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# THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY - SUMMARY OF ISSUES RAISED AND POINTS MADE - SUBMISSION BY THE WTO SECRETARIAT

The Executive Secretary is pleased to circulate the attached note made available by the World Trade Organization (WTO) Secretariat for the information of participants in the eighth meeting of the Conference of the Parties. The note is a WTO Secretariat summary of the issues raised and points made in the work of the WTO Council for TRIPS on the question of the relationship between the TRIPS Agreement and the Convention on Biological Diversity.

The paper is being circulated in the form and language in which it was received by the Convention Secretariat.

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WORLD TRADE ORGANIZATION

IP/C/W/368/Rev.1
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**Council for Trade-Related Aspects of Intellectual Property Rights**

# THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

## SUMMARY OF ISSUES RAISED AND POINTS MADE

Note by the Secretariat

Revision

*This document has been prepared under the Secretariat's own responsibility and without prejudice to the positions of Members and to their rights and obligations under the WTO*

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## I. INTRODUCTION

1. At its meeting of 17-19 September 2002, the Council for TRIPS requested the Secretariat to periodically update its summary notes on issues raised and points made in the Council's work on three items of its agenda: namely the review of the provisions of Article 27.3(b); the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD); and the protection of traditional knowledge and folklore. It was requested that this be done not after every meeting, but when significant new material had been presented. The present document, which replaces the earlier summary note in IP/C/W/368, responds to this request with respect to the relationship between the TRIPS Agreement and the CBD.

2. This note, like the original note, seeks to summarize the relevant material presented to the TRIPS Council, whether in written or oral form, and lists all the relevant documentation tabled in the Council since 1999. To avoid undue duplication, cross-references to the other two notes or to other sections of this note have been made in certain places. In accordance with the mandate given to the Secretariat, the note only contains issues raised and points made by delegations in the Council for TRIPS and does not cover the documentation of the Committee on Trade and Environment and of the General Council, unless the relevant paper has also been circulated as a Council for TRIPS document. Nor does it cover the discussions in the Director-General's consultative process on outstanding implementation issues.

3. The TRIPS Council documentation relevant to its work on all the three issues is listed in the Annex to this note. Specific documents are also referred to in the footnotes which reflect the sources for the points made in the compilation. In many cases, the same point has been made more than once; the footnotes do not purport to contain references to all such occasions. Where a group of delegations has made submissions, the footnotes use an abbreviated reference rather than listing the sponsoring delegations in full. The full lists can be found in the Annex to this note.

4. It is emphasized that this note is an attempt to summarize the work done so far. By its very nature, it cannot include a full reflection of all the interventions made and documents submitted. It is structured around the issues raised rather than the positions of individual Members. Therefore any reader wishing to appreciate fully the position of a particular Member should consult the statements made and any papers submitted by that Member.

5. This note is divided into three major sections. The first concerns general views on the relationship between the TRIPS Agreement and the CBD, the second concerns patentability of genetic resources and the CBD, and the third concerns the TRIPS Agreement and prior informed consent/ benefit sharing.

## II. GENERAL VIEWS ON THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CBD

6. Two general issues concerning the overall relationship between the TRIPS Agreement and the CBD that have been raised in the discussion are:

- whether or not there is conflict between the TRIPS Agreement and the CBD;

- whether something needs to be done, at least on the TRIPS side, to ensure that the two instruments are applied in a non-conflicting and mutually supportive way, and if so, what.

7. With regard to these two questions, the views expressed appear to fall into four broad categories:

- there is no conflict between the two Agreements and governments can implement the two in a mutually supportive way through national measures;

- there is no conflict between the two Agreements and, while governments can implement the two in a mutually supportive way through national measures, further study is required to determine whether any international action in relation to the patent system is called for;

- there is no inherent conflict between the two Agreements but there is a case for international action in relation to the patent system in order to ensure or enhance, in their implementation, the mutual supportiveness of both Agreements. There are differences of view on the exact nature of the international action needed, including on whether or not an amendment is needed to the TRIPS Agreement, to promote the objectives of the CBD as discussed in Section IV.B below;

- there is inherent conflict between the two instruments, and the TRIPS Agreement needs to be amended to remove such conflict.

8. With regard to the first category of views, the following are the main reasons that have been put forward in support of the view that there is no conflict between the TRIPS Agreement and the CBD and little or no likelihood of a conflict in practical implementation:

- the TRIPS Agreement and the CBD have different, non-conflicting objectives and purposes and deal with different subject-matter and can and should be implemented in a mutually supportive manner at the national level[1];

- correctly applying the criteria for patentability will ensure the grant of valid patents over inventions that use genetic material; such patents do not prevent compliance with the provisions of the CBD regarding the sovereign right of countries over their genetic resources, prior informed consent and benefit sharing[2]; and

- no specific examples of conflict have been cited.[3]

9. Pursuant to these views, it has been said that no change is required to the TRIPS Agreement to accommodate the implementation of the CBD and that implementation of each should be pursued in separate frameworks.[4] In fact, implementation of the TRIPS Agreement is supportive of measures that would implement the obligations of the CBD most effectively: for example, patents can be instrumental in the sharing of benefits and the conservation of biological diversity based on voluntary contracts; the requirements of the patent system material to patentability and inventorship can help prevent bad patents; the control over production and distribution given to patent owners and their licensees can facilitate the sharing of technology; and the protection of undisclosed information could

[1] Australia, IP/C/W/310, IP/C/M/47, para. 55, IP/C/M/46, para. 62, IP/C/M/40, paras. 100-101, IP/C/M/38, para. 236, IP/C/M/36/Add.1, para. 222; Canada, IP/C/M/47, para. 66, IP/C/M/40, para. 115, IP/C/M/37/Add.1, para. 232, IP/C/M/36/Add.1, para. 229; Japan, IP/C/W/236, IP/C/M/47, para. 69, IP/C/M/39, para. 137, IP/C/M/26, para. 77, IP/C/M/25, para. 93; Korea, IP/C/M/46, paras. 52-53, IP/C/M/42, para. 104; United States, IP/C/W/434, IP/C/W/257, IP/C/W/209, IP/C/W/162, IP/C/M/43, para. 55, IP/C/M/42, para. 109.

[2] United States, IP/C/W/209, IP/C/W/162, IP/C/M/46, para. 24, IP/C/M/25, para. 71.

[3] United States, IP/C/W/209, IP/C/W/162, IP/C/M/29, para. 181.

[4] Australia, IP/C/W/310, IP/C/M/46, para. 62, IP/C/M/42, para. 118, IP/C/M/40, para. 100, IP/C/M/36/Add.1, para. 222; Japan, IP/C/W/236; Korea, IP/C/M/28, para. 164; Singapore, JOB(00)/7853, IP/C/M/49, para. 147, IP/C/M/29, para. 168; Switzerland, IP/C/W/400/Rev.1, IP/C/M/43, para. 59; United States, IP/C/W/434, IP/C/W/257, IP/C/M/47, para. 42, IP/C/M/46, para. 23, IP/C/M/45, para. 44, IP/C/M/43, para. 55, IP/C/M/40, para. 122, IP/C/M/30, para. 154.

help the implementation of biosafety and benefit-sharing rules.[5] Benefit sharing provisions of the CBD can also be implemented through governmental fund-granting activities[6] and the financial mechanism provided for under Articles 20 and 21 of the CBD.[7]

10. The view has been expressed that Members appear to share several broad policy objectives, including those of ensuring authorized access to genetic resources, achieving equitable sharing of benefits arising from the use of traditional knowledge and genetic resources and preventing the grant of erroneously issued patents, and that the most effective means to achieve these objectives is through tailored national solutions, including contracts, to meet practical concerns and actual needs.[8]

11. In support of the second category of views, that there is no conflict between the two Agreements and that further study is necessary to determine whether any international action in relation to the patent system is called for, it has been said that:

- no conflict between the TRIPS Agreement and the CBD has been demonstrated nor has it been shown that there is any crisis in the existing patent system[9];

- there is very little concrete evidence at this stage that national systems for regulating access to genetic resources and benefit sharing are *per se* insufficient to deal with so-called misappropriation of such resources. More analysis and sharing of national experiences is necessary in order for Members to better understand the implications of some of the legal and theoretical concepts before any action is taken at the international level to ensure that the two Agreements are mutually supportive[10];

- there are other options, short of amending the TRIPS Agreement, that could be used to address the problem and which require the strengthening of legal and administrative regimes outside the field of intellectual property. These options include information sharing between patent offices or mechanisms to improve disclosure of relevant information, such as establishment of databases[11];

- the importance of both the prevention of biopiracy and misappropriation of genetic resources and traditional knowledge, as well as the promotion of a balanced patent system that benefits patent applicants and the public interest should be recognized.[12]

12. The proponents of the first two categories of views have suggested that discussion in the TRIPS Council should be fact-based, review past national experiences and situations that have prompted various concerns[13] and consider how each proposed approach could have been used to provide appropriate solutions.[14] For example, it may be helpful for those Members with access and

[5] United States, IP/C/W/434, IP/C/W/257, IP/C/M/30, para. 154.
[6] Japan, IP/C/W/236.
[7] United States, IP/C/W/257.
[8] Australia, IP/C/M/46, para. 62; United States, IP/C/W/434, IP/C/W/257, IP/C/W/209, IP/C/M/46, paras. 30-32, IP/C/M/43, para. 55, IP/C/M/42, para. 109, IP/C/M/40, paras. 122 and 124, IP/C/M/39, paras. 129-130, IP/C/M/38, para. 234, IP/C/M/37/Add.1, paras. 234-235 and 250, IP/C/M/36/Add.1, para. 231.
[9] Australia, IP/C/M/48, paras. 84 and 86, IP/C/M/46, para. 65, IP/C/M/40, para. 101; Canada, IP/C/M/47, para. 66, IP/C/M46, para. 55, IP/C/M/40, para. 115; New Zealand, IP/C/M/47, para. 54, IP/C/M/46, para. 61.
[10] Australia, IP/C/M/46, para. 65, IP/C/M/40, para. 101; Canada, IP/C/M/47, para. 66, IP/C/M46, para. 55, IP/C/M/40, para. 115; New Zealand, IP/C/M/47, para. 54, IP/C/M/46, para. 61.
[11] Australia, IP/C/M/40, para.101; Canada, IP/C/M/40, para. 115.
[12] Canada, IP/C/M/48, para. 69.
[13] Switzerland, IP/C/M/47, para. 75.
[14] Australia, IP/C/M/46, para. 65; Canada, IP/C/M/46, para. 55; Japan, IP/C/M/46, para. 77; New Zealand, IP/C/M/47, para. 54, IP/C/M/46, para. 61; Singapore, IP/C/M/49, para. 147; United States, IP/C/W/434, IP/C/M/48, para. 34, IP/C/M/47, para. 48, IP/C/M/46, para. 36.

benefit-sharing systems currently in place to identify the perceived problems, in particular with respect to monitoring and enforcement under such systems, in order to have a fact-based discussion in the WTO.[15] There have been questions raised by some who, while welcoming the discussion on the proposals made in terms of the supporting role that intellectual property systems could play in achieving the objectives of the CBD, have sought more clarity.[16]

13. In support of the third category of views, it has been said that, while there may be no inherent conflict between the two Agreements, there is a case for enhanced international action in relation to the patent system to ensure or enhance, in their implementation, the mutual supportiveness of both Agreements and avoid potential conflict in their application in practice.[17]

14. It has been suggested by those who take this view that some international action is needed to require patent applicants to disclose the source and/or country of origin of any biological resources or traditional knowledge used in inventions. Three proposals have been discussed in this regard:

- that the TRIPS Agreement should be amended to incorporate certain requirements of the CBD. In particular, a suggestion has been made that patent applicants should be required to disclose the source and country of origin of any biological resources or traditional knowledge used in inventions, and to demonstrate that they had obtained prior informed consent from the competent authority in the country of origin and

[15] United States, IP/C/M/48, para. 34.

[16] Chinese Taipei, IP/C/M/46, para. 71; Hong Kong, China, IP/C/M/46, para. 88; Malaysia, IP/C/M/45, para. 37, IP/C/M/44, paras. 40-41, IP/C/M/39, para. 138; New Zealand, IP/C/M/49, para. 119, IP/C/M/47, para. 52, IP/C/M/46, para. 60, IP/C/M/44, para. 45 .

[17] Andean Community, IP/C/M/37/Add.1, para. 231; Brazil, IP/C/W/228, IP/C/M/48, para. 35, IP/C/M/32, para. 128, IP/C/M/29, paras. 146, 148 and 234, IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/356, para. 10; China, IP/C/M/47, para. 57, IP/C/M/42, para. 119, IP/C/M/39, para. 132, IP/C/M/38, para. 239, IP/C/M/37/Add.1, para. 229, IP/C/M/36/Add.1, paras. 227-228; Colombia, IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; EC, IP/C/W/383, IP/C/W/254, IP/C/M/48, para. 62, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 226, IP/C/M/35, para. 233; Egypt, IP/C/M/37/Add.1, paras. 203-204, IP/C/M/36/Add.1, para. 215; India, IP/C/W/198, IP/C/W/195, IP/C/M/48, para. 53, IP/C/M/38, para. 232, IP/C/M/36/Add.1, para. 212, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217, IP/C/M/32, para. 135; Kenya, IP/C/M/47, para. 68, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Norway, IP/C/W/293, IP/C/M/38, paras. 241-242, IP/C/M/32, para. 125; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/48, paras. 92-93, IP/C/M/36/Add.1, para. 203; Philippines, IP/C/M/47, paras. 79-80; Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/48, para.16; Thailand, IP/C/M/48, para. 61, IP/C/M/42, para. 105, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.

entered into fair and equitable benefit-sharing arrangements[18] or that they followed national legal requirements[19];

- that the Regulations of the PCT of WIPO should be amended so as to explicitly enable countries to require patent applicants to disclose the source of genetic resources and traditional knowledge, if the inventions are directly based on these resources or this knowledge; the proposals would also grant applicants the possibility of satisfying this requirement at the time of filing an international patent application, or later during the international phase. This declaration of source would be included in the publication of the international patent application in order to render it accessible to the public at the earliest stage possible[20];

- that a mandatory disclosure requirement should be established relating only to origin or source of genetic materials for all patent applicants at the national, regional and international levels, with penalties for non-compliance outside the patent system.[21] Work on these ideas should be pursued in WIPO, CBD and FAO and, where and when relevant, in the TRIPS context to ensure policy coherence in all forums dealing with issues relevant to the interplay between TRIPS and CBD in order to facilitate an integrated approach across institutions.[22]

15. In respect of the fourth category of views, two main reasons have been put forward to support the view that there is an inherent conflict between the TRIPS Agreement and the CBD:

- the TRIPS Agreement, by requiring that certain genetic material be patentable or protected by *sui generis* plant variety rights and by not preventing the patenting of other genetic material, provides for the appropriation of such genetic resources by private parties in a way that is inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD[23];

[18] Andean Community, IP/C/M/37/Add.1, para. 231; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/403, IP/C/W/356; Brazil, IP/C/W/228, IP/C/M/49, para. 154, IP/C/M/46, para. 81, IP/C/M/42, para. 101, IP/C/M/39, para. 126, IP/C/M/38, para. 230, IP/C/M/37/Add.1, para. 237, IP/C/M/36/Add.1, para. 219, IP/C/M/33, para. 121, IP/C/M/32, para. 128, IP/C/M/29, paras. 146, 148, IP/C/M/28, para. 135, IP/C/M/27, para. 122; China, IP/C/M/47, para. 57, IP/C/M/37/Add.1, para. 229, IP/C/M/36/Add.1, paras. 227-228; Colombia, IP/C/M/46, para. 57, IP/C/M/42, para. 119, IP/C/M/40, para. 121, IP/C/M/38 para. 239; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; India, IP/C/W/198, IP/C/W/195, IP/C/M/49, paras. 86-90 and 134-146, IP/C/M/45, para. 25, IP/C/M/42, para. 113, IP/C/M/40, paras. 81-82; IP/C/M/36/Add.1, paras. 212 and 214, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/49, para. 159, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Kenya, IP/C/M/47, para. 68, IP/C/M/46, para. 67, IP/C/M/42, para. 114, IP/C/M/40, para. 107, IP/C/M/37/Add.1, para. 239, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/40, para. 84, IP/C/M/36/Add.1, para. 203; Philippines, IP/C/M/47, paras. 79-80; Thailand, IP/C/M/42, para. 105, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.

[19] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76-79.

[20] Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115, IP/C/M/46, para. 22, IP/C/M/45, paras. 47-48, IP/C/M/44, para. 25, IP/C/M/42, paras. 97 and 99, IP/C/M/40 para. 71.

[21] EC IP/C/W/383, IP/C/M/49, paras. 123-124, IP/C/M/46, paras. 43-49; Norway, IP/C/W/293, IP/C/M/47, paras. 64-65.

[22] EC, IP/C/W/383, IP/C/W/254, IP/C/M/35, para. 234, IP/C/M/30, paras. 144 and 146; Norway, IP/C/W/293, IP/C/M/47, para. 65, IP/C/M/32, para. 125.

[23] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76-79; Kenya, IP/C/M/47 para. 68, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144.

- the TRIPS Agreement provides for the patenting or other intellectual property protection of genetic material without ensuring that the provisions of the CBD, including those relating to prior informed consent and benefit sharing, are respected.[24]

Similar points have been made about the relationship between the TRIPS Agreement and the provisions of the CBD relating to the traditional knowledge of indigenous peoples and local communities.

16. It has been suggested by those who hold the fourth category of views that Article 27.3(b) of the TRIPS Agreement be amended so as to oblige all Members to make life forms and parts thereof non-patentable.[25] If this were not possible, at least patents for those inventions based on traditional or indigenous knowledge and essentially derived products and processes should be excluded and the TRIPS Agreement should be amended so that patents inconsistent with Article 15 of the CBD are not granted.[26] With respect to the protection of plant varieties, it has been proposed that a balance be struck between the interests of the community as a whole and protecting farmers' rights and traditional knowledge and ensuring the preservation of biological diversity.[27] (These views have been contested by others. See Section III of this note and the summary of discussion on these issues in IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1). The proponents of this view have supported the disclosure proposal outlined in the first indent of paragraph 14 above.

17. On the issue of which is the appropriate forum to discuss this issue, it has been said that, while the mandate given at Doha to the WTO is recognized, WIPO, in particular the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) or the Working Group on PCT reform[28], provides the more appropriate forum since it has more technical expertise on these issues, and duplication of work should be avoided.[29] In response it has been said that, given the mandate in paragraph 19 of the Doha Ministerial Declaration, particularly with regard to fully taking into account the development dimension, it is the TRIPS Council that provides a fully appropriate forum to examine this issue further although the work in other relevant international organizations should be taken into account.[30] The view has also been expressed that solutions to the concerns raised about the TRIPS Agreement should be found in the WTO, and "forum shopping"

[24] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163; Brazil, IP/C/W/228, IP/C/M/48, para. 37, IP/C/M/29, paras. 146 and 148; IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/356; Colombia, IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; EC, IP/C/W/383, IP/C/W/254, IP/C/M/48, para 63, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 226, IP/C/M/35, para. 233; India, IP/C/W/198, IP/C/W/195, IP/C/M/48, para.52, IP/C/M/36/Add.1, para. 212, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Peru, IP/C/W/447, IP/C/M/48, paras. 18-19; Thailand, IP/C/M/48, para. 61, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.

[25] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76 and 107, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Bangladesh, IP/C/M/42, para. 103; Zambia, IP/C/M/28, para. 147.

[26] India, IP/C/W/196, IP/C/M/37/Add.1, para. 224, IP/C/M/25, para. 70.

[27] African Group, IP/C/W/404.

[28] Switzerland, IP/C/W/400/Rev.1, IP/C/M/47, para. 75, IP/C/M/46, para. 76, IP/C/M/44, para. 26, IP/C/M/42, para. 99, IP/C/M/40, para. 73.

[29] Australia, IP/C/M/46, para. 64, IP/C/M/39, para. 140; Canada, IP/C/M/47, para. 67, IP/C/M/46, para. 54, IP/C/M/42, para. 116, IP/C/M/40, para. 116, IP/C/M/36/Add.1, para. 229; EC, IP/C/W/383, IP/C/W/254, IP/C/M/44, para. 28, IP/C/M/43, para. 41, IP/C/M/37/Add.1, para. 242, IP/C/M/35, paras. 238-239; Japan, IP/C/M/48, para. 64, IP/C/M/45, para. 46, IP/C/M/43, para. 48, IP/C/M/40, para. 96, IP/C/M/37, para. 216, IP/C/M/36/Add.1, para. 226; Korea, IP/C/M/46, para. 52; New Zealand, IP/C/M/46, para. 61; United States, IP/C/M/40, para. 123, IP/C/M/35, paras. 241-242.

[30] Brazil, IP/C/M/49, para.155, IP/C/M/42, para. 101, IP/C/M/36/Add.1, para. 199; India, IP/C/M/49, para. 86, IP/C/M/47, para. 87, IP/C/M/43, para.67, IP/C/M/42, para. 113; Pakistan, IP/C/M/42, para. 112; Venezuela, IP/C/M/44, para. 44, IP/C/M/36/Add.1, para. 208.

should be avoided.[31] This discussion is set out more fully in the Secretariat's revised summary note on the protection of traditional knowledge and folklore (IP/C/W/370/Rev.1).

18. The issue of what can be learnt about the relationship between the TRIPS Agreement and the CBD from the way in which the CBD refers to intellectual property matters and other international agreements has also been discussed:

- one view is that Article 16.5 of the CBD itself acknowledges a conflict between the objectives of protecting intellectual property rights and those of the conservation of biological diversity when it states that "[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives"[32]; thus, patent rights are not to be enjoyed at the expense of violating the provisions of national-level regimes for implementing the objectives of the CBD.[33] Indeed, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (hereinafter the Bonn Guidelines), which serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit sharing, urge contracting parties of the CBD to take specific measures in this context[34];

- another view is that the mere fact that the CBD refers to the possibility of conflict does not mean that one exists. Moreover, the CBD itself recognizes, in Article 16.2, the need for adequate and effective protection of intellectual property rights. This demonstrates that the two instruments are not in conflict.[35] Further, Article 22.1 of the CBD states that "provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity".[36] Indeed rather than conflicting, the provisions of the TRIPS Agreement are supportive of measures that would implement the obligations of the CBD most effectively.[37]

## III. PATENTABILITY OF GENETIC MATERIALS AND THE CBD

19. As indicated in the previous Section, one view that has been expressed about the relationship between the TRIPS Agreement and the CBD is that allowing patents to be granted in respect of genetic material is in itself inconsistent with the CBD because they limit access to such genetic material and can conflict with the sovereign rights of countries over their genetic resources.[38]

20. It has also been said that problems of consistency with the CBD can arise more particularly where Members do not follow closely enough the criteria for patentability laid down in the TRIPS

[31] Brazil, IP/C/M/47, paras. 32 and 86, IP/C/M/36/Add.1, para. 219; Brazil et al, IP/C/W/443, IP/C/W/429; Pakistan, IP/C/M/42, para. 112; Peru, IP/C/M/47, para. 16.

