do not create unnecessary obstacles to international trade. The certificate could be considered a technical regulation and it must take into account the relevant provisions of the TBT Agreement, especially article 2.2: technical regulations shall be no more restrictive than necessary to fulfil a legitimate objective and the requirement that technical measures shall be the less trade restrictive in light of applicable risks²³.

- **Technology transfer as an element of the benefit-sharing component of the IR.**

25. Annex I to Decision IX/12, under section III. B. on “Fair and equitable benefit-sharing” also includes as a component to be further elaborated, the access and transfer of technology. A technology transfer measure could be developed in the context of the BS component of the IR²⁴. It is outside the scope of the study to analyze the relationship between IPRs in general, and TRIPS in particular, and technology transfer in the context of the CBD. However, it is clear that technology transfer is a key element of the ABS CBD provisions²⁵ and of the IR. As one study has pointed out “The provisions of

²⁰ Report of the meeting of the Group of Technical Experts on an international recognized certificate of origin/source/legal provenance UNEP/CBD/WG-ABS/5/7.

²¹ Tobin, Brendan, Burton, Geoff and Hernández, José Carlos, *Certificates of clarity and confusion: the search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT*; UNU-IAS Report, 2008.

²² *Ibid.*

²³ See Louafi, Selim and Morin, Jean Frederic, *Certificates of Origin for Genetic Resources and International Trade Law*; IDDRI, 2004, unpublished manuscript in the file of the author, have suggested that in order to ensure consistency with WTO rules, any certification system should be designed on a product basis- not on that of a country or an individual company.

²⁴ Transfer of Technology has also been identified as a benefit sharing option in Appendix 2 of the Bonn Guidelines.

²⁵ In this regard article 1 of the CBD has been pointed out “ It is noteworthy that this fundamental provision of the Convention already includes an explicit reference to technology transfer as a means to implement its third objective”, see *The Role of intellectual property rights in technology transfer in the context of the Convention on*

the Convention on technology transfer reflect the consensus of the international community laid down in key international policy documents, that the development, transfer, adaptation and diffusion of technology and the building of capacity is crucial for achieving sustainable development”²⁶. For instance, technology transfer could be one element of structuring mutually agreed terms and benefit sharing arrangements.

26. At the same time, transfer of technology (e.g. protected by IPRs) may create some links between the IR and TRIPS provisions on this matter.²⁷

2.2. Factual overview of relevant provisions/developments/processes at WIPO

27. Discussions in different WIPO Committees are particularly relevant for genetic resources and TK²⁸, including the Committee on Development and IP²⁹. For reasons of space this study will focus on the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore only.³⁰

2.2.1. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

28. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the WIPO General Assembly in October 2000 as a forum for debate and dialogue on the relationship between intellectual property, traditional knowledge, genetic resources and traditional cultural expressions. It was considered that these topics did not fall within the scope of other WIPO bodies.³¹ The IGC’s mandate consists of analysing aspects of intellectual property related to genetic resources, traditional knowledge and the protection of expressions of folklore. One of the topics the Committee had considered – and continues to do so under its current mandate – is precisely the relationship between intellectual

Biological Diversity, op cit. Decision VII/19 makes an explicit reference to the elaboration and negotiation of the IR to effectively implement the provisions in article 15, 8 (J) and three objectives of the CBD.

²⁶ See *The Role of intellectual property rights in technology transfer in the context of the Convention on Biological Diversity, op cit.*

²⁷ Par 2 of article 16 provides that technology subject to patents or other IPRs access and transfer must be provided “on terms which recognize and are consistent with the adequate and effective protection of IPR”. The inclusion of the phrase “adequate and effective” makes a direct link to the TRIPs. See Bragdon, Susan; Garforth, Kathryn and Hapala, John, *Safeguarding Biodiversity: The Convention on Biological Diversity (CBD)*, in Tansey, Geoff and Rajotte, Tasmin (eds), *The Future Control of Food*; Earthscan, London, 2008.

²⁸ Other aspects related to the topic of disclosure of origin are also being discussed by other WIPO Committees, such as the Standing Committee on Patent Law, in its work on the elaboration of a Substantive Patent Law Treaty, and the Working Group on Reform of the Patent Cooperation Treaty (PCT).

²⁹ In 2007 the WIPO General Assembly did move forward the WIPO Development Agenda and as recommended by the Provisional Committee for the Development Agenda (PCDA), it approved the creation of a new Committee on Development and IP. The main task of the new Committee will be the implementation of the PCDA consensus proposals which were adopted. In particular, the immediate implementation of a list of 19 proposals. One of these proposals is to “ To urge the IGC to accelerate the process on the protection of genetic resources, traditional knowledge and folklore, without prejudice to any outcome, including the possible development of an international instrument or instruments.”

³⁰ See document UNEP/CBD/COP/8/INF/41, “Update on the Activities of the World Intellectual Property Organization (WIPO) in Cooperation with the Convention on Biological Diversity”.

³¹ See further details at www.wipo.int/tk/en/igc/.

property and genetic resources (including disclosure of origin in patent applications) and the protection of TK. The Committee has met on several occasions (13).