[32] Brazil, IP/C/M/47, para. 84, IP/C/M/26, para. 62; China, IP/C/M/36/Add.1, para. 227; India, IP/C/M/48, para. 49.

[33] India, IP/C/M/37/Add.1, para. 224.

[34] Brazil et al, IP/C/W/356; EC, IP/C/W/383.

[35] United States, IP/C/M/29, para. 193.

[36] United States, IP/C/W/434, IP/C/W/257, IP/C/M/30, para. 154.

[37] United States, IP/C/W/257.

[38] African Group, IP/C/W/163; Brazil et al, IP/C/W/356.

Agreement, namely those of novelty, inventive step (or non-obviousness) and industrial applicability (or usefulness) and grant over-broad patents.[39]

21. In this regard, concern has been expressed about:

- the granting of patents covering genetic material in its natural state. A concern has been expressed that the TRIPS obligation to provide patent protection for micro-organisms could mean the patenting of a range of genetic materials in their natural state[40], particularly because some Members define inventions to include discovery of naturally occurring matter[41];

- the granting of patents in respect of genetic material that has been merely isolated from nature and not otherwise modified. In this connection, the view has been expressed that for a micro-organism to be patentable in a way that would avoid conflict with the CBD, it should have undergone some genetic modification at the hands of man[42];

- the granting of erroneous patents on inventions based directly or indirectly on genetic resources or traditional knowledge that do not qualify as being novel or inventive. It has been said that the patent system, as currently operated, frequently gives rise to situations in which inventions pass the novelty or inventiveness tests when they should not do so.[43]

22. Concern has also been expressed that the grant of overly broad patents could impede access to and use of genetic resources in a way which gives rise to questions of compatibility with the CBD.[44] A related concern has been expressed about patent rights over genetic resources that restrict research by third parties.[45]

23. In response, it has been said that:

- the granting of patents on inventions which use genetic resources does not stand in the way of fulfilling the provisions of the CBD relating to the sovereign right of countries over access to genetic resources in their territories and prior informed consent as a condition of such access [46];

- holding a patent on isolated or modified genetic materials does not amount to ownership of the genetic materials themselves, nor does it provide property rights with regard to the source from which the original material is obtained. A patent on an isolated, identified and modified gene provides the patentee only with the ability to

[39] Brazil, IP/C/W/228; Peru, IP/C/W/447.
[40] Kenya, IP/C/M/28, para. 141; Peru, IP/C/M/29, para. 175.
[41] Kenya, IP/C/M/28, para. 141.
[42] Brazil, IP/C/W/228.
[43] Brazil, IP/C/W/228, IP/C/M/48, para. 37, IP/C/M/32, para. 128, IP/C/M/29, paras. 146 and 148, IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/356; Colombia, IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; India, IP/C/W/198, IP/C/W/195, IP/C/M/48, paras. 57-59, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Peru, IP/C/W/447; Thailand, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/32, para. 136, IP/C/M/28, para. 165.
[44] Brazil, IP/C/W/228, IP/C/M/29, para. 146; India, IP/C/M/28, para. 126; Singapore, IP/C/M/37/Add.1, para. 219.
[45] African Group, IP/C/W/206; Kenya, IP/C/M/28, para. 141.
[46] EC, IP/C/W/254, IP/C/M/30, para. 143; United States, IP/C/M/40, para. 122.

prevent others from producing, marketing and using the modified gene. The source from which the gene is taken would be unaffected by the patent[47];

- life forms in their natural state would not satisfy the criteria for patentability in the TRIPS Agreement. However, if the subject-matter of a patent has involved sufficient human intervention, such as production by means of a technical process or isolation or purification, and if the isolated or purified subject is not of a previously recognized existence, then it is capable of constituting an invention[48];

- when the criteria for patentability are properly applied, most concerns raised in this context would be avoided[49], but occasions do arise where patents are granted for inventions that do not fully meet the tests for patentability set out in the TRIPS Agreement, notably because of inadequate information available to the patent examiner. While patent offices around the world do face significant workload burdens, the patent system, in fact, works quite well and erroneously granted patents are the rare exception rather than the rule[50];

- implementation of post-grant opposition or re-examination proceedings could be used to rectify those rare cases when patents are issued erroneously. These procedures are far less costly than litigation and could alert national patent authorities to new information that is relevant to the patentability of the invention. A number of granted patents have been successfully challenged when it was demonstrated, through opposition processes, that they should not have been granted, including patents relevant to turmeric and neem in the United States and European patent offices. Indeed, the perceived instances of misappropriation often cited in the TRIPS Council as involving a wrongful determination of inventorship or prior art could have been satisfactorily addressed by existing procedures in the patent system[51];

- in order to prevent the grant of erroneously issued patents, requirements regarding information material to patentability and organized, searchable databases of the knowledge, innovations and practices of indigenous and local communities could be established to improve examination of patent applications in order to ensure that inventions that are granted patents meet the criteria of patentability.[52] Patent examiners worldwide could use such databases of genetic resources and traditional knowledge when examining patent applications. This could aid in the discovery of relevant prior art and thereby improve examination of patent applications in the relevant fields[53];

- databases would also create sources of information that could be used by potential licensees searching for knowledge, innovations and practices that might relate to their field of work and could indicate contact points, qualifications for licensees, conditions for licensing, etc. This would go toward meeting the second and third objectives of Article 8(j) of the CBD, i.e., to promote the wider application of the

[47] United States, IP/C/W/209, IP/C/W/162, IP/C/M/46, para. 24, IP/C/M/25, para. 71.
[48] EC, IP/C/W/254; Japan, IP/C/W/236, IP/C/M/29, para. 151.
[49] Switzerland, IP/C/M/30, para. 164.
[50] United States, IP/C/W/449, IP/C/W/434, IP/C/M/46, para. 35, IP/C/M/32, para. 131.
[51] United States, IP/C/W/449, IP/C/W/434, IP/C/M/46, para. 35, IP/C/M/32, para. 131.
[52] EC, IP/C/W/383, IP/C/M/43, para. 39, IP/C/M/40, para. 94, IP/C/M/37/Add.1, para. 242, IP/C/M/32, para. 137; India, IP/C/W/198, IP/C/M/37/Add.1, para 253; Japan, IP/C/M/48, para. 76, IP/C/M/29, para. 157, IP/C/M/32, para. 142; Switzerland, IP/C/W/400/Rev.1, IP/C/W/284, IP/C/M/42, para. 98, IP/C/M/30, para. 164; United States, IP/C/W/449, IP/C/W/434, IP/C/W/257, IP/C/W/209, IP/C/M/48, para. 33, IP/C/M/46, para. 34.
[53] Chinese Taipei, IP/C/M/43, para. 58; EC, IP/C/M/37/Add.1, para 242; United States, IP/C/W/434; Venezuela, IP/C/M/37/Add.1, paras. 243-244.

knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity with the approval and involvement of such communities, and would encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.[54]

24. In response to this, it has been said that:

- the basis for the "rare exception" claim for erroneously granted patents is not known but examining the numerous patent applications and grants to check whether inappropriate patents are being applied for or granted and then taking action to revoke them is a burdensome and expensive process, especially for developing countries[55];

- post-grant opposition or re-examination proceedings are costly and burdensome because holders of genetic resources or traditional knowledge would have to initiate them in different jurisdictions. Moreover, these are curative mechanisms for the problem of the issue of bad patents, unlike the suggested disclosure requirement which is a preventive step[56];

- although misappropriation of traditional knowledge through the grant of bad patents is a well-acknowledged problem, revocation of these patents has been sought in only very few cases. Challenges to patents granted could be sustained in the turmeric and neem cases owing to the engagement of the government in the first case and a consortium of non-governmental organizations in the second case.[57]

25. With respect to databases, it has been said in response that:

- while these could play a key but complementary role in facilitating the work of a patent examiner[58], given the vast breadth and depth of such knowledge, the inherent limitation of such documentation is that it cannot be comprehensive of all traditional knowledge available in a country, particularly where such knowledge is based on oral traditions or documented only in local languages.[59] Databases are still incomplete and compilation is an ongoing process. Such efforts would still not amount to an effective international regime, thus requiring every Member individually and collectively to enforce international obligations to prohibit and take measures to prevent misappropriation[60];

- based on experience so far, the use of databases and sharing of information before the grant of patents has not been effective in combating cases of misappropriation of genetic resources or traditional knowledge used in inventions.[61] In cases such as

[54] United States, IP/C/W/257.

[55] Bolivia, IP/C/M/48, para. 83; Brazil, IP/C/M/48, para. 37, IP/C/M/39, para. 126, IP/C/M/28, para. 135; Brazil et al, IP/C/W/403, IP/C/W/356; India, IP/C/M/48, para. 51, IP/C/M/28, para. 126; Indonesia, IP/C/M/36/Add.1, para. 217; Pakistan, IP/C/M/36/Add.1, para. 211, IP/C/M/28, para. 157; Peru, IP/C/M/46, para. 51, IP/C/M/43, para. 44.

[56] Brazil et al, IP/C/W/459, IP/C/W/403; Indonesia, IP/C/M/36/Add.1, para. 217; Peru, IP/C/M/46, para. 51.

[57] India, IP/C/M/48, para. 60.

[58] African Group, IP/C/W/404; Brazil, IP/C/W/228, IP/C/M/37/Add.1, para. 255; Brazil et al, IP/C/W/403; China, IP/C/M/36/Add.1, para. 228; Venezuela, IP/C/M/37/Add.1, para. 243; Zimbabwe, IP/C/M/36/Add.1, para. 201.

[59] African Group, IP/C/W/404; Brazil, IP/C/M/48, para. 39; Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/403; India, IP/C/M/39, para. 123, IP/C/M/37/Add. 1, para. 253.

[60] African Group, IP/C/W/404; Peru, IP/C/M/48, para. 18.

[61] Peru, IP/C/M/46, para. 51.

those relating to turmeric, neem tree, hodia and ayahuasca, absence of the relevant prior art has been used to justify improper determination of patentability[62];

- reference to databases by patent examiners is voluntary and there is no guarantee that, in fact, patent examiners in different countries would consider this information in prior art searches[63];

- the appropriateness of use of databases can be questioned for reasons of high cost and loss of confidentiality of the traditional knowledge which is not in the public domain.[64]

26. A suggestion has been made to establish obligations, guidelines or recommendations to improve and substantially tighten up the search systems in respect of information that is relevant to genetic resources and traditional knowledge so as to evaluate novelty and inventiveness. It has also been suggested that patent offices could be required to observe much stricter procedures when conducting searches for the assessment of novelty and inventiveness and that lack of candour in the provision of information could be sanctioned by non-application of the right granted.[65]

27. See also the revised summary notes on the review of the provisions of Article 27.3(b) (IP/C/W/369/Rev.1) and on the protection of traditional knowledge and folklore (IP/C/W/370/Rev.1).

## IV. THE TRIPS AGREEMENT AND PRIOR INFORMED CONSENT/BENEFIT SHARING

28. As indicated in Section II of this paper, concern has been expressed that the TRIPS Agreement allows the granting of patents for inventions that use genetic material without requiring that the provisions of the CBD in relation to prior informed consent and benefit sharing are respected. Two approaches, not necessarily mutually exclusive, have been taken by Members in addressing these and other concerns regarding the mutual supportiveness of the two Agreements. One approach is to use national solutions, including legislation on access and benefit sharing and contracts (hereinafter referred to as the "national-based approach"); the discussion on this is contained in sub-section A below. The other approach is to advocate some kind of "disclosure" requirement on patent applicants as a supplementary measure to national legislation and contracts (hereinafter referred to as the "disclosure approach"), including in international forums other than the WTO; the discussion on this is contained in sub-section B below.

### A. NATIONAL-BASED APPROACH

#### 1. Proponents' description of the national-based approach

29. The proponents of the national-based approach have made suggestions for achieving what they consider to be the widely shared policy objectives of: ensuring authorized access i.e., that prior informed consent is obtained; achieving equitable sharing of benefits arising from the use of traditional knowledge and genetic resources; and preventing the issuance of erroneously granted patents. They are of the view that the concerns expressed on these matters could most efficiently be addressed through tailored national solutions outside the intellectual property system that directly and effectively regulate the conduct in question. In accordance with the CBD, countries could incorporate in their national legislation requirements for the conclusion of contracts between the authorities competent to grant access to genetic resources and any related traditional knowledge and those who

[62] Brazil, IP/C/M/48, para. 39.
[63] African Group, IP/C/W/404; India, IP/C/M/45, para. 20.
[64] Brazil, IP/C/M/37/Add.1, para. 225; Brazil et al, IP/C/W/403; Venezuela, IP/C/M/37/Add.1, paras. 243-244.
[65] Peru, IP/C/W/447.

wish to make use of such resources and knowledge.[66] Indeed, national regimes could have many components, including the use of permits, contractual obligations, visa systems and civil and/or criminal penalties for non-compliance.[67] With regard to concerns of erroneously granted patents, solutions are available in the patent system itself such as the requirement to provide information material to patentability, post-grant opposition, re-examination and revocation proceedings as well as the establishment of databases of traditional knowledge so as to strengthen the prior art resources available to patent examiners.[68]

(a) Prior informed consent and benefit sharing

30. With respect to the realization of the objectives in regard to prior informed consent and fair and equitable benefit sharing, it has been said that the suggested national-based approach could have the following features:

- contractual arrangements could be used to establish the rights and obligations of the entities involved prior to any access to genetic resources; this would ensure that prior informed consent is achieved[69];

- countries could also establish permit systems that impose civil and/or criminal penalties for extracting genetic resources without a permit, where the permit would serve as evidence of prior informed consent[70];

- a contract-based system would provide a mechanism to transfer benefits as it could be used to effectively control the collection of resources and ensure the sharing of benefits from their use[71];

- contracts could include requirements on mandatory disclosure to appropriate authorities of any future commercial application utilizing the relevant traditional knowledge or genetic resource, whether or not a patent is filed or granted over the relevant application [72];

- points of contact, such as the government and/or indigenous representatives authorized to provide access to materials, could be clearly delineated before a party seeks to use or collect traditional knowledge or genetic resources since a researcher or collector needs to know where to go, who to contact and which persons are authorized to grant approval in order to receive prior informed consent[73];

- within the contract, a party could require the researcher or other party accessing the genetic resources and traditional knowledge to report regularly to the point of contact regarding progress of his research[74];

- a party to any access agreement could be obliged to notify the appropriate authorities in the event that an invention is developed using genetic materials collected under the

[66] EC, IP/C/W/383; United States, IP/C/W/434, IP/C/W/257, IP/C/M/48, para. 26, IP/C/M/42, para. 109, IP/C/M/40, para. 122, IP/C/M/39, paras. 129-131, IP/C/M/38, para. 234, IP/C/M/37/Add.1, para. 234, IP/C/M/36/Add.1, para. 231.

[67] United States, IP/C/M/42, para. 109, IP/C/M/39, para. 129, IP/C/M/38, para. 234.

[68] United States, IP/C/W/449, IP/C/W/434, IP/C/M/46, para. 35, IP/C/M/32, para. 131.

[69] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/37/Add.1, para. 235.

[70] United States, IP/C/W/434.

[71] United States, IP/C/W/434, IP/C/M/46, para.31.

[72] United States, IP/C/W/434, IP/C/M/46, para.31, IP/C/M/37/Add.1, para. 235.

[73] United States, IP/C/W/434.

[74] United States, IP/C/W/434.

contract and to share the benefits that arise from the utilization of genetic resources for both commercial and non-commercial purposes[75];

- applicants could be required to disclose the relevant contract in any patent application filed that claims an invention that uses genetic resources or traditional knowledge.[76]

(b) Legal effects of non-compliance

31. With regard to the legal effects of non-compliance with contractual obligations or national measures, the view has been expressed that:

- criminal and/or civil liability provisions could be used to directly regulate and effectively enforce regimes for access and benefit sharing as is done in the case of other distinct regulatory systems. Such provisions could be part of civil and criminal codes specifically designed to enforce access and benefit-sharing laws[77];

- successful suits for breach of contract against those who fail to follow the terms of contracts entered into could result in court orders for specific performance or damages, including punitive damages[78];

- choice of law provisions can also be specified in contracts with third parties licensed to make use of genetic resources or traditional knowledge, so that all parties are aware of the law that will apply should disputes arise. Contracts can be litigated in the specified jurisdiction and judgments enforced around the world under international agreements regarding the recognition of judgments[79];

- contracts could also be associated with Members' visa systems so that domestic law would be respected by foreign nationals seeking to collect such materials.[80]

(c) Erroneously granted patents

32. With respect to concerns raised about erroneously granted patents, the view has been expressed that[81]:

- while there are valid concerns regarding erroneously granted patents, there are effective solutions to directly address these concerns such as post-grant opposition, re-examination and revocation proceedings as well as the establishment of databases of traditional knowledge so as to increase the information on prior art available to patent examiners[82];

- Members could consider introducing in their patent legislation a requirement for patent applicants to disclose any information known by the applicant to be material to patentability, that is to say to determining prior art, to ascertaining inventorship and to preventing mistakenly granted patents. For example, in the United States, the patent

[75] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/37/Add.1, para. 235.
[76] Japan, IP/C/M/29, para. 155; Korea, IP/C/M/30, para. 171; United States, IP/C/M/30, para. 177.
[77] United States, IP/C/W/434, IP/C/M/42, para. 109, IP/C/M/40, para. 122, IP/C/M/39, para. 130-131, IP/C/M/37/Add.1, para. 235.
[78] United States, IP/C/W/434, IP/C/M/42, para. 109, IP/C/M/40, para. 122, IP/C/M/39, paras. 130-131, IP/C/M/37/Add.1, para. 235.
[79] United States, IP/C/W/434, IP/C/W/257, IP/C/M/39, para. 130, IP/C/M/37/Add.1, para. 235.
[80] United States, IP/C/W/434, IP/C/M/39, para. 129, IP/C/M/38, para. 234.
[81] United States, IP/C/W/434.
[82] Switzerland, IP/C/W/400/Rev.1.

law requires inventorship for entitlement to a patent to be determined and determinations of inventorship would be directly enhanced by such a requirement.

(See further discussion in Section III above.)

(d) Claimed advantages of the national-based approach

33. Advantages of the national-based approach, other than those mentioned above, have been said to be that:

- a contract system would provide the necessary flexibility to take account of differences in interests in the negotiations[83] and a balance between the value attributable to the genetic resources and that attributable to the efforts of the inventors and developers could be ensured. This would take into account situations where the economic value of inventions resulting from the exploitation of the biological resource might be largely attributable to the inventive efforts of the inventor and the commercialization efforts of the patent owner and not so much to the biological resource as such.[84] Where genetic resources could be obtained from a number of sources, the party seeking access would be likely to seek the resources from the territory that provides the most favourable terms[85];

- a system of access and benefit sharing based on contracts could be put in place immediately, based on existing contract law, and therefore would not require waiting for the outcome of discussions in the TRIPS Council or other bodies[86];

- the system would provide for penalties against those few who might take genetic resources without entering into an access agreement with the required party[87];

- the system could be appropriately tailored so as not to have unintended, negative consequences on the intellectual property system[88];

- contracts granting access could clarify the definition of terms that may not be so clear otherwise, such as the definition of the term "genetic resources", and this could clarify rights and obligations on both sides at the outset and help to avoid misunderstanding and confusion[89];

- contracts could be used to effectively control the collection of resources and ensure the sharing of benefits from their use[90];

- a contract-based system could be easily adaptable to each country's legal system and could provide countries the flexibility to protect their traditional knowledge or genetic resources without the risks of undermining the economic development incentives of strong intellectual property protection and without the risk of undermining benefit sharing in the cases where the products based on genetic resources or traditional knowledge are not covered by patents[91];

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[83] United States, IP/C/M/47, para. 44, IP/C/M/46, para. 31, IP/C/M/39, para. 130.
[84] Japan, IP/C/W/236, IP/C/M/29, para. 156; United States, IP/C/W/257.
[85] Japan, IP/C/W/236, IP/C/M/29, para. 156; United States, IP/C/W/257.
[86] United States, IP/C/M/37/Add.1, para. 234.
[87] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/42, para. 109, IP/C/M/40, para. 122, IP/C/M/39, paras. 130-131, IP/C/M/37/Add.1, para. 235.
[88] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/42, para. 109, IP/C/M/40, para. 122, IP/C/M/39, paras. 130-131, IP/C/M/37/Add.1, para. 235.
[89] United States, IP/C/W/257.
[90] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/39, para 130.
[91] United States, IP/C/W/434, IP/C/M/46, para. 31.

- Article 19 of the CBD on the handling of biotechnology and the distribution of its benefits could also be implemented most effectively through contractual means.[92]

34. In regard to why the national-based approach is the desirable way to achieve the objectives of prior informed consent and benefit sharing, the following views have been expressed:

- only contractual arrangements can establish the rights and obligations of the entities involved prior to any access to genetic resources and can ensure that prior informed consent is achieved[93];

- contracts could ensure the sharing of benefits arising from the commercialization of the results of research and development based on materials to which access has been provided, whether or not these results are the subject of a patent. In other words, benefits could be shared whether or not any invention has been developed that qualifies for patent protection and whether or not the commercial application results in a patent application being filed[94];

- contractual arrangements could provide for benefits in both monetary and non-monetary form to be shared. For instance, those seeking access to genetic resources for research and development could be required to share the benefits flowing from any patents that might be granted for inventions developed from those genetic resources, including by providing access to the technology[95];

- the addition of a reporting requirement would keep the authorities informed of how the relevant traditional knowledge or genetic resource is being used and would keep communication channels open.[96]

(e) Examples given of experiences with use of the national-based approach

35. To illustrate how its suggestions can be implemented, the United States submitted two documents:

- one, describing the practices of the US National Cancer Institute's Departmental Therapeutics Programme (NCI-DTP), i.e. its drug discovery programme, in collecting genetic materials for screening for potential therapeutic uses related to cancer, as well as describing the policies of the US National Institutes of Health-Office of Technology Transfer (NIH-OTT)[97]; and

- another, describing the regime for access to genetic materials in US national parks.[98]

This sub-section describes the main points made in these documents. Further detail can be found in the documents themselves.

36. According to the first document, the NCI-DTP, as it investigates the potential of natural products in drug discovery and development, seeks to promote the conservation of biological diversity, and recognizes the need to collaborate with source country organizations in the development of any drug from an organism collected within a source country's borders from source

[92] United States, IP/C/W/257.
[93] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/37/Add.1, para. 235.
[94] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/37/Add.1, para. 235.
[95] United States, IP/C/W/434, IP/C/M/48, para. 29, IP/C/M/40, para. 122.
[96] United States, IP/C/W/434.
[97] United States, IP/C/W/341.
[98] United States, IP/C/W/393.

country organizations and peoples and, in the event of commercialization of any drug so developed, to provide compensation or other benefits resulting from that commercialization. Most of the sample materials screened by NCI-DTP have been obtained under Letters of Collection (LOC) or Memoranda of Understanding (MOU) negotiated with or involving the source countries.[99]

37. The NCI-DTP screens synthetic compounds and natural product materials derived from plants, marine macro-organisms and microbes as potential sources of novel anti-cancer drugs. Since 1986, the Natural Products Branch of the NCI-DTP has acquired 53,000 plant and 13,000 marine invertebrate samples, in addition to 3,000 marine plants and 25,000 fungal extracts from more than 30 tropical or sub-tropical source countries or their source country organizations. Aqueous and organic extracts (methylene chloride/methanol) of each of these materials have been prepared and are now available for high throughput screening in 1,650 microtiter plate maps (88 extracts per plate). In addition, taxonomy is available for each specimen. The chief use for screening such a unique resource is to isolate, identify and characterize a lead compound whose activity can be further developed through combination with other compounds or other synthesizing methodologies. The extracts are available (under a Natural Products Repository-Material Transfer Agreement, NPR/MTA) to other scientific laboratories for screening against all diseases.

38. It was said that the NCI recognizes the value of the natural resources (plant, marine, microbial) being investigated and of the significant contributions made by source country organizations and indigenous peoples to the NCI programmes, and because of this it has established policies that facilitate collaboration with and compensation of countries participating in the NCI drug discovery programme. NCI-NPB complies with the principles of the Convention on Biological Diversity by providing in its negotiated agreements that source countries share, in a fair and equitable way, in the results of research and development and in any benefits arising from commercial and other use of their genetic resources. In addition, the agreements provide that source country people and organizations are to be compensated if a drug (which originated from natural materials or compounds submitted to the NCI) is commercialized by a potential licensee.

39. Both the NCI and the NIH-OTT require licensees to negotiate agreements with source countries or source country organizations that address concerns of both parties, ensuring that, *inter alia,* pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate. The royalties payable to any source country depend upon the relationship of the marketed drug to the original lead from the extract. To increase the efficacy of source country compensation, generally the licensee is expected to begin and complete negotiations with the source country or source country organization as soon as possible (typically within one year of signing the licensing agreement). In no case, however, may a licensee initiate negotiations later than the commencement of clinical trials, or complete negotiations later than the commercialization/sale of a drug. To ensure that potential licensees understand these obligations, the NIH-OTT, in disseminating licensing announcements in the US Federal Register concerning such natural product materials, includes the following language: "Since [compound] was originally isolated from flora primarily located in [location], the NIH is concerned that the collection and utilization of the natural material comport with all applicable Federal and [location] policies related to biodiversity. In order to comport with such policies, the successful applicant will also be required to negotiate and enter into agreements with the appropriate [location] Government agencies".

40. In instances in which additional supplies of a naturally occurring material or compound are required, they must be sought first in the original source country, if possible, in order to promote development of the agent within that source country. NCI-DTP also seeks to transfer knowledge, expertise, and technology related to drug discoveries and development to source country organizations, subject to the provision of mutually acceptable guarantees for the protection of any patented technology. NCI sponsors a programme whereby source country scientists are able to work

[99] Copies of the basic Natural Products Repository-Material Transfer Agreement, the Letters of Collection, and the Memorandum of Understanding were included as annexes to IP/C/W/341.

as guest researchers at NCI or other mutually acceptable organizations for up to one year. While in the past, NCI-DTP scientists had predominantly isolated and characterized the biologically active extract constituents, under the MOU, qualified source country organizations are encouraged to isolate and characterize biologically-active constituents themselves and patent the active agents solely or jointly. The NCI-DTP would collaborate with the source country organization through pre-clinical development of a drug. Under a MOU, joint patents may be sought on all inventions made by the source country organization and NCI working jointly with inventorship being determined in accordance with the relevant patent laws.

41. For compounds determined to possess significant anti-cancer potential and, therefore, scheduled for clinical trials, the United States Government receives a royalty-free, irrevocable, non-exclusive licence to manufacture and/or use, by or for the United States Government, the invention(s) or process(es) claimed in any patent(s) obtained, or that may be obtained by a source country organization on such compounds. Such licences are limited to compounds relying on NCI-DTP anti-cancer screening data, and are only for purposes of medical research related to or connected with cancer therapies and not for commercial use.

42. NCI has MOU agreements for direct collaboration with the following entities: Australia - Australian Institute of Marine Sciences, Townsville, Queensland; Bangladesh - the University of Dhaka; Brazil - Fundacao Oswaldo Cruz – FIOCRUZ, Rio de Janeiro, South American Organization for Anti-cancer Drug Development, Porto Alegre, Universidade do Paulista, Sao Paulo, Universidade Federal do Parana, Universidade Federal do Ceara, Forteleza; China - Hong Kong University of Science and Technology, Kunming Institute of Botany, Yunnan, Peking University and State Key Laboratory, Beijing; Costa Rica - Instituto Nacional de Biodiversidad (INBio); Fiji - University of the South Pacific, Suva; Iceland - the University of Iceland, Reykjavik; Korea - Korean Research Institute of Chemical Technology (KRICT); Mexico - Instituto de Quimica, Universidad Nacional Autonoma de Mexico, Mexico City; New Zealand - National Institute of Water and Atmospheric Research (NIWA), Wellington; Nicaragua - Universidad Nacional Autonoma de Nicaragua, Leon; Pakistan - HEJ Research Institute of Chemistry, University of Karachi; Papua New Guinea - University of Papua New Guinea, Port Moresby; Panama - University of Panama; South Africa - Council for Scientific and Industrial Research (CSIR), Division of Food, Biological and Chemical Technologies (BIO/CHEMTEK), Pretoria, Rhodes University, Grahamstown; and Zimbabwe - Zimbabwe National Traditional Healers Association (ZINATHA). In addition, negotiations for MOUs are currently in progress with the following organizations: Brazil - Centro Pluridisciplinar Pesquisas Quimicas, Universidade do Campinas (UNICAMP); Egypt - National Research Center, Cairo (under negotiation); Jamaica - University of the West Indies; and Russia - Cancer Research Center, Russian Academy of Medical Sciences, Moscow.

43. The NCI has LOC agreements for collaboration in the collection of plants and marine organisms with the following: Bangladesh - Bangladesh National Herbarium, Dhaka; Cambodia - Forest and Wildlife Research Institute, Department of Forestry and Wildlife, Phnom Penh; Ecuador - the AWA Peoples Federation; Gabon - Centre National de la Recherche Scientifique et Technologique (CENAREST), Libreville; Ghana - University of Ghana, Legon; Laos - Research Institute of Medicinal Plants, Ministry of Public Health, Vientiane; Madagascar - Centre national d'application des recherches pharmaceutiques, Antananarivo; Papua New Guinea - University of Papua New Guinea, Port Moresby; Philippines - Philippines National Museum, Manila; Malaysia - State Government of Sarawak, State Department of Forests; Tanzania - Traditional Medicine Research Institute, Muhumbili University College of Health Sciences, University of Dar Es Salaam; and Viet Nam - Institute of Ecology and Biological Resources, National Center for Natural Science and Technology, Hanoi.

44. NCI collections have also been performed in a number of other countries, which have not, as yet, signed official LOC agreements. NCI, however, is totally committed to the terms of the LOC irrespective of whether or not an official agreement has been signed. These countries were: Bahrain, Belize, Bolivia, Cameroon, Central African Republic, Colombia, Dominica, Dominican Republic,

Federated States of Micronesia (Chuuk, Yap etc.), Guatemala, Guyana, Honduras, Indonesia, Malaysia, Maldives, Marshall Islands, Martinique, Mauritius, Nepal, Palau, Paraguay, Peru, St. Lucia, Thailand, Tonga.

45. With regard to the regime established for access to genetic materials in US national parks, the second document submitted by the United States explains that the collection of biological specimens for scientific research in US national parks is not new, since the first research permit in the national park system, which authorized collection of microbial specimens from hot springs at Yellowstone National Park, was issued over a century ago. Over the years, research permits have continued to be granted authorizing collection of specimens from the parks.

46. In 1916, legislation was enacted creating the US National Park Service to administer US national parks, in particular to "conserve the scenery and the national and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations". Over the years, research permits have continued to be granted authorizing collection of specimens from the parks. The National Park Service's current regulations governing the collection of specimens for scientific research were put in place in 1983.

47. In order to illustrate the public benefits of permitting access to genetic resources, the document describes a case study. In 1966, Thomas Brock was studying micro-organisms living in Yellowstone's hot spring pools. In the laboratory, he named one of the curious organisms he had discovered *Thermus aquaticus* and submitted a living sample for safekeeping to the American Type Culture Collection, an organization that collects and maintains micro-organisms. Two decades after Dr. Brock's academic work in Yellowstone, his discoveries produced a practical application that he had never imagined. In 1985, a biotechnology company named Cetus Corporation was seeking to develop a new way to duplicate genetic material. At the time, chromosomes were very difficult to study because they are made of genes and genes are composed of DNA, but DNA is too small to study effectively. Dr. Kary Mullis, a Cetus scientist, invented a useful method for DNA duplication, called Polymerase Chain Reaction (PCR), but, unfortunately, the high temperatures required by PCR destroyed the polymerase enzymes, requiring laboratory technicians to add fresh enzymes throughout the PCR process, making that process tedious and resource intensive.

48. Other scientists at Cetus added an enzyme, named Taq polymerase, to the PCR, which was isolated from a sample of *Thermus aquaticus* obtained from the American Type Culture Collection. Taq polymerase had the unusual ability to keep working even at high temperatures. The scientists learned to reproduce the enzyme in the laboratory so that it would not be necessary to use original samples. The PCR using Taq polymerase was so effective that a whole new scientific field flourished as scientists finally had a convenient way to reproduce and study DNA. The DNA copying process, made practical because of the study of a Yellowstone micro-organism, has now become a major part of DNA studies around the world. Taq polymerase helped permit the uses of DNA that are so familiar today – from matching DNA in criminal investigations, to medical diagnoses or cures, bioremediation of toxic wastes, and research into the basic building blocks of life.

49. While the results of such research on materials collected from national parks flowed to the world, there was no provision for ensuring that benefits flowed back to the parks that supplied the original materials. The National Parks Omnibus Management Act of 1998 expressly authorizes "negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements" in connection with research conducted in national parks. The Act also mandates increased scientific research in the national parks and the use of science in park management decisions. The law encourages the national parks to be places for scientific study by public as well as private sector researchers, and mandates long-term inventory and monitoring programmes that provide baseline information, and document trends relating to the condition of park resources.

50. A lawsuit in 1998 challenged the legality of a cooperative research and development agreement (CRADA) negotiated between the Yellowstone National Park (Yellowstone) and Diversa

Corporation (Diversa), a biotechnology company that develops new technologies for discovering and modifying genes. The judge dismissed the case with prejudice to the plaintiff, ruling that benefit-sharing CRADAs are consistent with the National Park Service Organic Act and the Yellowstone National Park enabling act.

51. As an example of benefit sharing under the CRADA between Diversa and Yellowstone, Diversa, in 1999, at no charge to the federal government, developed a DNA pedigree for the endangered Yellowstone wolves, the first such pedigree ever established. This pedigree, which the Yellowstone National Park could not have afforded to pay for, helps in understanding the dynamics of the wolf population, assessing the genetic health of the park's wolf population, identifying wolves that are killed illegally, detecting when wolves from other areas immigrate to Greater Yellowstone, and documenting breeding in the wild. This knowledge is used by Yellowstone staff in carrying out their charge to conserve the wildlife in the park so that it can be enjoyed by this and future generations.

52. The National Park Service has separate requirements for collecting research materials from parks, depending on the use to which the research is to be put. For collections aimed solely at basic research and education, the superintendent of each national park has the authority to issue research permits addressing the resources and needs of the park the superintendent oversees. A Scientific Research and Collecting Permit is required for most scientific activities involving fieldwork or specimen collection, particularly if the research has the potential to disturb resources or visitors. In some instances, other federal or state agency permits or approvals may also be required to be submitted with the application for a Scientific Research and Collecting Permit before the superintendent of the national park will consider the application. For example, research proposals involving threatened or endangered species must be accompanied by a permit from the US Fish and Wildlife Service and the National Marine Fisheries Service. Application materials, including *Guidelines to Researchers for Study Proposals*, can be obtained from the Internet (www.nps.gov) or by contacting the park in which the proposed research is to take place. Specimen collection for scientific research would be authorized only if the collection is necessary for the stated scientific goals included in the written research proposal. The research proposal must detail the activities that will occur in the park together with the analyses that will occur elsewhere, such as in the scientists' laboratory or office.

53. Each proposal is reviewed to ensure compliance with the National Environmental Policy Act and other relevant laws, regulations and policies. Depending on the complexity and sensitivity of the proposal, the superintendent may also require a review by relevant scientific experts, internal or external. Permits may be issued only if the proposed research will not have an adverse impact on public health and safety, environmental or scenic values, natural or cultural resources, other scientific research, management responsibilities, allocation and use of facilities, and visitor activities.

54. Researchers granted permits to work in National Park System areas must complete an Investigator's Annual Report on the required form for each year of the permit, including the final year. This may be done on paper or over the Internet. The reports themselves document the accomplishments of research conducted in the parks. The principal researchers are accountable for the accuracy and content of their reports. In addition to the reports, park research coordinators can request copies of field notes, data, reports, publications and other documents and materials related to studies conducted in the National Park System Areas.

55. As noted above, specimens and components of specimens collected under permit are to be used for scientific or educational purposes only; specimens collected in parks may be loaned by the NPS for scientific purposes but may not be sold for any purpose; research results derived from NPS specimens may not be used for commercial or other revenue-generating purposes without further permission.

56. According to National Park Service policy, any party that submits an application for a Scientific Research and Collecting Permit proposing to use the results of research for commercial or

revenue-generating purposes must enter into a CRADA or other approved benefit-sharing agreement with the NPS. Under a CRADA, the National Park Service makes a clear distinction between sale or other transfer to third parties of collected research specimens or materials and the sale or other transfer of the results of research based upon the collected research specimens or materials. The sale or other transfer to third parties of collected specimens or components thereof is strictly prohibited. The party to the CRADA, however, may make commercial or other revenue-generating use of the results of its research, with benefit sharing to the National Park Service as provided for in the CRADA.

57. The scientific research and collecting permit issued by the National Park Service to the other party spells out the terms and conditions under which that party is permitted to collect research specimens or other materials from the park and the purposes to which such specimens or other materials may be put. The CRADA or other benefit-sharing agreement identifies the allocation of ownership in any inventions made, and the other rights and obligations of the parties, including reporting requirements and the manner in which any disputes should be handled. Some contracts may provide for express damages in the event of a breach of any of the provisions of the agreement by the party seeking to collect research specimens or other materials. Reporting requirements may include notification of the development of any invention based upon research using research specimens collected in the parks and identification of the contract in any patent application claiming an invention developed as a result of the research on collected specimens or other materials.

58. Only one CRADA has been negotiated by the NPS up to the date of the submission of document IP/C/W/393. The litigation in 1998 imposed a requirement to comply with the National Environmental Policy Act and the NPS is developing an environmental impact statement to consider the effects of benefit sharing within the National Park System.

59. The proponents of this approach have said that a similar system, adapted to the legal systems and government structures of other countries, would work well in promoting the sustainable use of genetic resources and in ensuring that benefits resulting from any research using those resources are shared with the source of the resources. Such benefits could include training for scientists, direct application of the research results (as in the example of the genetic pedigree of the endangered Yellowstone wolves), or monetary remuneration.

**2. Discussion of the national-based approach**

(a) Transboundary use of genetic resources and traditional knowledge

60. The issue of whether the national-based approach can adequately address transboundary use of genetic resources and traditional knowledge has been raised. One view is that:

- the national-based approach, including contracts, while helpful and even required under the CBD, as paragraphs 4 and 7 of Article 15 of the CBD require access and benefit sharing to be on mutually agreed terms, cannot be the only solution in cases of erroneously granted patents and transboundary use of genetic resources and/or traditional knowledge.[100] Given the transboundary nature of the problem, often involving the acquisition of material in one country and the seeking of a patent in another, reliance on national or regional measures alone may not be sufficient to

[100] African Group, IP/C/W/404; Bolivia, IP/C/M/37/Add.1, para. 241; Brazil, IP/C/M/48, para. 40, IP/C/M/47, para. 27, IP/C/M/46, paras. 79-81, IP/C/M/40, para. 90, IP/C/M/39, para. 126, IP/C/M/37/Add.1, para. 238, IP/C/M/36/Add.1, para. 220; Brazil and India, IP/C/W/443; Colombia, IP/C/M/36/Add.1, para. 209; China, IP/C/M/40, para. 120; India, IP/C/M/48, para. 53, IP/C/M/47, para. 34, IP/C/M/45, para. 25, IP/C/M/37/Add.1, para. 223; Indonesia, IP/C/M/36/Add.1, para. 217; Kenya, IP/C/M/42, para. 114; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/W/447, IP/C/W/441/Rev.1, IP/C/M/48, para. 18, IP/C/M/40, paras. 84-85, IP/C/M/36/Add.1, para. 203; Switzerland, IP/C/M/46, para. 75; Zimbabwe, IP/C/M/36/Add.1, para. 201.

increase transparency, and multilateral approaches are needed.[101] While such actions may be illegal under the law of the country providing the genetic resources, there may be little that can be done under that law when the genetic material and traditional knowledge is used outside that jurisdiction. Thus, contractual arrangements or similar mechanisms in national laws would only suffice if they are obligatory and enforceable across borders[102];

- contracts alone cannot deter those with the intent of acting in bad faith as contracts may not be concluded in accordance with national access and benefit-sharing regimes[103];

- there is no obligation in international law on all Members to legislate on the issue of prior informed consent and benefit sharing, particularly for Members not party to the CBD.[104] It is not clear how the national-based approach could be reconciled with a commitment to negotiations for an access and benefit-sharing regime that were launched at the World Summit on Sustainable Development (WSSD) at Johannesburg in 2003[105];

- if voluntary contracts are a sufficient means of ensuring respect of the rights of the country or community of origin of genetic material/traditional knowledge, why would a similar logic not also apply in respect of the protection of intellectual property and why is specific IP legislation that applies even in the absence of contracts considered necessary? Such an approach would be akin to arguing that, in order to ensure the effective operation of the patent system, for example, only national patent laws are needed and that no international agreement, such as the TRIPS Agreement, is necessary.[106]

61. In response, the following views have been expressed:

- the reference to "national laws" does not imply that international norms have no relevance nor that the solutions proposed are not international in character. Indeed, appropriate international guidelines, such as the Bonn Guidelines and guidance from the IGC at WIPO, which address issues of appropriate access and benefit sharing outside the patent system, may be relevant and helpful to Members in achieving the shared objectives[107];

- a national contract-based system can be international in its outlook and may contain, *inter alia*, choice of forum, choice of law, or international arbitration provisions relevant to cross-boundary dispute or enforcement issues governing cases where

[101] African Group, IP/C/W/404; Bolivia, IP/C/M/37, para. 241; Brazil, IP/C/M/48, para. 26, IP/C/M/47, para. 27, IP/C/M/46, paras. 79-81, IP/C/M/40, para. 90, IP/C/M/39, para. 126, IP/C/M/37/Add.1, para. 238, IP/C/M/36/Add.1, para. 220; Brazil et al, IP/C/W/403; Brazil and India, IP/C/W/443; Chile, IP/C/M/40, para. 126; China, IP/C/M/40, para. 120; IP/C/M/47, para. 57; Colombia, IP/C/M/36/Add.1, para. 209; India, IP/C/M/48, para. 49, IP/C/M/47, para. 34, IP/C/M/45, para. 25, IP/C/M/37/Add.1, para. 223; Indonesia, IP/C/M/36/Add.1, para. 217; Kenya, IP/C/M/42, para. 114; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/48, para. 18, IP/C/M/46, para. 50, IP/C/M/40, para. 84, IP/C/M/36/Add.1, para. 203; Switzerland, IP/C/M/47, para. 78, IP/C/M/46, para. 75.

[102] Brazil and India, IP/C/W/443.

[103] Peru, IP/C/M/46, para. 50; Switzerland, IP/C/M/46, para. 75.

[104] Brazil, IP/C/M/37/Add.1, para. 238, IP/C/M/36/Add.1, para. 220; Brazil et al, IP/C/W/403; India, IP/C/M/37/Add.1, para. 223.

[105] EC, IP/C/M/48, para. 65.

[106] Brazil, IP/C/M/32, para. 128; Brazil and India, IP/C/W/443; India, IP/C/M/47, para. 34; Peru, IP/C/M/36/Add.1, para. 203.