29. The scope of work of the IGC includes the possible development of an international instrument or instruments on IPRs and genetic resources as well as traditional knowledge.³²

30. To date, the main work of the WIPO related to the IR content can be summarised as follows:

- **Access to genetic resources**

31. Regarding access to genetic resources, the WIPO has prepared several analyses of the IPR clauses in the agreements on access to genetic resources and benefit-sharing, including materials transfer agreements and model clauses. A data base with public examples has also been created, with an emphasis on IPR clauses. Draft guidelines have also been prepared on IPR clauses in access and benefit-sharing agreements with the aim of providing support to providers and users of genetic resources when negotiating, defining and drafting IP elements of the mutually agreed terms for access and benefit sharing.

32. In addition, in COP Decision VI/24, the WIPO was invited to “prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*: a) genetic resources utilised in inventions; b) the country of origin of the genetic resources utilised in the inventions; c) the associated traditional knowledge, innovations and practices utilised in the inventions; d) the source of the associated traditional knowledge; e) evidence of prior informed consent”. This study, called the Technical Study on Disclosure of Origin Requirements in Patent Systems Related to Genetic Resources and TK, was presented at the COP 7 in Malaysia and was well-received by the COP (Decision VII/19/E). In addition, the COP 7 requested that WIPO prepares a new technical study including the examination and discussion, as appropriate, of aspects related to the relationship between access to genetic resources and disclosure of origin in patent applications, including the following aspects, among others:

- a. Options for model provisions on proposed disclosure requirements
- b. Practical options for IPR application procedures with regard to the triggers of disclosure requirements
- c. Options for incentive measures for applicants
- d. Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties
- e. Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.

33. The WIPO responded to the COP invitation by preparing a new technical document (WO/GA/32/8) entitled “Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications”.

34. WIPO has also jointly prepared a study with UNCTAD and the CBD Secretariat on the role of IPR in technology transfer in the context of the CBD.

³² Following successive decisions of the WIPO General Assembly in 2003, 2005 and 2007, the mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) has provided that “no outcome is excluded,” including the possibility of an international instrument or instruments; the mandate has also laid emphasis on the “international dimension” of the Committee’s work (WO/GA/30/8, para. 93). For a summary of the options on the international dimension outcome see WIPO/GRTKF/IC/13/6.

35. The work of the IGC on genetic resources has also involved the consideration of proposals to improve the recognition of genetic resources in patent examinations, as well as enhanced IT capacity to monitor and review the status of international patent applications making use of genetic resources.

36. In summary, three clusters³³ of substantive questions have been identified in the course of the Committee's work, namely: (i) defensive protection of genetic resources; (ii) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention and alternative proposals for dealing with the relationships between the patent system and genetic resources; and (iii) intellectual property issues in MATs for the fair and equitable sharing of benefits arising from the use of genetic resources, including the preparation of databases and guidelines for the IP content in ABS agreements.³⁴ However, it is unclear whether this debate will result in the elaboration of new legally binding obligations for disclosure of origin requirements³⁵.

37. With regard to a legally binding amendment³⁶, Switzerland has proposed- in essence-, to amend the Regulations under the PCT (PCT Regulations) to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if the invention is directly based on such resources or knowledge (see proposed new Rule 51bis.1 (g)). Furthermore, Switzerland proposes to afford patent applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase (see the proposed new Rule 4.17 (vi)). Under present Rule 48.2 (a)(x), such declaration of the source would be included in the international publication of the international application concerned. In order to advance the discussions on its proposals, Switzerland presented two further submissions to the WIPO Working Group on PCT Reform in April 2004 and April 2005, respectively, containing more detailed explanations on its proposals. These submissions address the use of terms, the concept of the "source" of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, the possible legal sanctions for failure to declare the source or for wrongful declaration of the source, and its optional vs mandatory introduction at the national level.

- **Traditional knowledge**

38. WIPO has prepared an extensive number of documents on positive and defensive measures for the protection of traditional knowledge³⁷. In addition, a range of activities of interest have been carried out on this subject, such as:

- a. The systematic study and clarification of legal options for the protection of traditional knowledge.
- b. The analysis of cases of the use of IPR for the protection of TK, as well as of the establishment of *sui generis* protection systems.
- c. Case studies and analyses of practical experiences.
- d. A draft of a Tool Kit to document traditional knowledge associated with genetic resources.
- e. The progressive recognition of traditional knowledge in patent systems, through the development of guidelines for patent examiners; mechanisms involving links to

³³ Nnandozie, *op cit*.

³⁴ For a update description of the activities and options under the three clusters see WIPO/GRTKF/IC/13/8(a).

³⁵ This statement holds true for all the international discussions on this issue.

³⁶ See submission by EC and its Member States reproduced in document UNEP/CBD/WG-ABS/4/5, section III, B See also Switzerland proposals to modify the PCT and the Patent Law Treaty Agreements PCT/R/WG/4/13 and PCT/R/WG/5/11/rev available at www.wipo.int/pct. The proposals have been submitted to the IGC and also have been presented to the TRIPS Council and the WG-ABS.

³⁷ See WIPO, *Intellectual Property and Traditional Knowledge*, Booklet No 2.

databases to ensure a better understanding of TK as prior art; the incorporation of TK in minimum standards for novelty search by the Patent Cooperation Treaty (PCT).

- f. The development of a draft set of policy objectives and basic principles on TK (the Draft Provisions). These provisions are considered compatible with the CBD although their scope is broader than traditional knowledge related to biodiversity, and they have taken into account the contributions and progress of the Working Group on Article 8 (j).