[107] United States, IP/C/W/449.

commercialization that might lead to benefit sharing has taken place in a different country[108];

- the case has not been made for why a contractual system that would apply to the vast majority of those seeking access within the framework of national laws would not serve effectively.[109] It is possible that a few individuals could ignore the legal requirements and simply put an herb in their pocket, in the same way that some individuals counterfeit trademarks or pirate copyrighted works, but this does not negate the value of a contractual system that would apply to the vast majority of those seeking access, just as trademark and copyright laws apply in their spheres. Just as is done in the case of trademark counterfeiting and pirated copyrighted works, criminal provisions and/or civil liability for failure to comply can be included in the country's laws for those few who might take genetic resources without entering into an access agreement with the appropriate party[110];

- cases where no contract has been concluded in violation of the domestic access and benefit-sharing regime would be governed by the requirements and penalties, whether criminal and/or civil, of national regimes[111];

- in regard to the point relating to the WSSD declaration, a country could promote and encourage prior informed consent and equitable sharing of benefits on mutually agreed terms at the national level without being a party to the CBD.[112] Countries not parties to the CBD have ensured that bioprospectors and researchers from their countries are made aware of the national access and benefit-sharing systems in other countries.[113]

62. In response to the point made about the effectiveness of a "national contract-based system with an international outlook", the question has been raised as to why bad patents and instances of misappropriation are increasing when such a system is already in place.[114] It has also been said that the suggestion for the use of private forums to enforce provisions dealing with matters of state responsibility is unnecessary when the WTO with its dispute settlement mechanism is itself an appropriate forum. Further, there is no merit in relegating an issue of state responsibility to private international law through arbitration procedures that bind Members only when they agree to them, particularly when there are equity issues that need to be addressed.[115] In response to the comparison with trademark and copyright laws, it has been said that, while there are penalties to redress trademark and copyright infringement, such as the revocation of the right itself, such remedies cannot be found in the contract system.[116] With respect to countries not party to the CBD, while it is acknowledged that they may be taking certain measures to promote the objectives of the CBD, these are insufficient since there is no legislation to ensure that acts of non-compliance of their citizens with respect to the CBD legislation in other countries can be remedied.[117]

(b) Bargaining power of parties to the contract

63. The issue of the bargaining power of the two parties to the contract has also been raised. One view is that:

[108] United States, IP/C/W/449, IP/C/M/49, para. 99.
[109] United States, IP/C/W/449.
[110] United States, IP/C/W/257.
[111] United States, IP/C/M/49, para. 100
[112] United States, IP/C/M/48, para. 25.
[113] United States, IP/C/M/49, para. 94.
[114] Brazil et al, IP/C/W/459.
[115] Brazil et al, IP/C/W/459; India, IP/C/M/48, para. 52.
[116] China, IP/C/M/39, para. 135.
[117] Brazil et al, IP/C/W/459.

- while contractual arrangements may have a role to play, the unequal bargaining strength of the parties to the contract and the lack of an obligation to enter into or enforce a contract renders them insufficient both in terms of entering into contracts in the first instance as well as enforcing them outside the country of origin of the biological resource and/or associated traditional knowledge[118];

- indigenous and local communities lack legal training in the negotiation of contractual terms and it would be difficult for them to negotiate equitable and beneficial terms.[119] The majority of owners of genetic resources are not aware of the benefits to be obtained from their resources.[120] Such unequal bargaining power may lead to unfair results since developed countries might take advantage of their strong position on technology to force developing countries to accept unfair contracts.[121]

64. In response it has been said that:

- one flexibility of the proposed system is that Members may, if appropriate, regulate the terms of agreement through national laws or rules. In such cases, the country of origin would determine, for any cases it deems appropriate, certain terms of collection without the need for arms-length bargaining in the typical sense[122];

- the seeking of information by outsiders on knowledge, innovations and practices would create an opportunity to educate communities that are unfamiliar with the basics of negotiations, contracts and various forms of intellectual property, that might be relevant to them in marketing their knowledge, innovations, and practices for use by those outside their communities, and for obtaining an equitable share of the benefits arising from the utilization of their knowledge, innovations and practices. Likewise, it would also provide an opportunity for indigenous and local communities to indicate that they do not want their knowledge, innovations and practices disclosed or shared with the larger community. This would be an appropriate time to provide information on the use of trade secret law as a tool for maintaining limitations on the circulation of the knowledge, innovations and practices.[123]

(c) Transaction costs

65. With respect to transaction costs under the national-based approach, it has been said that:

- transparency and predictability in access and benefit sharing, including prior informed consent, cannot be established through a fragmented and costly nation-by-nation system, but only through an internationally established and enforced system[124];

- myriad separate and different national systems with no common denominator cannot effectively regulate the relationships between entities, persons and activities taking place in different countries[125];

[118] Brazil, IP/C/W/228, IP/C/M/36/Add.1, para. 220; Brazil et al, IP/C/W/438, IP/C/W/403; India, IP/C/M/46, para. 38; Pakistan, IP/C/M/28, para. 158; Peru, IP/C/M/46, para. 50, IP/C/M/40, para. 85, IP/C/M/36/Add.1, para. 203, IP/C/M/35, para. 236, IP/C/M/32, para. 133.
[119] Peru, IP/C/M/40, para. 85, IP/C/M/36/Add.1, para. 203.
[120] Kenya, IP/C/M/46, para. 67.
[121] China, IP/C/M/47, para. 57.
[122] United States, IP/C/W/449.
[123] United States, IP/C/W/257.
[124] Brazil and India, IP/C/W/443.
[125] Brazil and India, IP/C/W/443.

- it is not clear how the national-based approach takes into account the generally long-term nature of research and development activities involving genetic resources.[126]

66. In response it has been said that:

- a contract-based system need not entail high transaction costs if implemented in an effective and systematic manner, e.g., by providing clear points of contact and setting forth clear statements of agreement to minimize disputes[127];

- contract-based access and benefit sharing, with appropriate monitoring and enforcement, including regular reporting to the points of contact, would help to centralize monitoring and would not be a "fragmented" system[128];

- there is adequate flexibility under a contract-based system to address issues related to the long-term nature of R&D activities involving genetic resources, such as regular reporting requirements and the sharing of benefits in cases of patent expiry or assignment of patent.[129]

(d) Effectiveness of remedies proposed

67. With respect to the effectiveness of the remedies proposed, it has been said that civil and criminal remedies provided for under national laws in the country providing the genetic resources would not provide a sufficient deterrent to check illegal use in third countries[130] in cases where no contracts on access and benefit sharing are concluded[131] and bio-prospecting and use of genetic resources and traditional knowledge takes place without the authorization of the competent national authority.[132]

68. In response it has been said that, in the vast majority of cases, compliance will be facilitated through cooperation between the holders, or other appropriate authorities, and users of the genetic resources and/or traditional knowledge. The rare cases where a party violates the national regime would be subject to criminal and civil provisions, similar to those in other areas of misconduct, such as breaches of environmental law, health and safety laws and other fields in which governments have an important regulatory interest.[133]

69. Questions have been asked as to whether it would be the national or international authorities who would be involved in monitoring an international contracts-based access and benefit-sharing regime and, if international, under which jurisdiction they would operate.[134]

B. DISCLOSURE APPROACH

70. Three proposals put forward in the Council's work for disclosure requirements in patent applications are briefly set out below, followed by a sub-section on their advantages as claimed by their proponents. Following this description of the three proposals, the discussion on these proposals is summarized.

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[126] Switzerland, IP/C/W/446.
[127] United States, IP/C/W/449.
[128] United States, IP/C/W/449.
[129] United States, IP/C/M/49, para. 101.
[130] India, IP/C/M/36/Add.1, para. 212.
[131] Switzerland, IP/C/M/46, para. 75.
[132] Indonesia, IP/C/M/36, para. 217; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/35, para. 236, IP/C/M/32, para. 133; Switzerland, IP/C/M/47, paras. 77-78.
[133] United States, IP/C/W/434, IP/C/W/257.
[134] Canada, IP/C/M/49, para. 106.

## 1. Proponents' description of the disclosure approach

(a) Main features of the proposed disclosure requirements

*The TRIPS disclosure proposal*

71. A proposal has been made that the TRIPS Agreement should be amended in order to oblige Members to require that an applicant for a patent relating to biological materials or to traditional knowledge provide the following information, as a condition of acquiring patent rights:

(i) the source and country of origin of the biological resource and of the traditional knowledge used in the invention;

(ii) evidence of prior informed consent from the authorities under the relevant national regime; and

(iii) evidence of fair and equitable benefit sharing under the relevant national regime.

This proposal is hereinafter referred to as "the TRIPS disclosure proposal".[135]

72. With such an amendment, it would be mandatory for Members to have the proposed disclosure requirements in their national laws and regulations and these requirements would be obligatory for patent applicants applying for patents in these jurisdictions whenever they use genetic resources and/or associated traditional knowledge in their inventions. There should be a reporting obligation on issues relating to the patenting or commercialization of inventions.[136]

73. The obligation to provide evidence of prior informed consent would be discharged by a declaration in the patent application, accompanied, where relevant, by a certificate issued by a relevant national authority or a duly certified contract between the applicant and the national authorities of the country of origin.[137] The obligation to provide evidence of fair and equitable sharing of benefits with the source and country of origin and/or local/indigenous communities, would be fulfilled by providing evidence, at the time of the patent application, of an existing or future benefit-sharing arrangement that is premised upon mutually agreed terms and is fair and equitable in the circumstances.[138] The terms of benefit sharing would cover elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanisms of the benefits to be shared. The patent applicant would also have to indicate how the national authority (and community, where applicable) would enforce such an arrangement.[139] The onus on the patent applicant would be limited

[135] African Group, IP/C/W/404, IP/C/M/40, para. 76; Andean Community, IP/C/M/37/Add.1, para. 231; Brazil, IP/C/W/228, IP/C/M/46, para. 81, IP/C/M/42, para.101, IP/C/M/39, para. 126, IP/C/M/38, para. 230, IP/C/M/37/Add.1, para. 237, IP/C/M/36/Add.1, para. 219, IP/C/M/33, para. 121, IP/C/M/32, para. 128, IP/C/M/29, paras. 146 and 148; IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/403, IP/C/W/429/Rev.1, IP/C/W/356; China, IP/C/M/47, para. 57, IP/C/M/37/Add.1, para. 229, IP/C/M/36/Add.1, paras. 227-228; Colombia, IP/C/M/46, para. 57, IP/C/M/42, para. 119, IP/C/M/40, para. 121, IP/C/M/38, para. 239, IP/C/M/37/Add.1, para. 231, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; India, IP/C/W/198, IP/C/W/195, IP/C/M/45, para. 25, IP/C/M/42, para. 113, IP/C/M/40, paras. 81-82, IP/C/M/36/Add.1, paras. 212 and 214, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M49, para. 159, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Kenya, IP/C/M/47, para. 68, IP/C/M/46, para. 67, IP/C/M/42, para. 114, IP/C/M/40, para. 107, IP/C/M/37/Add.1, para. 239, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/36/Add.1, para. 203, IP/C/M/40, para. 84; Thailand, IP/C/M/42, para. 105, IP/C/M/25, para. 78; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208; IP/C/M/32, para. 136; IP/C/M/28, para. 165; Zimbabwe, IP/C/M/36/Add.1, para. 201.

[136] Brazil, IP/C/M/47, para. 25.

[137] Brazil, IP/C/M/47, para. 29; Brazil et al, IP/C/W/438; India, IP/C/M/46, para. 39.

[138] Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/442.

[139] Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/442.

to providing information and evidence that is known to him, or should have been known to him.[140] It has been said that, since traditional communities are often weak in the negotiation process, a benefit sharing agreement primarily entered into with them be subsequently supplemented and confirmed by the national regulatory authority.[141]

74. Prior informed consent and benefit sharing, as embodied in the CBD, would have to be respected even in cases where specific access and benefit-sharing regimes may not have been set up in the countries of origin.[142] Where there is no national regime, the applicant would be required to state that fact and that there has been consent at least from the authority or community in charge of the location where the genetic resources and/or traditional knowledge has been accessed or that there is a benefit-sharing arrangement, or a future one is envisaged, with the authority or community in charge of the location from which the resources or the knowledge is accessed, in full compliance with other applicable laws, regulations and practices of the country of origin.[143]

75. As regards the legal effects of non-disclosure or inadequate or wrongful disclosure of any of the three components required under this proposal, it has been said that[144]:

- at the stage of processing of the patent application, the processing of the application would be delayed until the necessary declaration and evidence of prior informed consent reaches the authorities. This would be accompanied by penalties and time-limits within which the proper declaration and evidence must be provided; otherwise the application would be deemed withdrawn;

- at the post-grant stage, the patent would be revoked, particularly where fraudulent intent is established;

- criminal and/or administrative sanctions would follow outside the patent system to ensure punitive damages or adequate compensation;

- full or partial transfer of the rights to the invention would also follow where full disclosure would have shown that another person or community or governmental agency is the inventor or part inventor;

- there would be a narrowing of the scope of the claims where part of the claims is affected due to lack of novelty or fraudulent intention or where full disclosure would have led to refusal to admit those parts of the claims;

- the above remedies would be subject to the possibility of a judicial review.

[140] Brazil, IP/C/M/48, para. 36.
[141] India, IP/C/M/49, para. 144.
[142] Brazil, IP/C/M/47, para. 85.
[143] Brazil, IP/C/M/47, para. 29; Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/438; India, IP/C/M/46, para.39.
[144] Brazil et al, IP/C/W/438, IP/C/W/429/Rev.1, IP/C/W/403; India, IP/C/M/46, para. 40, IP/C/M/45, paras. 22-23.

76. It has also been said that, while a certain degree of leeway may be given to the exact legal effect for each infraction, Members should nevertheless have an obligation to ensure that the effect of insufficient, wrongful or no disclosure is effective in terms of its deterrent, compensatory and equity value.[145] It would be left to countries to define in their domestic legislation the penalties applicable in cases of failure to comply with the requirements and the above-mentioned requirements are offered as options.[146] Remedies available would be retrospective so as to cover past use.[147]

77. It has been said that any use, including incidental use, of genetic resources and or associated traditional knowledge, the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention and the scope of the claim, and/or is necessary for understanding or carrying it out, should be sufficient to trigger the disclosure requirement i.e. to require the applicant to disclose the requisite information. Such uses of genetic resources and/or associated traditional knowledge could include those that result in forming part of the claimed invention; use during the process of developing the claimed invention; use that is a necessary prerequisite for the development of the invention; or use to facilitate the development of the invention where it forms part of the necessary background material for the development of the invention.[148]

78. As regards the burden of proof in case of non-compliance with disclosure requirements, it has been said that applicants should be required to positively discharge a burden of proof that the genetic resources and/or traditional knowledge have been legally and legitimately accessed and that benefit sharing had taken place or would take place if a patent is granted with respect to the invention that used the biological resources and/or traditional knowledge.[149] Applicants are expected to employ all reasonable measures to determine the country of origin and source of material used but the onus on them would be limited to disclosure of evidence that is known or should have been known to them.[150]

79. As regards the legal form that such an amendment to the TRIPS Agreement might take, the following suggestions have been made:

- an amendment to Article 27 of the TRIPS Agreement[151] in the form of a further exception to patentability, with the following wording[152]:

> "[Members may also exclude from patentability]:
>
> (c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.
>
> Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity."

[145] Brazil et al, IP/C/W/429/Rev.1; India, IP/C/M/45, para. 22.
[146] Peru, IP/C/W/447, IP/C/M/48, para. 22.
[147] China, IP/C/M/36/Add.1, para. 228.
[148] Brazil et al, IP/C/W/429/Rev.1; India, IP/C/M/45, paras. 22 and 53.
[149] Brazil et al, IP/C/W/438, IP/C/W/429/Rev.1; India, IP/C/M/45, para. 24.
[150] Brazil et al, IP/C/W/429/Rev.1; Colombia, IP/C/M/46, para. 57.
[151] Brazil, IP/C/W/228, IP/C/M/33, para. 121, IP/C/M/32, para. 128; Peru, IP/C/W/447, IP/C/M/48, para. 20.
[152] Peru, IP/C/W/447, IP/C/M/48, para. 20.

- an amendment to Article 29[153] consisting of the addition of a paragraph as set out in the following alternative texts proposed:

> "Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."[154] or
>
> "Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted." [155]

- the introduction of a new article in the TRIPS Agreement.[156]

80. An option suggested has been an authoritative interpretation of Article 29 of the TRIPS Agreement.[157]

*The PCT disclosure proposal*

81. Another proposal that has been discussed is that the Regulations under the Patent Co-operation Treaty (PCT) of WIPO be amended so as to explicitly enable the national patent legislation of contracting parties to the PCT, to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if an invention is directly based on such resource or knowledge (hereinafter referred to as "the PCT disclosure proposal"). The proposal would also grant applicants the possibility of satisfying this requirement at the time of filing an international patent application, or later during the international phase. This declaration of source would be included in the international publication of the patent application.[158]

82. The proposed disclosure requirement would be permissive, explicitly enabling Members to incorporate it into their national laws and regulations. But, once so incorporated, it would be obligatory for patent applicants who apply for patents in those Members' jurisdictions whenever they directly base their inventions on the genetic resources or traditional knowledge. The point has been made that the optional nature of the requirement would allow the national governments and the international community to gain experience with the disclosure requirement without prejudice to further international efforts.[159]

83. It is proposed that patent applicants be required to declare the "source" of genetic resources and traditional knowledge. The term "source" should be understood in its broadest sense possible. This is because, according to the CBD, the Bonn Guidelines and the International Treaty of the FAO, a multitude of entities may be involved in access and benefit sharing. The entity competent (to be declared as the source) should first be the one to grant access to genetic resources and/or traditional knowledge or the one to participate in the sharing of the benefits arising out of their utilization.[160]

84. As regards the legal effects, it has been said that the disclosure requirement should be a formal and not a substantive requirement.[161] In general, the legal effects of wrongful disclosure or

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[153] African Group, IP/C/W/404, IP/C/M/40, para. 76; China, IP/C/M/40, para. 121; Colombia, IP/C/M/40, para. 127; Cuba, IP/C/M/40, para. 117; India, IP/C/W/195, IP/C/M/24, para. 81; Peru, IP/C/W/447, IP/C/M/48, para. 20; Zimbabwe, IP/C/M/40, para. 76.

[154] African Group, IP/C/W/404.

[155] Peru, IP/C/W/447, IP/C/M/48, para. 21.

[156] Brazil et al, IP/C/W/403.

[157] Cuba, IP/C/M/40, para. 117.

[158] Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115.

[159] Switzerland, IP/C/W/433, IP/C/M/46, para. 74.

[160] Switzerland, IP/C/W/433.

[161] Switzerland, IP/C/W/433, IP/C/M/46, para.22.

non-disclosure, currently allowed for under the PCT and the PLT, should apply to failure to disclose or wrongful disclosure of the source of genetic resources and traditional knowledge.[162] If the patent applicant does not comply with the requirement to disclose within the set time-limit, not less than two months, national law may foresee that in the national phase the PCT application is not processed any further until the patent applicant has furnished the required declaration or consider it withdrawn on grounds of non-compliance. If, however, the applicant submits, with the international application or later during the international phase, the proposed declaration containing standardized wording relating to the declaration of the source, the designated office must accept this declaration and may not require any further document or evidence relating to the source declared, unless it reasonably doubts the veracity of the declaration concerned. Based on Article 10 of the Patent Law Treaty (PLT) of WIPO to which, through reference, such an amendment would also apply, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, national law may envisage the validity of granted patents being affected by a lack of or an incorrect declaration of the source, only if this is due to fraudulent intention. The possibility for judicial review has also been suggested. Other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.[163]

85. In order to apply the disclosure requirement or to trigger it for genetic resources, the proposal requires that the invention must be "directly based" on "a specific genetic resource to which the inventor has had access." This wording makes clear that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and that the inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource that are relevant for the invention. With regard to traditional knowledge the inventor must know that the invention is "directly based" on such knowledge; that is, the inventor must consciously derive the invention from this knowledge.[164] Based on the terminology used in the relevant international instruments and their scope of application, the traditional knowledge in question must be related to or associated with the genetic resources in question.[165]

86. It has also been suggested that a list of government agencies that are competent to obtain information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge be established.[166] Patent offices receiving such patent applications could inform the competent government agency in another country, through a standardized letter, that it had been declared as the source. The competent government agency could either be the national focal point foreseen under paragraph 13 of the Bonn Guidelines and/or national competent authorities for access and benefit sharing to be established under paragraphs 14 and 15 of these Guidelines. By making the list available on the internet, patent offices would have easy access to it and could, without much administrative burden or cost, provide the competent national authority with the information so that a country would not need to monitor patent applications worldwide to verify whether it had been declared as a source and if so, whether all access and benefit-sharing requirements had been fulfilled.[167] The two measures - the obligatory disclosure requirement at the national level and this information system - would allow a party to a contract on access and benefit sharing to verify whether the other party is complying with its obligations arising under that contract and would simplify the enforcement of these contractual obligations.[168]

*The mandatory disclosure proposal*

[162] Switzerland, IP/C/W/423.
[163] Switzerland, IP/C/W/423.
[164] Switzerland, IP/C/W/423, IP/C/W/400/Rev.1.
[165] Switzerland, IP/C/W/423.
[166] Switzerland, IP/C/W/400/Rev.1, IP/C/M/46, para.76, IP/C/M/42, para. 97.
[167] Switzerland, IP/C/M/49, para 115, IP/C/M/46, para. 76.
[168] Switzerland, IP/C/M/47, para. 77.

87. A further approach outlined in the Council, also submitted as a proposal in the WIPO IGC[169], is that each country would accept an obligation to require all patent applicants to disclose information on the country of origin or source of genetic resources used in the invention which patent applicants know or have reason to know (hereinafter referred to as "the mandatory disclosure proposal").[170] There could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if the applicant is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the definition of "traditional knowledge" has been suggested as being necessary.[171] The disclosure requirement would be legally binding and universal and would apply to all national, regional and international patent applications at the earliest stage possible.[172]

88. Such a disclosure requirement would not act, de facto or *de jure*, as an additional formal or substantial patentability criterion.[173] The requirement would only be a formal one. If the applicant fails or refuses to declare the required information or, despite being given the opportunity to do so, fails to remedy that omission, the patent application would then not be further processed and the applicant would be duly informed of this consequence. Once the patent is granted the legal effects of the non-respect of the requirement i.e. if the information provided were incorrect or incomplete, would lie outside the ambit of patent law, for example by providing effective, proportionate and dissuasive sanctions in civil law (e.g. claims for compensation) or in administrative law (e.g. fines for refusal to submit information to the authorities or for submitting wrong information). With this framework, each country would decide for itself how it would provide for sanctions in cases of violation of the disclosure requirement.[174]

89. Under this approach, the disclosure obligation would be triggered when the genetic resource or traditional knowledge forms part of the claimed invention or has been necessary for the development resulting in the invention. In other words, the invention must be directly based on the specific genetic resource.

90. The burden of proof in regard to compliance with the disclosure requirements would rest on the alleger that there has been non-compliance.[175] According to usual rules, it would be up to those who might wish to contest such disclosure in an administrative procedure or before a court to provide proof to the contrary.[176]

91. With respect to prior informed consent and benefit sharing, it has been said that a simple notification procedure to a centralized body could be followed by the patent office every time it receives a declaration.[177] A list of government agencies competent to obtain information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge could be established.[178] Such a list could be maintained by WIPO in close cooperation with the CBD. Alternatively, the clearing house mechanism of the CBD could be recognized as the central body to

[169] EC, IP/C/M/48, para. 62, IP/C/M/47, para. 58.

[170] EC, IP/C/W/383, IP/C/M/49, para. 124, IP/C/M/44, para. 29, IP/C/M/42, para. 107, IP/C/M/40, para. 95, IP/C/M/37/Add.1, para. 228, IP/C/M/35, para. 234, IP/C/M/30, paras. 144-146; Norway, IP/C/M/40, para. 86, IP/C/M/39, para. 120.

[171] EC, IP/C/M/47, para. 58.

[172] EC, IP/C/W/383, IP/C/M/42, para. 108, IP/C/M/39, para. 127, IP/C/M/38, para. 247, IP/C/M/37/Add.1, para. 228; Norway, IP/C/M/36/Add.1, para. 210.

[173] EC, IP/C/W/383, IP/C/M/42, para. 108, IP/C/M/39, para. 127, IP/C/M/38, para. 247, IP/C/M/37/Add.1, para. 228.

[174] EC, IP/C/W/383, IP/C/M/49, para. 124, IP/C/M/47, para. 58, IP/C/M/44, para. 32, IP/C/M/38, para. 247, IP/C/M/37/Add.1, para. 228.

[175] EC, IP/C/M/46, para. 47, IP/C/M/44, para. 33.

[176] EC, IP/C/M/44, para. 32.

[177] EC, IP/C/M/47, para. 58.

[178] EC, IP/C/W/383, IP/C/M/47, para. 59, IP/C/M/46, para. 47, IP/C/M/42, paras. 107-108, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 228.

which the patent offices would send the available information.[179] The information would then be available to all CBD parties as well as to the public.[180]

92. As regards legal form, the view has been expressed that discussion of this aspect would be premature as it would depend on what substance could be agreed upon. There are many options that could be considered if there were to be an agreement on substance, such as inserting a new article in the TRIPS Agreement or a new obligation in an existing Article provided it is properly calibrated.[181] Another view is that there should be a mandatory provision in the TRIPS Agreement[182]; one possibility would be to add such a provision to Article 29 of the TRIPS Agreement.[183]

(b) Claimed advantages of the disclosure approach

93. The view has been expressed that a requirement to disclose source or origin of genetic resources and traditional knowledge would have the following advantages:

- increase in transparency regarding access to genetic resources and traditional knowledge and benefit sharing and help source countries to monitor and keep track of compliance with access and benefit-sharing rules in a cost-effective way[184], since, in the view of some of the proponents, one of the major uses of genetic resources and of traditional knowledge associated with them, takes place through the patent system[185];

- facilitation and simplification of the enforcement of obligations under the CBD through the provision of incentives on patent applicants for the conclusion of contracts[186], such as material transfer agreements for the transfer of biological materials and information transfer agreements for the transfer of traditional knowledge.[187] In the view of some of the proponents, this applies particularly where the legal effects include revocation of the patent.[188] It would thus help improve the operation of access and benefit-sharing systems and make it difficult for those involved in acts of misappropriation while benefiting victims of such acts[189];

- grant of better patents through more focused searches in patent offices and lessening of the need for burdensome challenges regarding patent validity which would contribute to a more effective implementation of the CBD and improve the operation of the patent system.[190] There would be an addition of information available to patent examiners on prior art regarding traditional knowledge[191], including that which only exists in oral form or is documented only in local languages.[192] Disclosing the source

[179] EC, IP/C/M/47, para. 58, IP/C/M/49, para. 124
[180] EC, IP/C/M/44, paras. 31 and 35, IP/C/M/42, para. 106.
[181] EC, IP/C/M/46, para. 49, IP/C/M/44, para. 33.
[182] Norway, IP/C/M/49, para. 120
[183] Norway, IP/C/M/39, para. 120, IP/C/M/38, para. 244.
[184] Brazil, IP/C/M/48, para. 38; Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/403, IP/C/W/356; EC, IP/C/M/46, para. 46, IP/C/M/44, para. 30, IP/C/M/37/Add.1, para. 228, IP/C/M/33, para. 121, IP/C/M/32, para. 128; India, IP/C/W/195, IP/C/M/48, para. 52, IP/C/M/40, para. 82; Peru, IP/C/W/447, IP/C/M/48, para. 18; Switzerland, IP/C/W/423, IP/C/M/42, para. 98.
[185] Brazil et al, IP/C/W/459.
[186] Switzerland, IP/C/W/423, IP/C/M/42, para. 98.
[187] Egypt, IP/C/M/37/Add.1, para. 204; India, IP/C/W/195, IP/C/M/37/Add.1, para. 223 .
[188] Brazil, IP/C/M/48, para. 41; Brazil et al, IP/C/W/403; India, IP/C/M/40, para. 82.
[189] Peru, IP/C/M/46, para. 51.
[190] EC, IP/C/M/46, para. 46, IP/C/M/44 para. 30; India, IP/C/M/48, paras. 57 and 60.
[191] EC, IP/C/M/37/Add.1, para. 228.
[192] Brazil et al, IP/C/W/403; India, IP/C/M/40, para. 82, IP/C/M/39, para. 123, IP/C/M/37/Add. 1, para. 253; Switzerland, IP/C/M/42, para. 98.

of origin would therefore enable searches that might be outside the scope of established databases[193];

- introduction of an important confidence-building measure that would help restore the trust of all stakeholders[194] in the patent system so that it works for all in an equitable manner and, more particularly, increase confidence among bio-collectors and biodiversity-rich countries and indigenous communities. Beneficiary countries or communities would have the incentive to generate less complex or burdensome but more effective national access and benefit-sharing regimes[195];

- development of a predictable environment for governments, investors, traditional communities and researchers that could lead to more biotechnological R&D in developing countries, thus creating a win-win situation for both providers and accessors[196];

- it would particularly help inculcate respect for the beliefs and rights of indigenous peoples and safeguard countries' interests in their genetic resources.[197]

94. In regard to the PCT disclosure proposal, the following more particular advantages have been claimed. It would:[198]

- explicitly enable the Contracting Parties of the PCT to introduce a disclosure requirement in their national laws. It would thus provide a sound legal basis at the international level for Members to introduce measures regarding the declaration of the source of genetic resources and traditional knowledge in their national patent laws;

- leave Members with adequate flexibility to develop an efficient national legislation according to their needs;

- not be so burdensome for patent applicants so as to deter them from filing for patents and encourage them to maintain secrecy over their inventions;

- enable the patent applicant to declare the source/s most appropriate with regard to the invention in question. In most cases patent applicants would be able to declare the source and, in exceptional cases, to declare that the source is unknown to them or the inventor. There would thus be little risk that the grant of patents for resulting inventions would be jeopardized by the lack of knowledge about the sources of the used genetic resource or traditional knowledge;

- enable measures to be in conformity with all international obligations under the relevant international agreements, including the TRIPS Agreement, the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and contribute towards their implementation by Members in a mutually supportive way;

- represent a specific measure to implement the Bonn Guidelines as it would enable those who have been identified as having contributed to the resource management

[193] Brazil, IP/C/M/48, para. 39.
[194] Switzerland, IP/C/M/46, para. 73.
[195] Brazil, IP/C/M/46, paras. 82 and 85; EC, IP/C/M/46, para. 46, IP/C/M/44, para. 30; India, IP/C/M/40, para. 82; Norway, IP/C/M/39, para. 121; Peru, IP/C/W/447, IP/C/M/48, para. 94 .
[196] Brazil, IP/C/W/228, IP/C/M/37/Add.1, para. 236; Brazil et al, IP/C/W/356; Indonesia, IP/C/M/36/Add.1, para. 217.
[197] Peru, IP/C/M/48, para. 18.
[198] Switzerland, IP/C/W/423, IP/C/M/42, para. 98.

> and to scientific and/or commercial processes to participate in the sharing of benefits as mentioned in paragraph 48 of these Guidelines.

95. In regard to the mandatory disclosure proposal, it has been said that the proposal, while facilitating the implementation of the objectives of the CBD, would not affect the balance of rights and obligations set out in the TRIPS Agreement, nor the rights of WTO Members to create a favourable environment for research and development activities in the field of biotechnology. The patent system would continue to be a highly effective tool for stimulating innovation, technological progress and economic development and, provided it was appropriately calibrated, the introduction of such a disclosure requirement would not necessarily be burdensome to patent offices or to applicants.[199]

(c) Examples given of experience with use of the disclosure approach

96. The main information provided in the TRIPS Council by delegations with respect to their countries' experience with use of the disclosure approach is set out below. Further detail can be found in the documents referenced in the footnotes.

97. The Council was informed that Norway has amended some of the provisions of its Patent Act, taking account of certain provisions of the CBD relating to benefit sharing and prior informed consent. Under the new provisions, patent applications concerning biological material should include information on the country of origin of the material. Should the national legislation of the providing countries so require, information on prior informed consent should also be submitted. These provisions do not, however, apply to international patent applications and the processing of national patent applications would not be prejudiced by them. Failure to provide correct information is subject to penalty in accordance with Section 166 of the General Civil Penal Code with respect to giving false testimony in writing to a public authority. The Norwegian policy on this issue is being reviewed and more definitive views and further information on national experiences will be submitted when the internal review is completed.[200]

98. The Council was also informed of the legislation of Peru and of the Andean Community.[201] Peru's regulation on protection of plant varieties is said to establish a direct and explicit link between intellectual property and access to genetic resources and protection of traditional knowledge. This regime determines the rules and the institutional framework applicable to the protection of the rights of plant breeders. Article 15 of the Regulation provides that the application "for the granting of a breeder's certificate shall be submitted to the Office of Inventions and New Technologies [of INDECOPI] and shall contain or have attached, as appropriate:

> (e) the geographical origin of the raw plant material of the new variety to be protected, including, where appropriate, the document certifying the legal provenance of the genetic resources, issued by the competent authority, with respect to access to genetic resources,
>
> (f) the origin and genetic content of the variety, including any known details with regard to the source of the genetic resources used in the variety or the breeding thereof, as well as any information on knowledge relating to the variety [including traditional knowledge], where appropriate".

The penalty for not submitting the required information, under Article 16 of the Supreme Decree, is that the application shall be declared to have lapsed.

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[199] EC, IP/C/M/49, para. 123.

[200] Norway, IP/C/M/48, para. 81, IP/C/M/47, para. 65, IP/C/M/43, para. 54, IP/C/M/40, paras. 87-88, IP/C/M/39, para. 121.

[201] Peru, IP/C/W/447, IP/C/M/48, para. 93.

99. The Andean Community Decision 391 on a Common Regime on Access to Genetic Resources, approved on 2 July 1996, provides for the adoption of legal requirements at the regional level (valid only among the five countries of the Andean Community), which is said to directly link the access regime to that of intellectual property and of patents in particular. The Second Supplementary Provision of Decision 391 provides that:

> "The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components [including traditional knowledge], that were obtained or developed through an access activity that does not comply with the provisions of this Decision.
>
> Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents".

In much more specific terms, the Third Supplementary Provision provides that:

> "The competent national offices on intellectual property shall require the applicant to give the registration number of the access contract and supply a copy thereof as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed from genetic resources or their by-products originating in any one of the Member Countries. The competent national authority and the competent national offices on intellectual property shall establish systems for exchanging information about the authorized access contracts and intellectual property rights granted".

100. Decision 486 on a Common Industrial Property Regime (14 September 2000) of the Andean Community which establishes the legal industrial property framework (patents, designs, utility models, marks, etc.) applicable in the countries of the Andean region is said to consolidate the idea of disclosure of origin and legal provenance. Article 26(h) and (i) of the Decision provides that applications for patents shall contain:

> "(h) if applicable, a copy of the access contract, where the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by-products originating in any one of the Member Countries;
>
> (i) if applicable, a copy of the document certifying the licence or authorization to use the traditional knowledge of indigenous, African American or local communities in the Member Countries, where the products or processes whose protection is being requested were obtained or developed from such knowledge originating in any one of the Member Countries, in accordance with the provisions of Decision 391 and the amendments and regulations thereto currently in force".

Article 75(g) and (h) of Decision 486 provides that a patent shall be declared absolutely void if the applicant has failed to submit a copy of the access contract or the document certifying the licence or authorization for use of traditional knowledge.[202]

101. Peru's Law No 27811 (Law Establishing the Regime for Protection of the Collective Knowledge of Indigenous Peoples Relating to Biological Resources, 10 August 2002) is said to aim, through a system of registers, licences and compensatory mechanisms, to achieve a degree of legal protection for the traditional knowledge of Peru's indigenous peoples. In the matter of disclosure of origin and legal provenance, the Second Supplementary Provision of Law 27811 provides that:

[202] Peru, IP/C/W/447, IP/C/M/48, para. 93.

> "Where a patent application relates to products or processes obtained from collective knowledge, the applicant shall be required to submit a copy of the licence contract, as a prerequisite for the granting of the relevant right, unless the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be grounds for refusing to grant the patent or, where appropriate, declaring it void."

This provision supplements at national level the provisions of Decision 486, specifically with regard to the disclosure of the origin and legal provenance of traditional knowledge that could form part of an invention.[203]

102. Peru's Law No. 28216 (Law on Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples, 1 May 2004), under which a National Commission for the Protection of Access to Peruvian Biological Diversity and Collective Knowledge (commonly known as the Commission for Prevention of Acts of Bio-piracy) was formally established, provides for a series of measures to deal with biopiracy. The third and final supplementary provision of the Law defines "biopiracy" as "access to and unauthorized use without compensation of biological resources or traditional knowledge of the indigenous people by third parties, without the necessary authorization and in contravention of the principles established in the Convention on Biological Diversity and the existing rules on the subject. This appropriation may come to light through physical inspection, through ownership rights in products incorporating such illegally obtained elements or, in some cases, through the invocation of such rights".

103. The Commission's functions, as defined in Article 4, include the following:

> "(c) to identify and follow up patent applications made or patents granted abroad that relate to Peruvian biological resources or collective knowledge of the indigenous peoples of Peru;
>
> (d) to make technical evaluations of the patent applications or patent grants referred to in the preceding paragraph;
>
> (e) to issue reports on the cases studied, and to transmit recommendations to the competent State authorities;
>
> (f) to lodge objections or institute actions for annulment concerning patent applications made or patents granted abroad that relate to Peruvian biological or genetic material or the collective knowledge of the indigenous and native peoples of Peru".[204]

104. Some of the work of the Commission on analyzing potential cases of biopiracy has been described in IP/C/W/441/Rev.1 (with respect to hercampuri, camu-camu, yacón, caigua, sacha inchi and chancapiedra) and IP/C/W/458 (with respect to camu-camu).

105. Other disclosure requirements established at the national or regional level have been mentioned in the Council. These include, at the regional level, the Organization of African Unity's Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources and Preambular paragraph 27 of the European Directive on the Legal Protection of Biotechnological Inventions (Directive No. 98/44/EC), and, at the national level, the laws of Belgium, Brazil, Costa Rica, India, the Philippines and Venezuela.[205]

106. In response to the Peruvian submission, IP/C/W/441/Rev.1, it was noted that the patentability of the claimed inventions in the cited, published but pending patent applications had not been

[203] Peru, IP/C/W/447, IP/C/M/48, para. 93.
[204] Peru, IP/C/W/447, IP/C/M/48, para. 93.
[205] India, IP/C/M/48, para. 97; Peru, IP/C/W/447.

determined, and, in relation to that point, it was not clear how the mere filing of a patent application could amount to an act of misappropriation. With respect to the patent applications relating to maca, a review of the US data base has revealed that all the applications disclosed the country of origin as Peru. Apparently, the inventors have created new, useful and non-obvious inventions from the genetic material that fully meet the patenting criteria under US patent law, for example patents pertaining to chemically active isolates, chemical compounds and compositions and not to the plant itself. This is also the case with respect to the patent applications relating to chancapiedra as they cover novel compositions useful in cosmetics that met the statutory requirements for patentability. Thus, while Peru has listed more than thirty species of plants from which the active ingredients might be derived and that were available from sources throughout the world, it has not identified any examples of misappropriation or biopiracy.[206] It was also said that after a preliminary check of the Japanese patent applications cited, there does not appear to be any biopiracy as the genetic resources referred to in the document were cultivated worldwide, including in Japan, and that the negative connotation in the words "potential cases of biopiracy" is unwarranted.[207]

107. In response, it was said that no case was sought to be made that the mere presentation of a patent application constitutes proof of misappropriation or biopiracy. The Peruvian National Anti-Biopiracy Commission has, in the initial phase of its work, identified approximately fifty products for which patent applications have been filed. In a second phase, the Commission would identify the applications where the Peruvian National Authorities consider that there could have been misappropriation in order to begin proceedings to refuse the grant of such patent applications. This is a very difficult task since the Peruvian patent system grants only five or ten patents annually, thus necessitating searches, not within the Peruvian patent system, where there is an obligation to disclose origin, but in countries where the majority of patent applications are presented and where the large corporations carry out research and development using foreign genetic resources. This demonstrates the need for a universal, legally binding patent disclosure requirement as it would be much easier for countries like Peru to search for specific cases, without having to go through expensive legal procedures. With respect to patents involving the use of maca the Peruvian government would have found it impossible to present the cases on revocation of patents in foreign countries were it not for international support from non-governmental organizations.[208]

108. With regard to the EC Directive (98/44/EC) on the legal protection of biotechnological inventions, it has been said that it was adopted on 6 July 1998 and subsequently transposed into the national law of the EU member States. The preamble of the Directive, in particular recital 27, lays down that if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known. This provision is without prejudice to the processing of patent applications or to the validity of rights arising from granted patents. This provision amounts to an encouragement to disclose the geographical origin of biological material in the patent application, along the lines indicated by Article 16(5) of the CBD, as this could be helpful for the process of equitable benefit-sharing.[209]

109. It has been said that certain patents granted for claimed inventions involving the use of turmeric and neem are examples of problems that could have been obviated, had a disclosure requirement been in place. Some examples, along with other views expressed in relation to them, can be found in Section B.2(k) below.

### *2.* Discussion of the disclosure approach

110. The discussion of the disclosure approach is grouped under eleven sub-sections. The first records discussion on the issue of how a requirement to disclose origin or source might work and its

[206] United States, IP/C/M/47, para. 45.
[207] Japan, IP/C/M/49, para. 111, IP/C/M/48, para. 77.
[208] Peru, IP/C/M/47, paras. 71 and 73.
[209] EC, IP/C/M/49, para. 127.

merits and demerits. The second focuses on similar issues in relation to disclosure of prior informed consent and benefit sharing. The third is focused on the issue of remedies for non-compliance with a disclosure requirement, including patent revocation. The fourth discusses what would trigger a disclosure requirement, in particular, the degree of closeness of the relationship between genetic resources and traditional knowledge in question and the invention itself that would be necessary. The fifth is about definitions of terms used such as biopiracy, genetic resources and traditional knowledge. The next three treat the subject of the relationship of a disclosure requirement with the PCT/PLT, the TRIPS Agreement and the CBD. The last three discuss the implications of a disclosure requirement for achieving prior informed consent and benefit sharing, for preventing erroneously granted patents and for the patent system.

(a) Disclosure of origin and/or source of genetic resources and traditional knowledge

111. The implementation of a suggested disclosure requirement with respect to geographical origin and/or source of the genetic resources and traditional knowledge under the proposals made has been discussed. The proponents of the national-based approach have said that proposals for new patent disclosure requirements regarding origin and/or source would not achieve their purported objectives of ensuring appropriate access and equitable benefit sharing, nor the goal of preventing erroneously granted patents. Further, proposals for such new patent disclosure requirements would introduce many negative consequences, including the addition of new uncertainties, into the patent system, imposing significant administrative burdens on Members, undermining the role of the patent system in promoting innovation, and undermining potential benefit-sharing.[210]

112. In response, it has been said that new patent disclosure requirements would not only help source countries to monitor and keep track of compliance with access and benefit-sharing rules in a cost-effective way[211], but would facilitate and simplify the enforcement of obligations under the CBD through the provision of incentives on patent applicants for the conclusion of contracts.[212] In the view of some of the proponents, this applies particularly where the legal effects include revocation of the patent.[213] (See also Section B.1.(b) above).

113. Clarifications have been sought from the proponents of the disclosure approach as to:

- what the definitions are of "source" and "country of origin" in their proposals and how these concepts relate to traditional knowledge; whether it would be necessary for patent applicants to disclose both or would disclosure of either one of them be sufficient[214];

- what would happen if patent applicants access genetic resources from a source different to the country of origin - since there would be situations where the genetic resource is indigenous to one country but freely available in several countries - and in such a situation which is the country to be disclosed[215];

- why the proponents refer only to the country of origin even though Article 15 of the CBD refers to the contracting party providing genetic resources[216];

[210] United States, IP/C/W/434, IP/C/W/449.

[211] Brazil, IP/C/M/48, para. 38; Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/403, IP/C/W/356; EC, IP/C/W/228, IP/C/M/46, para. 46, IP/C/M/44, para. 30; Egypt, IP/C/M/37/Add.1, para. 204; India, IP/C/W/195, IP/C/M/48, para. 52, IP/C/M/40, para. 82; Peru, IP/C/W/447, IP/C/M/48, para. 18; Switzerland, IP/C/W/423, IP/C/M/42, para. 98.

[212] Switzerland, IP/C/W/423, IP/C/M/42, para. 98.

[213] Brazil, IP/C/M/48, para. 41; Brazil et al, IP/C/W/403; India, IP/C/M/40, para. 82.

[214] Switzerland, IP/C/W/446.

[215] Chinese Taipei, IP/C/M/48, para. 89.

[216] Switzerland, IP/C/M/47, para. 76.