39. The General Assembly (2007) of the World Intellectual Property Organization renewed the mandate of the IGC to continue its work on intellectual property and traditional knowledge, traditional cultural expressions and genetic resources, on questions included in its previous mandate.

40. The last Committee meeting was held in October 2008 in Geneva³⁸. Two detailed gap analysis reports from the Secretariat highlighting areas where international policy may be needed (for TK and Folklore) were produced and an African Group proposal calling for international instruments was circulated. The gap analysis on TK draw from all of the IGC previous work in outlining where there are protection for TK and where there are gaps in protection and potential ways forward. Despite intense negotiations, delegations were not able to agree on the working procedures required to deliver concrete outcomes. The Chairman of the ICG indicated that he would pursue informal consultations.

41. However, the mandate of the IGC still stands and the work of the IGC will resume when the IGC reconvenes in April 2009 for a regular meeting, with the possibility of intersessional work being again discussed.

2.2.2. Relationship between the IR and WIPO

Annex to Decision IX/12 addresses the protection of TK as one of the IR components³⁹. Several issues under discussion at WIPO are also related to the IR content. The following are the most relevant:

- **Traditional Knowledge**

42. One of the issues connecting the IR and WIPO is the treatment of TK, especially in the light of the development of the Revised Draft Provisions for the Protection of TK which could be seen as an "outline" for an international instrument on TK. Most of the content of the Draft is also closely related to the work carried out at the CBD, especially by the Working Group on Article 8(j) and Related Provisions. However, it should be noted that the Draft Provisions remains controversial and the ICG has not reached a consensus on the manner how to deal with the document or its content.

43. The Working Group on Article 8(j) and Related Provisions is the main CBD body in charge of dealing with TK issues⁴⁰. The WG has also considered, among other issues related to the WIPO

³⁸ ICTSD reporting, "WIPO Poised To Move To Talks On Potential Traditional Knowledge "Treaty," IP-Watch, October 17, 2008; "WIPO Committee On Traditional Knowledge And Folklore Running In Place," IP-Watch, 16 October 2008.

³⁹ Some of the elements for possible negotiation are measures to: ensure the fair and equitable sharing with traditional-knowledge holders of benefits; measures to ensure that access to traditional knowledge takes place in accordance with community level procedures; measures to address the use of traditional knowledge in the context of benefit-sharing arrangements; and identification of individual or authority to grant access in accordance with community level procedures, among others.

⁴⁰ It should be noted that although the COP 7 mandate clearly mentions the need for collaboration between the WGABS and the Working Group on Article 8(j) and Related Provisions, contact between them has been limited to holding a back to back meeting and to the usual information exchange and presentation of reports. See also Decision. See Decision VIII/5 C and Decisions IX/12/20 and IX/13/A.

work, the following⁴¹: non-IPR-based *sui generis* forms of protecting traditional knowledge; elements for *sui generis* regimes; reviewing the applicability of the Bonn Guidelines on this issue; assessing the role of databases and registries in the protection of traditional knowledge; exploring the potential and conditions under which the use of existing and new forms of IPRs can contribute to achieving the objectives of Article 8(j); recommendations regarding the ABS international regime to include *sui generis* systems and measures for the protection of traditional knowledge; draft elements of an ethical code of conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities relevant for the conservation and sustainable use of biological diversity; guidelines for documenting traditional knowledge, and commencing a number of new tasks from the programme of work (tasks 7, 10 and 12 and a terms of reference for task 15), which various Parties have indicated may or may not contribute to the International Regime.

- **Genetic resources and IP**

44. The IGC work has focused on the elaboration of guidelines, technical studies and exchange of experiences. In addition, some proposals have been presented to modify the PCT and the Patent Law Treaty to allow disclosure of source requirements which are intended to be a stand alone disclosure system and not only to be useful for the implementation of disclosure provisions of other fora (see paragraph 37 and footnote 37). The extensive work carried out by the Committee on this issue could be useful for the implementation of a potential disclosure provision or alternative mechanism to address the relationship of intellectual property rights and genetic resources developed in other fora (IR or the WTO).

- **Tools and instruments related to IP and GR and TK Protection.**

45. Finally, WIPO has developed a set of different tools and instruments which may help the future implementation of the components of the IR, e.g. guidelines for the drafting of the IP clauses in ABS agreements; a toolkit for documenting TK; mechanisms to make information on traditional knowledge more accessible to patent examiners, etc.

2.3 Factual overview of relevant provisions/developments/processes at UPOV⁴²

46. The International Convention for the Protection of New Varieties of Plants was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. The 1991 Act of the UPOV Convention entered into force in 1998. As of January 12, 2009 UPOV has 67 members (66 States and the European Community). The mission of UPOV is “to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society”. The UPOV Convention provides a *sui generis* form of intellectual property protection specifically adapted to the process of plant breeding and developed with the aim of encouraging breeders to develop new varieties of plants. To be eligible for protection, varieties have to be: (i) distinct from existing, commonly known varieties; (ii) sufficiently uniform in its relevant characteristics; (iii) stable; and (iv) new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection.⁴³ The Convention offers protection to the breeder, in the form of a “breeder’s right”, if his plant variety satisfies the above conditions. The 1991 Act of the UPOV Convention includes three compulsory exceptions (article 15(1)): namely, the breeder’s right shall not extend to (i) acts done privately and for non commercial purposes, (ii) acts done for experimental purposes; (iii) acts done for the purpose of breeding other varieties (breeder’s exemption). The breeder’s exemption

⁴¹ The WG has addressed many other issues of relevance. These are some of special interest for purpose of this study.