- whether, due to the reference to the "country of origin", plant genetic resources for food and agriculture under the International Treaty of FAO would be excluded from the proposed disclosure requirement[217];

- who would decide that the country of origin is not known to the patent applicant[218];

- if the patent application were to disclose source, but not origin, or vice versa, how would a possible conflict be resolved if the other country came forward to claim a share in a benefit-sharing arrangement[219];

- whether there would be a need to disclose the origin or source when the genetic resources are obtained from an *ex situ* country or available for legal purchase from the market in many countries[220];

- how would a dispute involving plants found transnationally[221] and also cultivated in the country of patent grant be resolved.[222]

114. In response, it has been said that under the TRIPS disclosure proposal, the following would apply:

- although the CBD refers to both "country of origin" and the "country providing genetic resources", it is the country of origin that is relevant in the context of prior informed consent and access and benefit sharing under the CBD, since genetic resources are the property of the country of origin through the recognition of sovereign rights under the CBD.[223] Country of origin is defined in the CBD as the country, which possesses genetic resources in *in situ* conditions. *In situ conditions* mean conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties[224];

- in accordance with Article 15.5 of the CBD, however, prior informed consent would have to be obtained from the country providing the resources, unless otherwise determined by that country. Black's Law Dictionary defines source as "a place where something is found or whence it is taken or derived; or a person or a thing that originates or sets in motion or is a primary agency in producing any course of action or result".[225] It is for these reasons that disclosure of both source and country of origin are recommended primarily in order to prevent the grant of bad patents that do not fulfil the patentability criteria of novelty and/or inventive step and to avoid misappropriation[226];

- in cases where the genetic material is available from multiple sources, the source would be the country from where the applicant has received the material and the country of origin is the country in which the genetic resource is indigenous[227];

[217] Switzerland, IP/C/M/47, para. 76.
[218] Switzerland, IP/C/W/446.
[219] Malaysia, IP/C/M/48, para. 82.
[220] Chinese Taipei, IP/C/M/48, para. 89.
[221] Canada, IP/C/M/48, para. 74.
[222] Japan, IP/C/M/48, para. 77.
[223] India, IP/C/M/49, paras. 137-138, IP/C/M/45, para. 53.
[224] India, IP/C/M/49, para. 137.
[225] India, IP/C/M/49, para. 138.
[226] Brazil et al, IP/C/W/459; India, IP/C/M/49, para. 138.
[227] Brazil et al, IP/C/W/459.

- it is within the spirit of the CBD to include the origin of knowledge associated with the resources i.e. the country which possesses the genetic resources in *in situ* conditions and/or the associated knowledge with them[228];

- plant genetic resources for food and agriculture would be included and the disclosure requirements applicable would be those within the scope and context of the FAO Treaty, although there may be other ways to reflect the concerns expressed in this regard.[229]

115. Also responding to the questions put, it has been said that, under the PCT disclosure proposal, the following would apply:

- if the patent applicant (or inventor) has information at hand about the primary source, this must be disclosed; if he has information on the primary and one or several secondary sources, the primary source must be disclosed whereas disclosure of the secondary ones would be optional; if he has information about a secondary source but not about a primary source, this secondary source must be disclosed; if he has information about several secondary sources but not about the primary source, the secondary source with the closest relationship to the primary source must be disclosed, but the rest would be optional[230];

- the term "source" should be understood broadly to cover the terms "Contracting Party providing genetic resources", "origin", "geographical origin", "country of origin of genetic resources", the Multilateral System established by the International Treaty of the FAO, and any other sources that may be relevant[231];

- definitions of "primary" and "secondary" sources are given in the CBD (Articles 15, 16, 19 and 8(j)) and the International Treaty of the FAO. Primary sources are the contracting parties providing genetic resources, indigenous and local communities and the multilateral system established by the International Treaty of the FAO. Secondary sources are *ex situ* collections such as gene banks, botanical gardens, scientific literature, and databases on genetic resources and traditional knowledge[232];

- the source/s to be declared should be the most appropriate one/s where an entity is competent to grant access to genetic resources and/or traditional knowledge or to participate in the sharing of the benefits arising out of their utilization. If such a source is not known, a declaration would be made to this effect. This is because a multitude of entities may be involved in access and benefit sharing and the objective of disclosure should be to increase transparency.[233] Limiting the number of sources permitted to be declared could hinder research activities and could prevent the development of innovations[234];

- the term "country of origin" is not used because the CBD, in the context of access and benefit sharing, refers to "Contracting Party providing genetic resources". Furthermore, it excludes the International Treaty of the FAO, since it is not based on

[228] India,, IP/C/M/49, para.138.
[229] Brazil, IP/C/M/48, para. 44; India, IP/C/M/49, para. 139.
[230] Switzerland, IP/C/W/433, IP/C/M/45, para. 49.
[231] Switzerland, IP/C/W/423, IP/C/M/44, para. 25, IP/C/M/43, para. 59, IP/C/M/42, paras. 97-99, IP/C/M/40, para. 71.
[232] Switzerland, IP/C/W/433, IP/C/M/45, para. 49.
[233] Switzerland, IP/C/W/433, IP/C/M/45, para. 49.
[234] Switzerland, IP/C/W/423, IP/C/M/42, para. 98.

a bilateral, country-by-country approach but establishes a multilateral system of access and benefit sharing.[235]

116. It has been said that, under the mandatory disclosure proposal, the following would apply:

- the country of origin that would be required to be disclosed should, whenever possible, be the country which possesses the genetic resources *in situ*. However, when this country is not known, the patent applicant's obligation would be to indicate the source of the specific genetic resource to which the inventor has had physical access and which is known to him.[236] This could be the research centre, gene bank or entity from which the inventor acquired the resource[237];

- the definition of the "country of origin" is based on Article 2 of the CBD which defines this as "the country which possesses those genetic resources in *in situ* conditions". Admittedly, "country of origin" does not reflect the wider concept of "country providing the genetic resources" reflected in Article 15 of the CBD. However, the proposal takes this into account because when the country of origin is not known to the applicant, it is possible to provide the "source" which can include the "country providing the genetic resources"[238];

- the term "disclosure of source of genetic resources" is preferred to "geographic origin" as, in principle, all applicants should know the source of genetic resources or traditional knowledge and, in certain circumstances, it might be impossible or unreasonably burdensome for the applicant to investigate the entire chain backwards to the origin. Under the proposal, no additional research would be required on the applicant's part[239] and it is the patent applicant himself who should judge if the country of origin is known to him[240];

- problems relating to the fact that genetic material originates from more than one country should be resolved through arrangements with the source countries concerned and in the context of the CBD.[241] One way to make the disclosure requirement work would be to have national authorities deliver an internationally recognized certificate which would provide evidence of the origin, prior informed consent and benefit sharing in one document, as is being discussed in the Access and Benefit Sharing Working Group of the CBD. However, many countries do not yet have national legislation on access and benefit sharing and are not in a position to deliver certificates of origin, and the negotiation in the Working Group is at a very early stage.[242]

[235] Switzerland, IP/C/M/47, para. 76.
[236] EC, IP/C/M/47, para. 58.
[237] EC, IP/C/M/46, para. 45.
[238] EC, IP/C/M/46, para. 45.
[239] EC, IP/C/M/46, para. 45.
[240] EC, IP/C/M/48, para. 66.
[241] EC, IP/C/W/383.
[242] EC, IP/C/W/383, IP/C/M/48, para. 64, IP/C/M/47, para. 61, IP/C/M/46, para. 45, IP/C/M/44, paras. 35-36.

117. A question was raised as to how benefits would be shared in case of access and use of genetic resources obtained from *ex situ* sources.[243]

(b) Disclosure of evidence of prior informed consent and benefit sharing

118. The issue of how the suggested requirement to disclose evidence of prior informed consent and benefit sharing might be implemented has been discussed. One view has been that:

- it is not feasible to require, in addition to the declaration of the source of genetic resources, evidence of prior informed consent and benefit sharing.[244] This is because patent offices are not capable of verifying this information. Among other reasons, the terms and conditions of a contract would remain confidential and are thus not accessible to the patent granting authority.[245] Such terms may vary with regard to the form of benefits shared, the timing and other conditions and what is fair and equitable may differ on a case-by-case basis[246] and patent offices would have no way of judging fairness or equity.[247] (See further discussion on this point in (k) below);

- determinations by the patent granting or other national authorities on prior informed consent and benefit sharing cannot be easily reconciled with contractual autonomy, particularly under the CBD where benefit sharing is to be on mutually agreed terms between the provider and user of the genetic resource[248];

- if the country of origin of the relevant traditional knowledge or genetic resources has no benefit-sharing infrastructure in place for the use of the traditional knowledge and/or genetic resources, there would not be any compensation to the custodians of the relevant knowledge or resource even if a patent relating to these materials is identified[249];

- it is premature to consider introducing a requirement on prior informed consent and benefit sharing since, for the time being, many countries do not possess national regimes to implement access and benefit sharing, nor have those that do made these fully operational or effective, they are not in a position to deliver certificates of evidence[250];

- the requirement to provide evidence of prior informed consent in patent applications is particularly problematic with regard to plant genetic resources for food and agriculture covered by the ITPGRFA because this treaty does not foresee that prior informed consent must be obtained. If this requirement is to be introduced, it would have to apply only to genetic resources covered by the CBD and not covered by the ITPGRFA. In such a case, patent-granting authorities would not only have to verify whether the provided evidence is correct but also whether the genetic resources in question were obtained according to the provisions of the CBD or ITPGRFA[251];

- the PCT disclosure proposal appears to recognize the shortcomings of a disclosure requirement in ensuring that the objectives of the CBD are met by suggesting that the

[243] Canada, IP/C/M/49, para. 107.
[244] EC, IP/C/M/44, para. 34; Norway, IP/C/M/38, para. 244; Switzerland, IP/C/W/400/Rev.1.
[245] Malaysia, IP/C/M/48, para. 82; Switzerland, IP/C/W/446, IP/C/W/400/Rev.1.
[246] Malaysia, IP/C/M/48, para. 82; Switzerland, IP/C/W/446, IP/C/W/400/Rev.1.
[247] Malaysia, IP/C/M/48, para. 82; Switzerland, IP/C/W/446, IP/C/W/400/Rev.1.
[248] Switzerland, IP/C/W/446.
[249] United States, IP/C/W/434, IP/C/M/46, para. 31.
[250] Australia, IP/C/M/36/Add.1, para. 222; EC, IP/C/M/47, para. 62, IP/C/M/44, paras. 33 and 37; New Zealand, IP/C/M/47, para. 53.
[251] Switzerland, IP/C/W/400/Rev.1.

proposal be implemented in conjunction with an apparently multilateral system of notification, in which national patent offices would identify and notify points of contact designated to receive such information in other governments.[252] In the context of this proposal, a clarification was sought as to who would determine which would be the designated government agencies and what would be their role[253];

- there is some incoherence in the TRIPS disclosure proposal between "requiring, as a condition for acquiring patent rights, that applicants furnish evidence of prior informed consent" and "requiring applicants to provide information known to them or which they should reasonably know".[254]

119. The following questions have also been raised:

- Who determines whether the requirements of benefit sharing have been met by the applicant: the patent authority or the national authority where the genetic resource originated?[255] If it is the patent authority, or even the courts of the country where the patent authorities are located, how would such authorities be able to judge adherence to laws that are outside their own jurisdiction?[256]

- Would the national legislation of the country of origin also be applicable to traditional knowledge, or would it be up to the indigenous and local community to determine whether the sharing of benefits is "equitable and fair in the circumstances"?[257] Who would decide whether the prior informed consent of local and indigenous communities is necessary and how would such procedures be carried out in practice by patent applicants?[258]

- With respect to certification systems of compliance at the national or international levels, how would this address cases where the beneficiaries are not clearly identifiable or if the source of origin is unknown?[259]

- If benefit sharing cannot take place, could the patent application still continue?[260]

- Would the three requirements mean that three separate documents should be given to the patent office?[261]

- Would evidence of benefit sharing have to be disclosed in regard to the provider of genetic resources or to the provenance of genetic resources?[262]

- How could patent applicants fulfil, in practice, the requirement of indicating how the national authorities would enforce arrangements to ensure future benefit-sharing arrangements without having to resort to expensive litigation?[263]

120. In response it has been said that:

[252] United States, IP/C/W/434.
[253] Canada, IP/C/M/49, para. 109.
[254] EC, IP/C/M/47, para. 60.
[255] Switzerland, IP/C/W/446.
[256] Canada, IP/C/M/49, para. 108; Malaysia, IP/C/M/47, para. 81.
[257] Switzerland, IP/C/W/446.
[258] EC, IP/C/M/48, para. 65; Switzerland, IP/C/W/446.
[259] Malaysia, IP/C/M/47, para. 81.
[260] Malaysia, IP/C/M/47, para. 81.
[261] EC, IP/C/M/48, para. 63.
[262] Malaysia, IP/C/M/44, para. 40.
[263] Switzerland, IP/C/W/446.

- it is the laws and practices of the country of origin that would provide the framework for determining whether appropriate benefit-sharing arrangements have been entered into. It is national authorities implementing such laws who would determine what is equitable and fair, in accordance with the CBD[264];

- the burden on patent offices would be reasonable since in order to invoke liabilities and sanctions, it would have to be proven by the country providing access that the evidence produced is false or that benefit sharing has not been fair and equitable. If it is false, the opponent must produce evidence before the patent office to prove this. The patent office would take a final decision in this matter, just as in the case of any other false document produced before it, following the provisions of the patent law. If it is alleged that the benefit sharing has not been fair and equitable, the opponent must take appropriate action under the domestic access and benefit-sharing regime in the relevant domestic jurisdiction and produce the result of this to the patent office, which would have to accept this. Thus the patent office would not need to interpret foreign laws on access[265];

- a reporting obligation would bind the person seeking access to inform the communities and/or the national authorities of all instances of commercialization and patenting. If this information is not given and if the benefits arising out of such utilization are not shared, it is clear that there is no fair and equitable benefit sharing. Any dispute in this regard would be addressed to the appropriate national authority under the access and benefit sharing laws and not to the patent office[266];

- contractual autonomy envisaged under the CBD is subject to prior informed consent and fair and equitable benefit sharing and cannot be used as an argument not to implement CBD provisions[267];

- whether traditional knowledge is included in the access and benefit-sharing regime is a matter for national policy. Similarly, whether prior informed consent of the local and indigenous communities is necessary depends upon the national policy of the country of origin/ the country providing genetic resources and also upon whether there is traditional knowledge associated with the concerned resource and whether the communities indicated are the source of the resources. If the knowledge and/or the resources rest with the communities and the domestic law mandates prior informed consent from them, the person seeking access to the resources or traditional knowledge would have to ensure that prior informed consent is obtained from them[268];

- while it is true that the quality of implementation of the disclosure approach could be enhanced through the building of better networks between designated focal points in various countries and clearing-house mechanisms established at the international level, this does not negate the need for the disclosure requirements nor dilute the contribution it could make to improving the access and benefit-sharing system and to the patent system.[269]

[264] India, IP/C/M/48, para. 97.
[265] Brazil and India, IP/C/W/443; India, IP/C/M/49, paras. 141-142
[266] India, IP/C/M/49, paras. 141-142.
[267] India, IP/C/M/49, para. 144.
[268] India, IP/C/M/49, para. 144.
[269] Brazil, IP/C/M/48, para. 39.

(c) Remedies for non-compliance with disclosure requirements, including patent revocation

121. The issue of remedies for non-compliance with disclosure requirements, including revocation or invalidation of the patent, has been discussed. The need for such a remedy has been questioned and concerns have been raised about its implications for the effective functioning of the patent system.[270] One view that has been expressed is that:

- instead of attempting to single out patent applications and trying to deal with them with new patent disclosure requirements that may negatively affect technological development, a more appropriate solution would be strengthening national regimes outside the patent systems in order to take a comprehensive, holistic approach and address all instances of commercialization of misappropriated resources and/or traditional knowledge that need to be addressed outside the patent system in any event[271];

- it has not been shown that legal consequences other than those based in the patent system would not have a sufficient deterrent effect on patent applicants who may not respect disclosure requirements[272];

- it is not clear what circumstances would justify the proposed sanctions of the revocation of the patent or the full or partial transfer of the rights to the invention under the TRIPS disclosure proposal[273] nor which rights could be foreseen to be partially transferred and who would be the appropriate recipient of such rights.[274]

122. In response it has been said that:

- the consequence of failure to disclose/wrongful disclosure should be addressed within the patent system as leaving it outside the patent system would nullify the disclosure requirement and reduce it to a mere formality.[275] This is because there would be no effective remedy to deliberate non-compliance by a patent applicant with the access and benefit-sharing regime and no other means of effectively ensuring that the providers are given back a share of the profits for the contribution they have made to the market value of the claimed invention[276];

- while invoking fines or other penalties outside the patent system in cases of non-compliance with the disclosure requirement would not affect the material outcome of patent applications, the intended objectives of requiring disclosure would not be met as they would not have the necessary deterrent effect against misappropriation.[277] However, in cases where it is found that prior informed consent and benefit sharing have taken place even when the required disclosure was not made, other kinds of penalties, outside the patent system, could be foreseen[278];

- revocation or invalidation would only be applicable in cases where, for fraudulent reasons, there is failure to disclose evidence of prior informed consent and benefit sharing. This would be similar to existing procedures in the patent system with

[270] EC, IP/C/W/383, IP/C/M/44, para. 32, IP/C/M/38, para. 247; Korea, IP/C/M/49, para. 121; Japan, IP/C/M/49, para. 110; Switzerland, IP/C/W/423; United States, IP/C/W/449.
[271] United States, IP/C/W/449.
[272] EC, IP/C/W/383, IP/C/M/44, para. 32, IP/C/M/38, para. 247.
[273] Chinese Taipei, IP/C/M/46, para. 71; Switzerland, IP/C/W/446.
[274] Canada, IP/C/M/49, para. 108.
[275] Brazil et al, IP/C/W/403; China, IP/C/M/39, para. 135; India, IP/C/M/40, para. 82, IP/C/M/39, para. 138, IP/C/M/38, para. 232.
[276] India, IP/C/M/49, para. 145.
[277] Brazil, IP/C/M/48, para. 41.
[278] Brazil, IP/C/M/48, para. 41.

regard to cases of revocation where fraudulent intention is found for insufficient, wrongful or lack of disclosure and where it is determined that proper disclosure of information would have led to the refusal to grant the patent either on the grounds of lack of novelty due to the existence of prior art or on grounds of *ordre public* or morality[279];

- forms of commercialization, other than through patents, would be dealt with under national access and benefit-sharing regimes. It does not follow that, since a patent disclosure requirement would not cover all instances of commercialization, such a requirement is not necessary[280];

- it would not be reasonable for Members to grant or maintain patents if an invention has infringed the rights of local people and has obtained genetic resources through biopiracy.[281] Yet, there may be no national level regulation in some countries that places restrictions on the use of patent rights acquired without respecting CBD-related obligations, other than costly revocation proceedings within the patent system.[282]

123. The consequences for benefit sharing of sanctioning patent revocation for non-compliance with disclosure requirements have been discussed. One view has been that this would reduce the benefits available to be shared for the following reasons:

- if a patent were issued, but later invalidated, or if an application were published but never issued, the invention would have been disclosed to the public and third parties would be free to use and commercialize the knowledge or resources disclosed without any obligation to share benefits[283];

- such a requirement could deter an inventor from seeking a patent and if a patent is never issued and the information never published, the inventor may still be able to commercialize the invention without disclosing the invention to the public and without any obligation to share benefits[284];

- if a patent applicant has entered into a valid benefit-sharing agreement with the custodians of the traditional knowledge or genetic resources but, due to uncertainties in the law, such disclosure is found to be invalid or if there is improper disclosure that results in revocation of a patent due to litigation by a third party not affiliated with a traditional knowledge or genetic resources holder, this could upset the pre-existing benefit-sharing agreement.

Thus, the remedy proposed could itself destroy, or have significant negative consequences on, the benefit being sought.[285] The rejection of the patent application or the invalidation of the patent would neither be in the interest of innovation nor of those who expect to share in the benefits.[286] On the

[279] Brazil, IP/C/M/48, para. 41; Brazil et al, IP/C/W/459.
[280] Brazil et al, IP/C/W/459.
[281] China, IP/C/M/39, para. 135.
[282] India, IP/C/M/48, para. 53.
[283] United States, IP/C/M/40, para. 122, IP/C/M/39, para. 131.
[284] Canada, IP/C/M/37/Add.1, para. 232; EC, IP/C/M/48, para. 63; Japan, IP/C/M/48, para. 75, IP/C/M/40, para. 97, IP/C/M/32, para. 142; Korea, IP/C/M/46, para. 53, IP/C/M/32, para. 140; United States, IP/C/W/434, IP/C/W/209, IP/C/M/46, para. 28, IP/C/M/45, para. 44, IP/C/M/39, paras. 128-129 and 131, IP/C/M/37/Add.1, para. 235.
[285] United States, IP/C/W/449.
[286] United States, IP/C/W/434.

other hand, patents, in combination with an effective national access and benefit-sharing regime, could be a valuable tool to generate benefits that could later be shared.[287]

124. In response it has been said that, while it is true that benefits from an invention would be diminished if patents are not issued, or are revoked, and inventions are commercialized, this is no different from situations involving any invention or patent and is not limited to patents involving disclosure of the country and source of origin. Such situations could be dealt outside the patent system, using other legal means to rectify the damage.[288] For example, the product could be commercialized by the communities themselves (in case of invalidation) or competition could be introduced in the market place with those who commercialize it (in cases of commercialization without patent rights).[289] Such situations would have to be addressed within the national regimes in conjunction with other international rules outside the patent system including, where applicable, by addressing issues relating to trade secret laws or competition laws.[290]

(d) Trigger for disclosure

125. The issue of the degree of closeness of the relationship between genetic resources and traditional knowledge in question and the invention itself that would be necessary for the disclosure requirement to be applicable has been raised (referred to as "trigger for disclosure"). In this respect one view is that:

- it would be difficult to determine the degree of closeness of the relationship between the claimed invention and the relevant genetic resources or traditional knowledge where it would be necessary to disclose origin or source[291];

- the proposal in the TRIPS disclosure proposal that the trigger for disclosure be "any use", even "incidental use", goes too far[292];

- the resources and knowledge related to an invention may be multifarious and the process of inventing sometimes involves different raw materials, including the compounds extracted from plants. Therefore, certain terms used in the patent application, such as "derived from", "used in" and "based on" could have unintended specific and legal implications related to the trigger for disclosure.[293]

126. Clarification has been sought as to whether:

- the term "immediate" used in the PCT disclosure proposal, where it is proposed that disclosure be required in cases where the invention has made "immediate use" of the genetic resource, denotes a time dimension rather than the making use of a specific property of the genetic resource[294];

- if the proposed declaration of source could be made to any one of the entities involved in granting access to genetic resources and traditional knowledge or as many as could be identified, it is not clear what the consequence of inadvertently leaving some out in patent applications would be.[295]

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[287] Australia, IP/C/M/47, para. 55; United States, IP/C/W/434, IP/C/M/47, para. 47, IP/C/M/46, paras. 24-25, IP/C/M/40, para. 122.
[288] Brazil and India, IP/C/W/443; India, IP/C/M/47, para. 36.
[289] Brazil and India, IP/C/W/443.
[290] Brazil and India, IP/C/W/443.
[291] United States, IP/C/M/46, paras. 27-28.
[292] EC, IP/C/M/46, para. 47.
[293] Chinese Taipei, IP/C/M/48, para. 89.
[294] Malaysia, IP/C/M/44, para. 41.
[295] Malaysia, IP/C/M/44, para. 41.

127. In response, it has been said that[296]:

- the invention would have had to have made immediate use of the genetic resource and that the inventor must have had physical access to this resource, i.e., the inventor must have possessed, or at least have had contact which is sufficient to identify the properties of the genetic resources that were relevant for the invention. Thus, for example, the source of a plant would have to be declared in the patent application if the corresponding invention related to a chemical compound which the inventor had extracted from this plant;

- with regard to traditional knowledge, the proposed new rule would require that the inventor know that the invention is "directly based" on this knowledge, i.e., had consciously derived the invention from this knowledge. Since traditional knowledge is of an intangible nature, physical access is not possible and therefore would not be a prerequisite. This is intended to avoid cases where, for example, the inventor uses a chemical compound derived from a plant to develop a new pharmaceutical, without knowing that an indigenous community had knowledge concerning the pharmaceutical use of the plant;

- the term "directly" should have no time dimension;

- according to the CBD, the Bonn Guidelines and the International Treaty of the FAO, a multitude of entities may be involved in access and benefit sharing. To take into account this multitude of entities, it is proposed to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications, the term "source" being understood in its broadest sense possible to include both primary and secondary sources. Only if the patent applicant (or the inventor) has no information at hand about the primary or secondary source, may he disclose that such source is unknown. Considering the broad understanding of the term "source," cases where neither a primary nor a secondary source is known are likely to be rare.[297] (See also Section IV. B. 2(a) above.).

(e) Use of terms: biopiracy and misappropriation, genetic material or genetic resources and traditional knowledge or knowledge, innovations and practices

128. There has been some discussion on the use of terms. The issue of the definition of the terms "biopiracy" and "misappropriation" has been raised.[298] In response, it has been said that these terms have been used variously to refer to illegal and/or illegitimate acts with respect to the acquisition and use of genetic resources and traditional knowledge from developing countries. The term "piracy" is defined in Black's Law Dictionary as the "unauthorized and illegal reproduction or distribution of materials protected by copyright, patent, or trademark law". In *A Treatise on the Law of Property in Intellectual Productions*, Eaton S. Drone states that "The test of piracy [is] not whether the identical language, the same words, are used, but whether the substance of the production is unlawfully appropriated". It has been said that the term biopiracy is, in many ways, similar to the term "piracy" and involves misappropriation. The definition of these terms is not a precondition for the establishment of a disclosure obligation just as the lack of an agreed WTO definition of the term "piracy" did not stop WTO Members from including in the TRIPS Agreement extensive enforcement provisions.[299] When asked why the definition of the terms "biopiracy" and "misappropriation" was

[296] Switzerland, IP/C/W/423, IP/C/M/45, para 48.
[297] Switzerland, IP/C/W/433.
[298] Switzerland, IP/C/W/446, IP/C/M/47, para. 76.
[299] Brazil, IP/C/M/48, para. 42.

limited only to acts taking place in developing countries[300], it was clarified that this was stated as a fact and not as a part of the definition.[301]

129. It has also been said that Peru's Law on Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (Law No. 28216) contained a definition of biopiracy (see Section IV.B.1.(c) of this note). In addition, at website: www.biopirateria.org, there is another definition that biopiracy is "illegal or unauthorized access to and use of biodiversity components (mainly genetic and biological resources) and associated traditional knowledge, as part of development and research processes and application of biotechnology". It is also associated with innovations protected by intellectual property rights (especially patents) and that incorporate these components or indigenous knowledge obtained directly or indirectly without prior consent of or authorization from their owners".[302]

130. It has also been said that the Action Group on Erosion, Technology and Concentration (ETC Group) defined biopiracy as "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge". WIPO defined misappropriation as "any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge". In the light of this, these two terms were used interchangeably.[303]

131. Clarifications have been sought as to why proposals made had referred to "biological resources" and "biological material" instead of "genetic resources", which is the terminology used in the CBD, the Bonn Guidelines and the International Treaty of FAO in the context of access and benefit sharing.[304]

132. With respect to whether the terms used should be "genetic resources" or "genetic material" or "biological materials", it has been said that the terms "biological resources" and "genetic resources" have been used interchangeably in national legislation, international forums and some regional arrangements.[305]

133. It has also been said that under the CBD, genetic resources are defined to be genetic material of actual or potential value, where genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity. On the other hand, biological resources are wider in scope and are defined to include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystem with actual or potential use or value for humanity. Therefore, biological resources may refer to those that exist in natural or crude form and to whole organisms, including human beings, while genetic resources are obtained only after some value addition such as through isolation from a particular biological resource. Most of the developing, mega-diverse countries do not have the capacity to isolate the valuable components and therefore provide access to biological resources in their crude or natural state and to the knowledge associated with their use. Since the definition of biological resources includes genetic resources, these terms should not create any confusion in the context of the new disclosure requirements.[306]

134. With regard to the terms "knowledge, innovations and practices" and "traditional knowledge", it has been said that these should be treated as synonymous to ensure consistency with the CBD, the

[300] Canada, IP/C/M/48, para. 74.
[301] Brazil, IP/C/M/48, para. 42.
[302] Peru, IP/C/M/48, para. 93.
[303] India, IP/C/M/49, para. 136.
[304] Switzerland, IP/C/W/446, IP/C/M/49, para. 139.
[305] Switzerland, IP/C/W/423.
[306] India, IP/C/M/49, para. 139.

Bonn Guidelines and the International Treaty of FAO. Based on international instruments the relevant knowledge, innovations and practices must be related to or be associated with the genetic resources. It has been suggested that, since the proposed measure is under patent law, the focus should be the knowledge, innovations and practices that can give rise to a technical invention. Other forms of knowledge should be beyond the scope of application of this measure.[307]

(f) Relationship with the Patent Co-operation Treaty, Patent Law Treaty

135. The question has been raised about the implications of the TRIPS and mandatory disclosure proposals for the PCT and PLT of WIPO.[308]

136. In response it has been said that:

- there could be many options with respect to the PCT and PLT, including that taken by the proponents of the PCT approach in their proposal and these could be discussed in the appropriate WIPO bodies[309];

- in the TRIPS Council the issue is the discharge of a mandate under the WTO work programme, not developments elsewhere. It is foreseen that the implementation of the disclosure obligation, once agreed and defined under the TRIPS Agreement, could also facilitate action elsewhere. However, changes elsewhere without the proposed changes to the TRIPS Agreement would not be sufficient to address either the mandate given or the problem that is to be addressed, as a disclosure obligation for WTO Members cannot be established through non-WTO instruments.[310] Thus, the proposed amendment to PCT regulations should be seen not as a substitute for the amendment to the TRIPS Agreement, but as an addition to it[311];

- a solution through establishment of transparency measures alone would not meet the objectives of establishing rights and obligations requiring prior informed consent, benefit sharing and disclosure of source or origin of genetic resources and/or traditional knowledge used in inventions.[312]

137. The view has been expressed that the proposal to amend the regulations under the PCT of WIPO would not be very useful in respect of those Members that are not WIPO contracting parties.[313]

(g) Relationship with the TRIPS Agreement

138. As regards the consistency of a disclosure requirement with the TRIPS Agreement, one view is that:

- substantive patentability criteria are set out in Article 27.1 and Article 29 lays down obligations that must or can be imposed on patent holders in order to check whether patentability criteria have been met. The existing disclosure rules in Article 29 are directly related to determining whether an invention meets the standards of patentability and to disclosing the technology for which patent protection is being sought to enable others to reproduce it and learn from it.[314] The new disclosure

[307] Switzerland, IP/C/W/423.
[308] Canada, IP/C/M/49, para. 107; Switzerland, IP/C/W/446, IP/C/M/48, para.16, IP/C/M/47, para. 76.
[309] EC, IP/C/M/49, para. 128, IP/C/M/48, para. 66.
[310] Brazil, IP/C/M/48, para. 45.
[311] Brazil, IP/C/M/47, para. 83; Colombia, IP/C/M/45, para. 39.
[312] Dominican Republic, IP/C/M/40, para. 110.
[313] Chinese Taipei, IP/C/M/46, para. 71.
[314] EC, IP/C/W/383, IP/C/M/44, para. 29, IP/C/M/43, para. 37, IP/C/M/42, paras. 107-108, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 228; Japan, IP/C/M/46, para. 77, IP/C/M/40, para. 97, IP/C/M/39, para. 137,

requirements proposed under the mandatory disclosure approach should not act as an additional substantive patentability criterion[315], as none of them, including information indicating country of origin, aim to ensure compliance with patentability requirements such as proper inventorship, novelty or inventive step[316];

- a disclosure requirement applicable to only some fields of technology might also conflict with Article 27.1 which provides for non-discrimination in patent availability between fields of technology[317];

- such disclosure requirements would also be contrary to Article 62.1 of the Agreement which only provides for "reasonable procedures and formalities"[318] and would modify the balance of rights and obligations found in the TRIPS Agreement[319];

- it is not clear if the proposed amendment to the TRIPS Agreement with respect to disclosure that allows revocation of a patent would impact on Members' other exisiting obligations under this Agreement.[320]

139. In response, it has been said that:

- the TRIPS Agreement provides Members with adequate flexibility and allows for the disclosure of source as proposed in the context of the PCT[321] or a disclosure of origin requirement[322], as long as failure to disclose does not result in invalidation of the patent;

- Article 29 does not preclude imposition of additional requirements for disclosure as long as the provisions are "reasonable" as provided for in Article 62.1[323];

- several countries have already established such requirements in their national legislation as a means of implementing the CBD and there would be legal certainty if the TRIPS Agreement were amended accordingly.[324] The WTO has recognized the need to reconcile health, safety and other regulatory standards with trade rules as seen from the Agreements on SPS and TBT. There is no reason why a similar reconciliation should not take place between TRIPS and the CBD[325];

- the proposed modification to the TRIPS Agreement would not violate the principle of non-discrimination as to the field of technology in Article 27.1 because the inherent difference in patent applications covering inventions using biological resources and associated traditional knowledge makes additional conditions on patent applicants necessary to enable better assessment of such applications[326];

- the objectives in Articles 7 and 8 and principles of the TRIPS Agreement would justify the need for evidence of prior informed consent to be available in the patent

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IP/C/M/37/Add.1, para. 216, IP/C/M/36/Add.1, para. 225, IP/C/M/29, para. 155; Norway, IP/C/M/39, para. 120; United States, IP/C/M/30, para. 177.

[315] EC, IP/C/M/42, para. 108, IP/C/M/37/Add.1, para. 228.
[316] United States, IP/C/W/434, IP/C/M/46, para.26.
[317] Japan, IP/C/M/29, para. 155.
[318] Japan, IP/C/M/29, para. 155.
[319] United States, IP/C/W/434, IP/C/M/48, para. 25.
[320] Canada, IP/C/M/49, para. 108.
[321] Switzerland, IP/C/M/42, para. 99.
[322] Norway, IP/C/M/40, para. 86.
[323] India, IP/C/M/37/Add.1, para. 224, IP/C/M/36/Add.1, para. 214.
[324] India, IP/C/W/198, IP/C/W/195, IP/C/M/29, para. 165.
[325] India, IP/C/M/48, para. 53.
[326] Brazil et al, IP/C/W/403; India, IP/C/M/40, para. 82, IP/C/M/37/Add.1, para. 224.

system thus establishing a mutually supportive and harmonious relationship between the TRIPS Agreement and the CBD.[327] It would encourage the development of the biotechnology industry, while taking into account the objectives of the TRIPS Agreement to promote biotechnological innovation and the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge.[328] Further there is a mandate under the Doha Declaration to fully take into account the development dimension.[329] With regard to benefit sharing, the disclosure proposal is a means to avoid monopolies being created where none is envisaged in the patent system, allowing market forces to play their role[330];

- it is not sufficient to have the option to require the requisite disclosure at the national or regional level.[331] It is necessary to link these elements to existing disclosure requirements in the TRIPS Agreement.[332] Incorporation of such an obligation in the TRIPS Agreement and its enforcement through the WTO dispute settlement system would provide a mechanism to help ensure compliance with the prior informed consent/benefit-sharing rules of the CBD.[333]

(h) Relationship with the CBD

140. With regard to the issue of the relationship of the disclosure requirement with the CBD, it has been said that:

- the disclosure proposal goes beyond the requirements of the CBD. The CBD leaves it to each country to establish its own system for controlling access to genetic resources and benefit sharing, without being prescriptive about how this should be done.[334] It does not even mention patent disclosure requirements. It only calls upon parties to condition access to genetic resources on prior informed consent and to encourage the equitable sharing of benefits arising from the utilization of genetic resources upon mutually agreed terms[335];

- the CBD has a mandate to elaborate and negotiate an international regime on access to genetic resources and benefit sharing. One outcome of the CBD process has been the Bonn Guidelines. After CBD parties gain experience from implementation of these Guidelines, they will have a better understanding on how to promote prior informed consent, access to genetic resources and related traditional knowledge, and equitable benefit sharing[336];

- the disclosure approach does not address the fact that an access and benefit-sharing infrastructure in a country and a mechanism for the resolution of disputes are necessary to enable the sharing of such benefits. Members appear to share the view

[327] Brazil et al, IP/C/W/438; Peru, IP/C/M/46, para. 50.
[328] Brazil, IP/C/M/37/Add.1, para. 236.
[329] Brazil, IP/C/M/43, para. 61; India, IP/C/M/47, para 40; Peru, IP/C/M/47, para. 72, IP/C/M/43, para. 45.
[330] India, IP/C/M/46, para. 42.
[331] Peru, IP/C/M/48, para. 92.
[332] Brazil et al, IP/C/W/438; India, IP/C/M/46, para. 42.
[333] African Group, IP/C/W/404, IP/C/W/206, IP/C/M/40, para 78; Brazil, IP/C/W/228; India, IP/C/M/29, para. 160; Norway, IP/C/W/293, IP/C/M/35, para. 237; Pakistan, IP/C/M/42, para. 112; Peru, IP/C/M/48, para. 92.
[334] EC, IP/C/W/254; Japan, IP/C/W/236; Singapore, JOB(00)/7853, IP/C/M/29, para. 168.
[335] United States, IP/C/W/449, IP/C/M/48, para. 25, IP/C/M/47, para 42.
[336] Switzerland, IP/C/M/45, para. 47; United States, IP/C/W/449, IP/C/M/49, para. 94.

that national, contract-based access and benefit-sharing systems are essential elements of any solution[337];

- effective implementation of the CBD objectives requires a combination of legislative and/or regulatory approaches setting the general rules, including the disclosure and contractual approaches.[338]

141. In response it has been said that:

- the CBD does not create obligations on patent disclosure requirements because it is not an intellectual property agreement[339];

- mandatory furnishing of evidence of prior informed consent by patent applicants would facilitate the monitoring of access and benefit sharing, and, with other laws on the enforcement of the provisions of the CBD, would ensure transparency in the administrative procedures for the grant of a patent[340];

- there is a significant international dimension to the question of the mutual supportiveness of the CBD and the TRIPS Agreement. Article 5 of the CBD envisages international cooperation with competent international organizations. The WTO sets minimum standards for patents based on biological resources and/or traditional knowledge and is therefore the competent international organization with respect to cross-border biopiracy and misappropriation.[341]

142. See also the views reflected in paragraph 18 of this note.

(i) Implications for prior informed consent and benefit sharing

143. The issue of whether a disclosure requirement to submit evidence of prior informed consent or benefit sharing is necessary or desirable to secure the implementation of prior informed consent and benefit sharing has been discussed. In support of the view that such a disclosure requirement is neither necessary nor desirable[342], the following reasons have been given:

- patent disclosure requirements *per se* cannot ensure prior informed consent or transfer benefits as such requirements would merely convey the information requested and would have no mechanism to transfer benefits between parties[343];

- patent disclosure requirements would be ineffective in enforcing a country's access and benefit-sharing regime where those who utilize genetic resources or traditional knowledge in their commercial products do not apply for a patent in the first place. This may occur because there are many ways of protecting ideas other than through patents, that lead to commercialization of products, including through trade secrets and unfair competition laws.[344] It may also occur because the product is not protectable in the source country. For instance, neither herbal remedies nor plant varieties may be patentable in a particular country[345];

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[337] Australia, IP/C/M/46, para. 65; United States, IP/C/W/434, IP/C/M/46, para. 25, IP/C/M/39, para. 131, IP/C/M/37/Add.1, para. 235.
[338] EC, IP/C/M/47, para 60; Switzerland, IP/C/M/46, para. 75.
[339] India, IP/C/W/459, IP/C/M/49, para. 87, IP/C/M/48, para. 49.
[340] India, IP/C/M/47, para. 35.
[341] India, IP/C/M/47, para. 35.
[342] Australia, IP/C/M/47, para. 55; United States, IP/C/W/434, IP/C/M/40, para. 124.
[343] United States, IP/C/M/40, para. 122.
[344] United States, IP/C/W/434.
[345] United States, IP/C/W/449.

- only contractual obligations that establish the rights and obligations of the entities involved prior to any access to genetic resources could ensure that prior informed consent is achieved.[346] Countries could establish systems of prior informed consent, such as permit systems that impose civil and/or criminal penalties for extracting genetic resources without a permit, so that the permit would serve as evidence of prior informed consent.[347] (see further discussion under Section A above);

- patent applicants with the intent of acting in bad faith would not be deterred by disclosure requirements[348];

- such disclosure requirements would lead to undue burdens on applicants seeking to comply with them, and may discourage applicants from seeking protection and encourage them to keep their inventions secret. This, in turn, could also undermine any potential benefit sharing and therefore be ineffective in achieving its objective[349];

- such disclosure requirements, particularly where the sanction proposed is revocation of the patent right, would provide an additional avenue to litigation and cause uncertainties that would undermine the role of the patent system, which again would have a negative effect on any benefit sharing that could be derived therefrom[350];

- work at the international level might be better focused on a limited number of issues that are likely to attract consensus such as disclosure of source or origin and not on evidence of prior informed consent and benefit sharing.[351] International efforts should focus on efforts to encourage the establishment of appropriate access and benefit-sharing systems that (1) improve compliance by providing users with clear rules for collection of genetic materials, and (2) help ensure that where uses of genetic resources or traditional knowledge are made, benefits are equitably shared with the appropriate parties.[352]

144. In response it has been said that:

- all the three elements of the TRIPS disclosure proposal are important in ensuring the mutual supportiveness between the TRIPS Agreement and the CBD and cannot be delinked from each other.[353] The requirements to furnish evidence of prior informed consent and benefit sharing are essential in ensuring that domestic access and benefit-sharing regimes are respected and implemented effectively by providing remedial action at the global level through the TRIPS Agreement against violation of domestic law by bioprospectors.[354] This is because there may be no national level regulation in some countries that places restrictions on the use of patent rights acquired without respecting CBD-related obligations, other than costly revocation proceedings within the patent system[355];

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[346] United States, IP/C/W/434, IP/C/M/39, para. 130.
[347] United States, IP/C/W/434.
[348] United States, IP/C/W/434.
[349] Canada, IP/C/M/37/Add.1, para. 232; EC, IP/C/M/48, para. 63; Japan, IP/C/M/48, para. 75, IP/C/M/40, para. 97, IP/C/M/32, para. 142; Korea, IP/C/M/46, para. 53, IP/C/M/32, para. 140; United States, IP/C/W/434, IP/C/W/293, IP/C/W/209, IP/C/M/46, para. 28, IP/C/M/45, para. 44, IP/C/M/39, paras. 128-129 and 131, IP/C/M/37/Add.1, para. 235.
[350] United States, IP/C/W/449.
[351] EC, IP/C/M/43, paras. 37 and 64; New Zealand, IP/C/M/46, para. 58, IP/C/M/45, para. 52.
[352] United States, IP/C/W/449.
[353] Brazil, IP/C/M/37/Add.1, para. 237; India, IP/C/M/38, para. 233.
[354] Brazil et al, IP/C/W/459; India, IP/C/M/38, para. 233.
[355] India, IP/C/M/48, para. 53.

- the disclosure system is not intended to be a stand-alone system and could not on its own be a satisfactory guarantee of the sharing of benefits arising from the use of genetic resources. Rather, it would complement the main legal instrument in this respect, i.e. the enforcement of a sound and effective national legislation for access, benefit sharing and the protection of traditional knowledge[356] through a system of contracts and civil and criminal law.[357] National laws could lay down the minimum standards for prior informed consent and benefit sharing, and their use could be further facilitated by model forms of material transfer agreements, which should not conflict with the basic CBD framework.[358] Thus the proposed disclosure requirements are intended to offer an effective incentive for patent applicants to comply with national access and benefit-sharing requirements[359];

- while it is true that the disclosure requirement by itself would not deter those intent on acting in bad faith, the legal consequences of the failure to comply with the disclosure requirements of the proposed international regime can, if properly calibrated as proposed, deter them.[360] It would thus act as a self-monitoring and auto-check mechanism leading to lesser instances of unauthorized use.[361] Applicants with good intentions committed to lawfully accessing genetic resources of mega-diverse countries would have nothing to fear from the proposed disclosure requirement[362];

- these requirements are useful even without national access and benefit-sharing systems being in place. In new and emerging policy areas, such as intellectual property, there have been examples when it has not been considered necessary to put in place national systems before international norms were set[363];

- the fact that benefit sharing may only take place after the grant of a patent and the commercialization of the relevant technology does not raise a problem with respect to furnishing evidence of benefit-sharing arrangements[364];

- admittedly if there is no patent, benefits derived from a patent cannot be claimed; but the possibility of getting benefits from commercialization or from the grant of access itself still exists.[365]

145. In response, it has been said that:

- since it has been considered that the disclosure requirement would supplement and not substitute for national systems, the narrower question is whether the requirement could be justified by its ability to ensure effective operation of national access and benefit-sharing regimes, notwithstanding its negative effects on the patent system, technological development and benefit sharing[366];

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[356] Brazil, IP/C/M/47, para. 26, IP/C/M/46, para. 81, IP/C/M/36/Add.1, para. 219; EC, IP/C/M/44, para. 30, IP/C/M/37/Add.1, para. 227, IP/C/M/30, para. 144; Brazil and India, IP/C/W/443; China, IP/C/M/39, para. 133; India, IP/C/M/40, para. 82, IP/C/M/36/Add.1, para. 212.

[357] African Group, IP/C/W/404; Brazil, IP/C/M/36/Add.1, para. 219; EC, IP/C/W/383, IP/C/W/254, IP/C/M/46, para 45, IP/C/M/44, para. 30; India, IP/C/M/36/Add.1, para. 212; New Zealand, IP/C/M/46, para. 60.

[358] India, IP/C/M/37/Add.1, para. 223.