⁴² A general description of the International Union for the Protection of New Varieties of Plants was provided in document UNEP/CBD/WG-ABS/3/2 which highlights its relationship to access and benefit-sharing.

⁴³ UPOV Publication No. 437 (E), November 10, 2003 edition.

optimizes variety improvement by ensuring that germplasm sources remain accessible to all breeders. The 1991 Act also contains an optional exception (Article 15(2)), such that “each Contracting Party may, within reasonable limits and subject to safeguarding of the legitimate interest of the breeder, restrict the breeder’s rights in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety”.

47. UPOV is of the opinion that the Convention on Biological Diversity and the UPOV Convention should be mutually supportive and the international regime on access to genetic resources and benefit-sharing should be designed so that the mutual supportiveness of the UPOV Convention and the CBD will not be affected. The views of UPOV with respect to the work of the Working Group on Access and Benefit-sharing on an international regime on access and benefit-sharing, adopted by the Council of UPOV at its thirty seventh ordinary session on 23 October 2003, were provided to the Secretariat prior to the second meeting of the Working Group. These are available at http://www.upov.int/en/news/2003/intro_cbd.html and provide a useful overview of issues related to the international regime from the perspective of UPOV.

48. A further contribution was provided by UPOV in preparation for the fourth meeting of the Working Group on Access and Benefit-Sharing and was made available in document UNEP/CBD/WG-ABS/4/INF/3 which highlights that the UPOV Convention is not an instrument relating to access and benefit-sharing. As further detailed in the UPOV contribution, it was requested that “consideration is made that any measures pursued in the international regime do not undermine plant variety protection according to the UPOV Convention. For its part UPOV supports the view that the Convention on Biological Diversity and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.”

49. UPOV has also prepared a study⁴⁴ on the impact of plant variety protection and its report is now available on UPOV’s website. The study indicates that “the UPOV system of plant variety protection provides an effective incentive for plant breeding in many different situations and in various sectors, and results in the development of new, improved varieties of benefit for farmers, growers and consumers” and that “farmers, growers and breeders have access to best varieties produced by the breeders throughout UPOV member territories” (pages 3 and 5 of the report).

50. The position of the UPOV Council on access to genetic resources and benefit-sharing related to plant breeders’ rights (PBR) (adopted by the UPOV Council in its session number 37, on 23rd October 2003), mentioned in paragraph 46 above, needs to be briefly presented here to fully understand the options and scenarios:

Access to genetic resources: “UPOV considers that plant breeding is a fundamental aspect of sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the “breeders’ exemption” in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding, and thereby, to maximize the use of genetic resources for the benefit of society”

Disclosure of origin: “[...] UPOV encourages information on the origin of the plant material, used in breeding of the variety, to be provided where this facilitates the examination [for compliance with the conditions of protection], but could not accept this as an additional condition of protection since the UPOV Convention provides that protection should be granted to plant varieties fulfilling the conditions of

⁴⁴ <http://www.upov.int/en/publications/impact.html>

novelty, distinctness, uniformity, stability and a suitable denomination and does not allow any further or different conditions for protection [...]"

" Thus, if a Country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection. A separate mechanism from the plant variety legislation, such as that used for phytosanitary requirements, could be applied uniformly to all activities concerning the commercialization of varieties, including, for example, seed quality or other marketing related regulations"

Prior Informed Consent: [...] " UPOV encourages the principles of transparency and ethical behaviour in the course of conducting breeding activities and, in this regard, the access to the genetic material used for the development of a new variety should be done respecting the legal framework of the country of origin of the genetic material. However, the UPOV Convention requires that the breeder rights should not be subject to any further or different conditions than those required to obtain protection. UPOV notes that this is consistent with article 15 of the CBD, which provides that the determination of access to genetic resources rests with the national governments and is subject to national legislation [...]"

Benefit-sharing: "UPOV would be concerned if any mechanisms to claim the sharing of revenues were to impose an additional administrative burden on the authority entrusted with the grant of breeder's rights and an additional financial obligation on the breeder when varieties are used for further breeding. Indeed, such an obligation for benefit sharing would be incompatible with the principle of the breeder's exemption established in the UPOV Convention whereby acts done for the purpose of breeding other varieties are not, under the UPOV Convention, subject to any restriction and the breeders of protected varieties (initial varieties) are not entitled to financial benefit sharing of varieties developed from the initial varieties, except in the case of essentially derived varieties (EDV). [...]" .

Access and PBR: The legislation on access to genetic material and the legislation dealing with the grant of breeders' rights pursue different objectives, have different scopes of application, and require a different administrative structure to monitor their implementation. Therefore, it is considered appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive.

51. Later, the UPOV Council, at its twenty-fifth extraordinary session held in Geneva on April 11, 2008, decided to request the COP IX to include in the IR decisions the following paragraphs: " Recognizing that UPOV supports the view that the Convention on Biological Resources and the UPOV Convention should be mutually supportive" and "Further Instructs the Ad-hoc Open Ended Working Group on Access and Benefit Sharing that any provisions which it develops for an international regime on access and benefit sharing should ensure mutual supportiveness with the UPOV Convention".

2.3.1 The Relationships between UPOV and the IR

52. UPOV has a direct relevance for the sustainable use of plant genetic resources and for the CBD objectives. However, in the light of the current IR negotiations, the most relevant issues connecting the IR and UPOV are the disclosure of origin/certificate and its relationship with UPOV provisions and the technology transfer (TT) measures related to Plant Breeders Rights. A potential disclosure requirement/check point for the certificate would be the plant breeders right applications⁴⁵, but UPOV

⁴⁵ In the case of plant varieties, there may be technical and practical obstacles to this provision unless it is carefully structured. Some difficulties have been pointed out regarding the applicability of a disclosure requirement to plant varieties, such as: problems that occur when plant varieties originate from genetic material which came from different countries and sources and from crosses and back-crosses; obstacles to determining the origin of the germplasm of a variety because of the lack of documentation and the length of time between its acquisition and its

is of the opinion that this could not be an additional condition of protection. Also TT provisions to be included in the IR could be related to Plant Breeder's Rights.

53. It does not seem that the current IR components as set forth in Annex to Decision IX/12 could negatively impact the basic principles of UPOV, including the freedom to use developed varieties that are protected solely by PVP for further breeding without the consent of the breeder (the breeder exemption)⁴⁶, except for the issue of disclosure of origin drafted as a condition for protection (see paragraphs 50 and 78). However, depending on the form of any future amendments or recommendations and resulting obligations, these may still have the potential to impact UPOV principles.

3. Options and Scenarios

3.1. The IR and the WTO.

54. There are three relevant aspects of the IR which may have an impact on the WTO rules: the disclosure of origin; the certificate of compliance and technology transfer. The following paragraphs explore the different scenarios and options.⁴⁷

- **Disclosure requirements/certificate of compliance developed in the CBD IR negotiations and its relationship to the WTO provisions.**

55. The inclusion and discussion of disclosure requirements and the use of the certificate in patent applications have been two contentious issues during the IR negotiations.⁴⁸ However, one potential scenario would be the inclusion of some form of disclosure requirement in the IR negotiations. In this regard, it has been suggested that the inclusion of mechanisms such as the disclosure of origin of genetic resources and TK or the certificate in patent or other IPR filing procedures as proposed would strengthen mutual supportiveness between the WTO's IPR system and the CBD ABS IR. If the result of the IR negotiations were to be a legally binding instrument, the countries should develop – in their national legislation – disclosure of origin requirements to comply with the international obligations. While there may be some variances with regard to the scope, consequences and practical operations of these requirements, some experts agree that⁴⁹ in general the requirements of disclosure do not run counter to the international IP agreements (see with regard to the UPOV Convention see paragraph 78) and the TRIPS agreement in particular⁵⁰. The same conclusion applies if the IR provisions on

use in breeding programmes, , etc. See also Dutfield, Graham, *Protecting Traditional Knowledge and Folklore. A review of progress in diplomacy and policy formulation*; Issue Paper No. 1, ICTSD and UNCTAD, 2003.

⁴⁶ See article 5(3) of the 1978 Act and Article 15(1)(iii) of the 1991 Act, and point 45.

⁴⁷ See Decision IX/12, Annex I, III (components of the IR) C (Compliance).

⁴⁸ COP Decision VII/ 19, reaffirms the fact that disclosure of origin in IPR applications is part of the terms of reference of the Annex to Decision VII/19 D for the development of the IR. It recognizes that this issue has been discussed in the WIPO and the WTO, and invites the relevant fora to begin (or continue) discussing the topic of disclosure of origin in IPR applications, bearing in mind the need to ensure that their work is supportive of and does not run counter to CBD objectives.

⁴⁹ See Nandozie et al, *op cit*; Sarnoff and Correa, *op cit*; Rojas, Martha et al (ed.) *Disclosure requirements: ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD*; IUCN, Gland and ICTSD, Geneva, 2005; Tobin et al *op cit*: Cabrera Medaglia Jorge,, *The international regimen for access and benefit sharing*; IUCN; Quito, 2006.

⁵⁰ Interpretation of the TRIPS agreement is undertaken under the procedures of the WTO (Article IX.2 of the WTO Agreement).For the intellectual property point of view existing standard on patentability scope and use of patents, such as those set out in articles 27, 29, 32, and 62 of the TRIPS agreement may afford some guidance to how WIPO and WTO Member States may address this concept. See WIPO Technical Study on patent disclosure requirements related to Genetic Resources and Traditional Knowledge, Study No. 3 available at www.wipo.int/tk.

disclosure were non-legally binding. In addition, there are ongoing negotiations regarding disclosure at the WTO and no final decision has been made yet whether to accept or not the disclosure requirements in the TRIPS Agreement.

56. Alternatively, a “soft version” of the disclosure could also be developed at the CBD to encourage the adherence of some countries which are already opposed to disclosure requirement (both in the WTO and the CBD). However, some delegations and stakeholders do not support any disclosure requirements in IP applications and support alternative mechanisms to address concerns regarding misappropriation. In their view new patent disclosure requirements will be ineffective in promoting the objectives sought and will introduce uncertainties into the patent system.

57. Under this scenario (the development of disclosure requirements in the IR) the IR negotiations could promote more clarity on relevant issues such as the meaning and implications of PIC and benefit-sharing requirements. Some of the objections to the disclosure provisions are related to the lack of clarity about the exact scope and the legal implications of the terms used. A number of terms and concepts which are central to the ABS regime, such as “fair and equitable benefit sharing”, “traditional knowledge” are not defined in the CBD, nor is “access to genetic resources” for that matter. The definition of terms is an ongoing process in the CBD and was included in the mandate of prior ABS Working Group meetings⁵¹. The IR could clarify issues of PIC, benefit-sharing, certificate of origin, etc. It also could offer guidance on key topics, such as the scope of the terms ‘genetic resource’, ‘biological resource’, etc.

58. This scenario would however present two main disadvantages: one the condition of non-CBD Party of a relevant IP country: the United States, and the difficulties for the integration of the disclosure requirements into the IP system if the provisions would be integrated in the CBD.⁵²

59. In relation to the certificate, the IR could provide the necessary practical and operational details for its use in IPR applications. The certificate as such has not been discussed at the WTO, but the development of appropriate provisions on the certificate under the IR could facilitate the use of the certificate for disclosure of origin purposes. It is clear that the certificate has a broader scope and objectives than merely serving as an instrument to promote disclosure⁵³. However, a certificate system which serves merely to demonstrate compliance with the requirements of the laws of the providing country and a legal title to use of the resources and identify the rights and limitations attached to the access and use would not appear to run counter the WTO rules. However, it would depend on how the certificate, if agreed, is finally designed. The certificate, if it is designed in a non discriminatory fashion, could be in harmony with the trade system and both instruments could be developed in a mutually supportive manner.

- **Disclosure of origin/source at the WTO.**

60. A different scenario is the incorporation of disclosure provisions at the WTO (in this case through a legally binding amendment to the TRIPS Agreement). The exact scope and precise content of a potential amendment of the WTO is still uncertain (whether or not sanctions for non-compliance will be outside the patent law or not; the necessity of proving compliance with PIC and benefit-sharing; etc) as well as the amendment per se. However, this scenario also would create mutual supportiveness between the IPR system of the WTO and the CBD ABS IR.

⁵¹ Decision IX/12 created an Expert Group on concepts, terms, working definitions and sectoral approaches.

⁵² Sarnoff and Correa, op cit “Locating such provisions within the CBD regime would not incorporate disclosure requirements directly into the intellectual property law system , and thus would complicate efforts to assure that disclosure obligations are adopted within the intellectual property treaty regimes. Further disclosure requirements mandated within the CBD would not directly apply to the intellectual property systems of countries that are not Parties of the CBD”. This is the case of the United States which is a signatory but has not yet ratified the CBD.

⁵³ About the certificates objectives see, the Report of the Technical Expert Group, op cit, par. 4.

61. In addition, under this scenario, the disclosure could also contribute to the “defensive protection”⁵⁴ of TK, therefore supporting the TK component as well as the compliance component under the IR. Requirements for disclosure of the origin of traditional knowledge associated with genetic resources may assist in ensuring prior informed consent and equitable benefit-sharing with regard to both traditional knowledge and the associated genetic resources.

62. Considering the large membership of the WTO and its economic relevance for the Contracting Parties, this amendment would promote a better and wider integration of the disclosure of origin in the IP system (and in the national laws) and would promote broad implementation of the instrument. In this case, the CBD may provide assistance and coordination in developing and implementing disclosure requirements by clarifying terms and instruments (including the certificate role in the disclosure)(see paragraph 57). A reference and description of the disclosure mechanism in the context of the compliance component of the IR could also be established, but the substantive provisions would be integrated into the TRIPS agreement.

- **No disclosure requirements in either instrument.**

63. Another scenario would be the absence of disclosure requirement provisions in both the CBD IR (whether in a legally binding form or not) and in the WTO. In this case there will be no conflict between the IR and WTO, but – in the view of some countries and experts – an opportunity to promote mutual supportiveness between IPR system (WTO) and the CBD ABS IR could be lost. However, some countries and stakeholders support this approach because it would avoid the alleged negative consequences of new patent disclosure requirements mentioned in paragraph 56. These delegations and stakeholders support other mechanisms to address concerns regarding misappropriation.

- **Technology transfer provisions developed in the IR**

64. Technology transfer (TT) provisions could be specifically developed in the context of the IR benefit sharing component in line with the current provisions and language of the CBD itself.

65. TT provisions could take place in different ways. IR outcome could be minimum benefit sharing conditions, including some TT measures. Therefore the IR could set minimum requirements for benefit-sharing to be included in the mutually agreed terms, including TT. Technology transfer measures could also be developed as a direct obligation for CBD Members. These provisions could be similar to the ones already included in the CBD (articles 15, 16 and 19).

66. Both types of provisions could be drafted to be in harmony and provide mutual supportiveness between the IR and the WTO/TRIPS IPR provisions⁵⁵. These measures would be compatible and mutually supportive of the WTO efforts and text regarding technology transfer, including the Doha Mandate (par. 19).

3.3. The IR and WIPO

⁵⁴ WIPO, *Intellectual Property and Traditional Knowledge*, Booklet No. 2

⁵⁵ See TRIPs Articles 7 (Objectives... “the protection and enforcement of IPR should contribute to the promotion of technological innovation and to the transfer and dissemination of technology...”) and 8 (principles “Members may, in formulating or amending their laws and regulations, adopt measures necessary to... promote the public interest in sector of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement); art 66.2 (Least Developed Country Members...“Developed Countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members...”). The TRIPs Council adopted a Decision on February 2003 which lays down an obligation to developed countries to submit reports on actions taken or envisaged to provide such incentives.

67. At the time of writing, the type of outcome of the IGC process is not known. Therefore there is not a legally binding or non-binding instrument which may conflict with or support the IR results.⁵⁶ However, there are different scenarios depending on the final outcome of the IGC.

- **IR and ICG continue their work in parallel without specific coordination.**

68. It could be argued, that the Draft Provisions⁵⁷ for the protection of traditional knowledge could provide the normative substance and content of an international outcome on the protection of traditional knowledge.

69. In essence, the Draft Provisions on TK protection which embody policy objectives and core principles could be the basis for a proposed international instrument, in line with the current mandate of the IGC which is to focus on the international dimension and contemplates the development of an international instrument for TK protection⁵⁸. The Draft is thus in full harmony with the CBD, even if the scope of the TK covered by the Draft Provisions is not limited to biodiversity-related TK⁵⁹. The Draft Provisions cover all TK falling within the scope of the definition contained in the principle B.3 of the Draft Provisions. As it was stated before the Draft Provisions remain controversial and the IGC has not reached an agreement about how to deal with the document or its content.

70. If the result of the IGC were to be a legally binding instrument – based on the current content of the Draft Provisions for the TK Protection – there would not be conflict with the IR process (whether the outcome of the latter is a binding or non-binding instrument)⁶⁰. Any binding or non-legally binding outcome of the IR would, in principle, support and be complementary to the IGC efforts. This outcome, of course, would likely finally depend on how these instruments are drafted.

- **IR focuses on specific TK issues taking into account the WIPO developments**

71. However, a different scenario may also be considered. Despite the fact that there is no potential conflict between the IR content on TK and the ICG outcomes, there is a likely overlap of some of the provisions under negotiation in both fora. If the final outcomes of the IGC and the IR are binding instruments this potential overlap could create some duplication of legal obligations.

72. Having this in mind, one possible option, taking into account the detailed developments found in the Draft Provisions, is that the IR could establish provisions for the TK protection focusing on specific issues to be agreed sometime during the IR negotiating process.

73. It could be an option that the IR would include, for instance, umbrella or general provisions. Among the elements to be considered for inclusion in the IR, emphasis could be placed on the following: the role of customary law in the protection of TK; the establishment of *sui generis* systems^{61 62}; the development of operational guidelines or procedures for obtaining PIC from local communities and indigenous peoples⁶³. Thus, the IR could contribute to establishing certain basic

⁵⁶ See WIPO/GRTKF/IC/13/6 options for the international dimension of the Committee's work

⁵⁷ Draft set of Revised Objectives and Principles for the Protection of Traditional Knowledge (the Draft Provisions). The Draft Provisions contained 16 policy objectives; 10 General Guiding Principles; and 14 substantive principles (protection against misappropriation; legal from of protection, etc).

⁵⁸ See WIPO, *Information Resources on IP and Genetic Resources, TK and TCE*: Information source, 2006.

⁵⁹ The Draft Provisions include a core principle 7 (g) "Respect for and cooperation with other international and regional instruments and processes".

⁶⁰ See the African Group proposal document WIPO/GRTKF/IC/13/9 (September 2008), which expressed the opinion that the ultimate objective of the process should be the development of and adoption of a legally binding instrument for the protection of TK, Folklore and Genetic Resources.

⁶¹ See Decision VIII/5 and Decision IX/13 H adopted at the last COP.

⁶² The Annex to Decision IX/12 does not expressly address the "Sui Generis Systems". However, Decision VII/19 did mention these systems as one of the potential "elements" of the IR.

⁶³ See Decision VIII/5 and Decision IX/13 H adopted at the last COP.

premises about PIC and benefit-sharing. In this way, the measures to support the PIC and MAT of indigenous peoples and local communities could constitute another element of the IR relating to the protection of TK. Specifically, the Regime could consider the acquisition of TK without having obtained PIC as an act of misappropriation. The WIPO IGC could continue its work on more detailed provisions for the TK protection e.g. those found in the current Draft Provisions.

74. However, this option presents several disadvantages, such as the following: the lack of concrete normative results of the WIPO IGC so far; the uncertainty about the potential outcome to be expected (both the content and the nature) at WIPO; the different Membership in both fora; and finally, the risk of lacking control by the CBD Members of the results to be achieved if some content of the negotiation is left under the WIPO process.

- **IR recognition of some IGC tools and instruments**

75. The IR could also benefit from the extensive information and resources developed at the IGC both in the area of TK and genetic resources. The technical input of the IGC could help in the implementation of the IR outcome. In this regard, the IR could *recognize* the relevance of these instruments to the IR content (e.g. for disclosure of origin purposes; for TK protection, for capacity building, etc) and decide to use these technical inputs and tools, as appropriate. It does not imply that the IR could not develop specific tools and instruments to address particular concerns/needs. With regard to disclosure requirements, the IGC work so far has focused more on technical studies and other related activities to improve the understanding of these requirements. Whether an outcome of the IR is a legally binding disclosure requirement or not, the IGC work could also facilitate the implementation of the disclosure provisions or alternative measures to address issues related to the relationships between intellectual property and genetic resource if included in the IR negotiations. Some delegations and stakeholders also expressed the notion that WIPO has the appropriate expertise to address intellectual property issues related to the IR negotiations.

- **IR and other WIPO Treaties**

76. Finally, even if some commentators and States are of the opinion that a disclosure requirement, when agreed internationally, would entail changes in two intellectual property rights treaties administered by the World Intellectual Property Organization, namely, the Patent Law Treaty (PLT) and the Patent Cooperation Treaty (PCT)⁶⁴, there is no final legal conclusion on the consequences of disclosure on these Treaties administered by the WIPO⁶⁵.

3.4 The IR and UPOV

77. Despite the UPOV Council position on the IR and the UPOV Convention, some authors are of the opinion that a disclosure of origin requirement does not necessarily conflict with UPOV basic rules.⁶⁶

⁶⁴ See paragraph 37, footnote 37.

⁶⁵ See Sarnoff and Correa *op cit.* consider unnecessary of such modification. It has been also indicated that the PCT does not have a mechanism for a distinct declaration concerning source of GR/TK as a separate element of form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is “not intended to be construed as prescribing anything that would limit the freedom of each Contracting Party to prescribe such substantive conditions of patentability as it desires” See WIPO Technical Study on patent disclosure requirements related to genetic resources and traditional knowledge. Study No. 3. For an analysis of the the reasons behind this proposal, see Girberger, Martin, Transparency Measures under Patent Law regarding Genetic Resources and Traditional Knowledge. Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing, *Journal of World Intellectual Property*, Vol. 7, No.4, July 2004, Geneva.

⁶⁶ Sarnoff and Correa “Although UPOV has suggested that disclosure obligations that would deny or invalidate plant rights conflict with the UPOV Convention, UPOV did not directly address the issue of entitlement to apply for such rights, but rather treated such requirements as an additional condition for protection”.

At the same time, there are no known initiatives within UPOV to modify the UPOV Convention for the inclusion of disclosure requirements. With regard to the WTO discussions on disclosure, these take place in the context of the patent system and it would not affect PBR protection.⁶⁷

- **Disclosure/ certificate requirements established for PBR in the IR**

78. For these reasons, a potential option to include the disclosure of origin in PBR as a result of the CBD IR negotiations could conflict with the UPOV interpretation about the compatibility between the disclosure requirements and UPOV conditions for protection⁶⁸, if the disclosure requirements were drafted as an additional condition for protection.

79. If the IR negotiations outcome on disclosure were to be contained in a legally binding instrument, a potential inconsistency between the two agreements would exist. Such an approach could be a disincentive for the UPOV members to become Parties to the legally binding IR.

80. Another option is to amend the UPOV Convention to include a disclosure of origin condition for the protection of Plant Breeders' Rights. However, there is no information that such a process has been suggested by UPOV members.

- **Exclusion of PBR from the disclosure/certificate or an alternative drafting**

81. One option is to exclude PBR applications from the disclosure provisions or to create a different and special system taking into account both the legal and technical implications of such system for the case of plant varieties. A special disclosure requirement could be designed taking into account the legal requirements and conditions established in the UPOV Convention and the process of the access and use of plant genetic material for the breeding of new varieties.

- **Technology transfer provisions and UPOV**

82. There are not specific technology transfer provisions as such in the UPOV Convention. However, similar arguments and conclusions than the ones presented in the WTO section (point 63) could be made with regard to TT provisions developed in the IR and UPOV⁶⁹. The IR could establish TT provisions related to plant variety protection which could co-exist in harmony and be mutually supportive of the UPOV Convention.

- **IR statement on mutual supportiveness with the UPOV Convention**

83. UPOV Council statements have called repeatedly for mutual supportiveness between both instruments. In addition, references to UPOV in the current IR negotiating text are found under some of the options for the IR Scope. One possible option is to expressly include a reference to the mutual supportiveness between the UPOV Convention and the IR. However, it could be objected on the grounds that similar statements could also be made not just for the UPOV Convention but for many other international instruments and processes.

⁶⁷ Sarnoff and Correa *op cit*. "Applying such disclosure requirements only in the context of patents, however, would not affect other intellectual property applications whose subject matter implicates CBD access and benefit sharing requirements. Of particular relevance such a limitation would not apply mandatory disclosure obligations to the subject matter of plant breeders rights".

⁶⁸ The same argument applies to the certificate as an instrument to facilitate the disclosure requirements.

⁶⁹ See *The Role of intellectual property rights in technology transfer in the context of the Convention on Biological Diversity*, *op cit*, paragraph 48, note 14.

4. Final Remarks

84. There is a lot space to strengthen mutual supportiveness between the IR outcome and the WTO, WIPO and UPOV processes and instruments. In principle, the IR whether binding or non-legally binding, could co-exist in harmony with the other treaties or processes, taking into account the arguments and options presented in this study.

85. The calls for mutual supportiveness between the CBD, WTO, WIPO and UPOV regimes can be read as implying the need to make compatible multiple regimes with very different objectives, approaches and values demanding and claiming legal protection⁷⁰.

⁷⁰ See Nnandozie et al, *op cit*.