[359] Brazil, IP/C/M/48, para. 36, IP/C/M/46, para. 81; Peru, IP/C/M/48, para. 19.

[360] Brazil and India, IP/C/W/443.

[361] EC, IP/C/W/383, IP/C/M/44, para. 30, IP/C/M/37/Add.1, para. 228; India, IP/C/M/40, para. 82, IP/C/M/37/Add.1, para. 223.

[362] Brazil, IP/C/M/46, para. 81.

[363] Brazil et al, IP/C/W/459.

[364] Brazil, IP/C/M/47, para. 28.

[365] Brazil et al, IP/C/W/459.

[366] United States, IP/C/W/434.

- examples of misappropriation given in the context of the discussions in the Council appear to relate to improper collection and/or use of genetic resources or traditional knowledge rather than the act of patenting *per se*, which does not amount to misappropriation. Such examples show that the patents were granted for new, useful and non-obvious inventions based on genetic materials and not on the materials themselves.[367] Since it has been clarified that "misappropriation" is not the act of patenting or applying for a patent, but rather the fact that traditional knowledge or genetic resources are accessed in violation of a national access regime and being exploited without obtaining prior informed consent and without providing for equitable benefit sharing, it is not a patent disclosure requirement that can help ensure prior informed consent and benefit sharing, but rather having in place a comprehensive and effective access and benefit-sharing regime that directly regulates inappropriate behaviour[368];

- it is not clear how disclosure requirements could be designed to supplement national legislation that is not in place as is the case of the majority of Members. Establishing national access and benefit-sharing systems, and evaluating experience with their operation in order to strengthen further such systems is essential before discussing supplemental disclosure requirements that would single out only commercial applications involving patents, which may negatively affect technological development[369];

- a country could promote and encourage prior informed consent and equitable sharing of benefits on mutually agreed terms at the national level without being a party to the CBD.[370] Even those not parties to the CBD have ensured that bioprospectors and researchers from their countries are made aware of the national access and benefit-sharing systems in other countries.[371]

(j) Implications for preventing erroneously granted patents

146. The issue of whether a disclosure requirement is necessary or desirable for preventing erroneously granted patents has been discussed. One view is that the new patent disclosure requirements proposed would be ineffective in achieving the objective of preventing erroneously granted patents for the following reasons:

- information regarding source and/or country of origin is generally not material to patentability. Even without such disclosure, examiners in the patent office can understand the invention in the application properly, and can examine the application so as to judge patentability.[372] A more effective approach in achieving the objectives of preventing erroneously granted patents would be one that focuses on information material to patentability. One significant advantage of this approach is that the information required is solely related to issues of patentability and thereby would not introduce new uncertainties of laws unrelated or tenuously related to the invention into the patent system[373];

- determination of inventorship is generally based in a country's patent law and on acts of invention. Information regarding the country of origin or the source (i.e. country

[367] United States, IP/C/W/434, IP/C/M/47, para. 44, IP/C/M/46, para. 24.
[368] United States, IP/C/W/449.
[369] United States, IP/C/M/48, para. 30.
[370] United States, IP/C/M/48, para. 25.
[371] United States, IP/C/M/49, para. 94.
[372] Japan, IP/C/M/48, para. 75; United States, IP/C/W/449.
[373] Japan, IP/C/M/49, paras. 110-111; United States, IP/C/W/449.

locations or *ex situ* collection sites) is not generally relevant to these considerations and would therefore be of little value in this process[374];

- lowering the standard for disclosure to information that is known or should have been known to the applicant would not help as such disclosure would still be irrelevant.[375]

147. In response it has been said that:

- a reason for bad or questionable patents is insufficient disclosure of existing knowledge and the inadequacy of the existing patent system to check the relevant details.[376] The disclosure requirement would give the patent office useful hints to enquire into the novelty and inventiveness claimed in the invention as information on source and country of origin in relation to the holders of the resources and/or the knowledge associated with them could be useful in the case of challenges to patents granted, whether in patent offices or in courts[377], as for example in the case of the turmeric patent.[378] Moreover, if the disclosure requirement is made mandatory, the patent examiner can require the applicant during the processing of the application to furnish more information to ensure that patents are not issued for ineligible inventions[379];

- while it is true that the mere disclosure of source and country of origin may not in and of itself help ascertain inventorship or patentability, it would be helpful to the extent that the disclosed information would help determine whether the biological resource and/or traditional knowledge is used: to form part of the claimed invention; during the process of developing the claimed invention; as a necessary prerequisite for the development of the invention; to facilitate the development of the invention; and/or as necessary background material and/or information for the development of the invention. Such information would be relevant in determining: the existence of prior art and the non-obviousness of the claimed invention; inventorship or entitlement to the patent; the scope of the claim; and/or for understanding or carrying out the invention[380];

- in cases of inventions based on biological resources and/or associated traditional knowledge, the source and origin of the biological resources and associated traditional knowledge would be critical for ascertaining whether the applicant has invented what is claimed or just found the "invention" in nature or obtained it from traditional cultures, especially if such knowledge is undocumented and exists in oral form or is documented in a local language[381];

- the disclosure of source proposed in the context of the PCT would support the determination of prior art regarding traditional knowledge through the simplification of the search of traditional knowledge databases and transparency measures. Traditional knowledge databases are increasingly being established at local, national, and regional levels. The international Internet portal for traditional knowledge proposed in the WTO and WIPO would present an additional and complementary measure. These transparency measures would also aid the determination of prior art with regard to traditional knowledge that only existed in oral form, because the

[374] United States, IP/C/W/449.
[375] Japan, IP/C/M/48, para. 75.
[376] Brazil and India, IP/C/W/443.
[377] Brazil and India, IP/C/W/443; New Zealand, IP/C/M/47, para. 52.
[378] India, IP/C/M/48, para. 55.
[379] Brazil et al, IP/C/W/459.
[380] Brazil et al, IP/C/W/459.
[381] Brazil, IP/C/M/48, para. 37.

declared source could provide an important starting-point for the further examination.[382]

148. See further discussion on the implications for the patent system in (k) below.

(k) Implications for the patent system

149. Three issues have been discussed, namely whether the proposed mandatory disclosure requirements would be burdensome on patent offices, whether it would be burdensome on patent applicants and how it would affect the operation of the patent system. With respect to whether a disclosure requirement would be burdensome on patent offices, one view is that:

- patent offices would have both legal and administrative difficulties in determining the geographical origin of genetic resources and traditional knowledge[383];

- patent examiners would be unable to carry out the task of verification of compliance with prior informed consent and benefit sharing not only because they may not have the necessary legal and technical competence to determine the correctness of evidence provided[384], but because the terms and conditions of a contract would remain confidential and would thus not be accessible to the patent-granting authority[385]. Even if these terms were made available, this verification task would overburden patent offices and create problems of legal interpretation, especially with respect to requirements to comply with foreign laws.[386] Patent offices would have no way of judging their fairness or equity.[387] These tasks could best be carried out by the parties to the contracts on access and benefit sharing[388];

- such requirements may lead to significant additional administrative costs, including for training and systems development in patent offices.[389] The case has not been made as to how disclosure requirements would not add to costs[390], nor why a contractual system would not serve effectively to regulate this area[391];

- it seems important to determine approximately how many patent applications per year could involve patent disclosure regarding genetic resources and/or associated traditional knowledge, if such an obligation were to be introduced. This would allow the impact of any disclosure regime to be appropriately assessed given each country's national situation.[392]

150. In response it has been said that:

- the role of patent offices would be essentially that of ensuring that the applications are complete. The proposal would not require patent examiners to determine the

[382] Switzerland, IP/C/M/42, para. 98.
[383] United States, IP/C/W/209.
[384] Australia, IP/C/M/47, para. 55; Chinese Taipei, IP/C/M/46, para. 71; EC, IP/C/W/383, IP/C/M/44, para. 35; Switzerland, IP/C/W/400/Rev.1.
[385] Malaysia, IP/C/M/48, para. 82; Switzerland, IP/C/W/446, IP/C/W/400/Rev.1.
[386] EC, IP/C/M/47, para. 59; Switzerland, IP/C/W/400/Rev.1; United States, IP/C/M/46, paras. 27-28.
[387] Malaysia, IP/C/M/48, para. 82; Switzerland, IP/C/W/446, IP/C/W/400/Rev.1.
[388] United States, IP/C/W/434..
[389] Australia, IP/C/M/47, para. 55, IP/C/M/46, para. 65; EC, IP/C/M/47, para. 59, IP/C/46, para. 65; Japan, IP/C/M/32, para. 142; Korea, IP/C/M/46, para. 53, IP/C/M/32, para. 140; United States, IP/C/W/434, IP/C/M/46, para. 28, IP/C/M/37/Add.1, para. 235.
[390] Australia, IP/C/M/46, para. 65.
[391] United States, IP/C/W/434, IP/C/M/46, para. 32.
[392] Canada, IP/C/M/48, para. 72.

validity of the information given about these arrangements in order to grant a patent.[393] Patent examiners would confirm that the patent application contains a declaration in the prescribed form indicating that prior informed consent has been obtained and that benefits have been shared and/or that there exists an arrangement for future benefit sharing in accordance with the relevant national law[394];

- assessment of the necessary evidence provided, in cases where there is fraud alleged, would be routine for patent offices as the proposed requirements would not be more burdensome than any other under the existing patent application procedures.[395] Patent offices would need to take decisions based on the documents providing evidence of prior informed consent and benefit sharing only when the validity of a patent is challenged in the pre- or post-grant opposition or revocation proceedings. In such cases the patent office would have evidence from both the parties to the proceedings and could take a decision just as it does on any other ground on which the grant of a patent is opposed or revocation of a patent is requested.[396]

- disclosure requirements could even be applied selectively, say only in cases where a Member has reasonable grounds to suspect that national biodiversity legislation has been violated by a patent applicant[397];

- the proposed disclosure requirements would increase the capacity of patent offices to examine patent applications that deal with biological resources and associated traditional knowledge[398];

- the perceived administrative burdens and costs of the disclosure proposal should be considered in light of the high costs of collecting evidence in revocation proceedings in the absence of disclosure requirements.[399] Moreover, in terms of implementation for the United States system, the proposed disclosure requirement would not be burdensome at all, as it could be covered under the existing requirement for information material to patentability. What would need to be included is evidence of prior informed consent and benefit-sharing arrangements [400];

- it is ironic that some countries are arguing that the disclosure mechanism should not be included because it would be burdensome when, in effect, TRIPS itself has already proven to be quite burdensome for developing countries and for consumers of technology in general.[401] The current patent system has not provided certainty for all stakeholders particularly those from mega-diverse countries who have been victimized by misappropriation of their traditional knowledge and/or genetic resources.[402]

151. The issue of the possible burden on patent applicants of the disclosure approach has been discussed. One view is that:

[393] EC, IP/C/M/47, para. 59; India, IP/C/M/47, para. 38.
[394] India, IP/C/W/198, IP/C/M/29, para. 166,.
[395] Brazil et al, IP/C/W/459; Brazil, IP/C/W/356, IP/C/W/228; India, IP/C/M/40, para. 82, IP/C/M/36/Add.1, para. 214, IP/C/M/29, paras. 165-166; Indonesia, IP/C/M/36/Add.1, para. 217; Thailand, IP/C/M/29, para. 173; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/36, para. 203.
[396] Brazil and India, IP/C/W/443.
[397] Brazil, IP/C/W/228; Thailand, IP/C/M/29, para. 173.
[398] Brazil, IP/C/M/48, para. 36.
[399] Brazil and India, IP/C/W/443; Hong Kong, China, IP/C/M/46, para. 88.
[400] India, IP/C/M/47, para. 38.
[401] Brazil, IP/C/M/47, para. 26.
[402] Brazil, IP/C/M/46, para. 82.

- such disclosure requirements would lead to undue burdens on applicants seeking to comply with them, and may discourage applicants from seeking protection and encourage them to keep their inventions secret[403];

- patent applicants would be required to submit double or even triple information which would bring little advantage to Members.[404]

152. In response it has been said with respect to the TRIPS disclosure proposal that:

- the onus on the patent applicant would be limited to providing information and evidence that is known to him or should have been known to him so that the administrative and cost burden on him would be minimal[405];

- the recording and collection of the information necessary to meet the obligation with respect to disclosure requirements should not require applicants to undertake significant effort outside what would need to be done in the process of developing a patent application for an invention i.e. such burdens would exist even where there is no disclosure obligation[406];

- in the case of evidence regarding prior informed consent, it is only if the knowledge and/or the resources rest with the communities, and the domestic law mandates prior informed consent from them, that the person seeking access to the resources or traditional knowledge would have to ensure that prior informed consent is obtained from them. This does not create any additional burden on the applicant because, in most of the countries, evidence of prior informed consent is a pre-requisite to the grant of access to biological resources and traditional knowledge[407];

- the burden imposed on patent applicants would be reasonable considering the serious nature of the problem to which a solution is being sought. Such a disclosure requirement would pave the way for international solutions that would result in cost saving for countries that are victims of biopiracy who would not need to divert resources in order to seek the revocation of patents based on illegally obtained resources or traditional knowledge.[408]

153. In regard to the PCT and mandatory disclosure proposals, it has been said that disclosure of source has been preferred as all applicants would know the source from which they obtained genetic resources or traditional knowledge. Such a requirement would not be burdensome nor would it deter the filing of patent applications.[409] Under the mandatory disclosure proposal, information on the country of origin would also be requested but only if it could be provided with no additional research on the applicant's part[410], and it would be the patent applicant himself who should judge if the country of origin is known to him.[411]

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[403]Canada, IP/C/M/37/Add.1, para. 232; Japan, IP/C/M/32, para. 142, IP/C/M/40, para. 97; Korea, IP/C/M/46, para. 53, IP/C/M/32, para. 140; United States, IP/C/W/434, IP/C/W/209, IP/C/M/46, para. 28, IP/C/M/45, para. 44, IP/C/M/39, paras. 128-129 and 131, IP/C/M/37/Add.1, para. 235.

[404] Switzerland, IP/C/W/400/Rev.1, IP/C/M/46, para.73.

[405] Brazil, IP/C/M/48, para. 36.

[406]Brazil et al, IP/C/W/459, IP/C/W/429/Rev.1; India, IP/C/M/45, para. 21; EC, IP/C/M/46, paras. 45-47.

[407] India, IP/C/M/49, para. 143.

[408]Brazil, IP/C/M/46, para. 83; Brazil et al, IP/C/W/403; India, IP/C/M/45, para. 21, IP/C/M/36/Add.1, para. 214; Indonesia, IP/C/M/36/Add.1, para. 217.

[409] EC, IP/C/M/46, para. 45; Switzerland, IP/C/W/423, IP/C/M/42, para. 98.

[410] EC, IP/C/M/46, para. 45.

[411] EC, IP/C/M/48, para. 66.

154. The issue of the possible consequences of the disclosure approach on the operation of the patent system and its ability to fulfil its underlying public policy purposes has been discussed. One view is that:

- information from new disclosure requirements regarding source or country of origin is not generally relevant to considerations of inventorship or prior art and therefore would be of little value to patent examiners in making such determinations[412];

- new disclosure requirements, particularly where the sanction proposed is revocation of the patent right, would provide an additional avenue to litigation and cause uncertainties that would undermine the role of the patent system in promoting innovation and technological development as they may discourage applicants from seeking protection and encourage them to keep their inventions secret. This, in turn, would undermine any potential benefit sharing and therefore be ineffective in achieving its objective;[413]

- patent law is not designed to regulate or enforce misconduct issues, such as misappropriation of traditional knowledge or genetic resources, but to promote progress of useful arts. As such it does not condone or legitimize violations of misappropriation of genetic resources or traditional knowledge just as it does not do so for violations of environment, health or safety laws.[414] Patents do not give right holders a right to use their inventions and restrictions are placed on the use of certain patented inventions. For example, there are laws and regulations regulating the use of pharmaceuticals or firearms and of emissions from automotive engines which are implemented and enforced outside the patent system. Similarly, a contract-based access and benefit-sharing system could effectively and adequately achieve domestic policy goals related to the conservation and sustainable use of genetic resources[415];

- recent studies indicate that patent-based access and benefit-sharing systems would have significant negative effects on the development of particular sectors, such as biotechnology, while there would be broad ramifications impacting more sectors[416];

- it is questionable whether the disclosure requirements could be justified by their ability to ensure effective operation of national access and benefit-sharing regimes, notwithstanding their negative effects on the patent system, technological development and benefit sharing. There may be an over-estimation of the "green gold" that may be available from the potential benefits from patenting of inventions based on genetic resources.[417]

155. A question has been raised as to what would be the impact on the international patent system in the case where possible sanctions for wrongful or no disclosure are placed outside the patent system.[418]

156. In response it has been said that new disclosure requirements proposed would help improve the operation of the patent system in that:

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[412] United States, IP/C/W/449, IP/C/W/434.

[413] Canada, IP/C/M/37/Add.1, para. 232; Japan, IP/C/M/32, para. 142; Korea, IP/C/M/46, para. 53, IP/C/M/32, para. 140; United States, IP/C/W/449, IP/C/W/434, IP/C/W/209, IP/C/M/46, para. 28, IP/C/M/45, para. 44, IP/C/M/39, paras. 128-129 and 131, IP/C/M/37/Add.1, para. 235.

[414] United States, IP/C/M/48, para. 28, IP/C/M/46, para. 32.

[415] United States, IP/C/M/47, para. 48, IP/C/M/46, paras. 28 and 32, IP/C/M/42, para. 109, IP/C/M/40, para. 124.

[416] United States, IP/C/W/49, para. 95.

[417] New Zealand, IP/C/M/47, para. 54.

[418] Canada, IP/C/M/49, para. 107.

- they would aid in the determination of whether the claimed invention is patentable. The process of examination would be facilitated through the introduction of the disclosure requirements[419] since these requirements would add to the information available to patent examiners on prior art regarding traditional knowledge, including that which only exists in oral form or is documented only in local languages.[420] Disclosing the source of origin would therefore enable searches that might be outside the scope of established databases.[421] Through more focused searches, patent offices could grant better patents and lessen the need for burdensome challenges regarding patent validity[422];

- with respect to the PCT disclosure proposal, the requirements would not be so burdensome as to deter patent applicants from fulfilling them[423] (see further details in paragraph 94 of this note);

- with respect to the mandatory disclosure proposal, they would not be burdensome to patent offices or applicants and would ensure that the patent system continues to be an effective tool to stimulate innovation, technological progress and economic development (see also paragraph 95 of this note);

- they do not create unacceptable risks, but add to the legitimacy and certainty of the patent system that only the eligible inventions are protected. Since the sanctions only affect fraudulent claims, without creating any additional uncertainty as alleged[424], they would improve the operation of the patent system to ensure its robustness, sustainability and relevance to the pursuit of the actual objectives of the intellectual property system [425];

- they would be useful in cases relating to challenges to patents granted, whether in patent offices or in courts.[426] For example, in the case of the turmeric patent, the applicant for the patent 5401504, on the date of application, i.e. 28 October 1996, acknowledged, but did not disclose the teaching about healing properties of turmeric. The USPTO did not take the next steps to check these teachings, and granted a patent. The same, and more, teachings had to be provided in the opposition proceedings, which became the basis of revocation on 21 April 1998 on the grounds of lack of novelty and non-obviousness. The information hidden by the applicant was material to patentability, and would have been provided by him had there been a disclosure requirement. This is evidence of the certainty that the disclosure requirement would introduce into the patent system[427];

- they would introduce an important confidence-building measure that would help restore the trust of all stakeholders[428] in the patent system so that it works for all in an equitable manner[429];

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[419] Brazil and India, IP/C/W/443; EC, IP/C/M/37/Add.1, para. 228; India, IP/C/M/48, para. 60.

[420] Brazil et al, IP/C/W/403; India, IP/C/M/40, para. 82, IP/C/M/39, para. 123, IP/C/M/37/Add.1, para. 253.

[421] Brazil, IP/C/M/48, para. 39.

[422] EC, IP/C/M/44, para. 30, IP/C/M/37/Add.1, para. 228.

[423] Switzerland, IP/C/M/42, para. 98.

[424] Brazil et al, IP/C/W/459; India, IP/C/M/48, para. 57; Switzerland, IP/C/M/42, para. 98.

[425] Brazil, IP/C/M/46, para. 83; EC, IP/C/M/46, para. 46, IP/C/M/44 para. 30; India, IP/C/M/45, para. 20, IP/C/M/40, para. 82.

[426] Brazil and India, IP/C/W/443; New Zealand, IP/C/M/47, para. 52.

[427] India, IP/C/M/48, para. 55.

[428] Switzerland, IP/C/M/46, para. 73.

- they would also be of significant advantage to researchers and bio-prospectors who use the patent system by facilitating future access to genetic resources and by reducing the probability and cost of litigation on patent validity or entitlement to the patent.[430] Beneficiary countries or communities would have the incentive to generate less complex or burdensome but more effective national access and benefit-sharing regimes.[431] This would help provide a predictable environment for governments, investors, traditional communities and researchers and could lead to more biotechnological R&D in developing countries, thus creating a win-win situation for both providers and accessors[432];

- various types of disclosure requirements are already an accepted norm in international patent law practice.[433]

157. In response to the specific example given of the turmeric patent in the United States, it was said that, while there is no way of completely eliminating the grant of erroneous patents, in this case the patent applicants were two Indian nationals who did reveal that India was the country of origin of turmeric. This information was, however, irrelevant to the patentability issues and did not help in preventing the grant of this patent. On the other hand, if it were true that the applicants withheld information material to patentability regarding the wound healing properties of turmeric that was known to them, then the patent would have been unenforceable under US law. In this case the patent was cancelled on the basis of the relevant prior art brought forward and taken into account in the re-examination proceedings and not on the basis of any alleged inequitable conduct for hiding known information. In this view, this leads to the conclusion that proposed disclosure requirements regarding, among other things, source and/or origin of genetic resources or traditional knowledge, would not be effective in addressing concerns over mistakenly granted patents and that other options should be pursued that more directly address this goal and do not have negative consequences on the patent system.[434]

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[429] Brazil, IP/C/M/46, paras. 82 and 85; EC, IP/C/M/46, para. 46, IP/C/M/44, para. 30; India, IP/C/M/40, para. 82; Norway, IP/C/M/39, para. 121; Peru, IP/C/W/447, IP/C/M/48, para. 94.

[430] Brazil and India, IP/C/W/443; Brazil et al, IP/C/W/438; India, IP/C/M/46, para. 39.

[431] Brazil, IP/C/M/46, paras. 82 and 85; EC, IP/C/M/46, para. 46, IP/C/M/44, para. 30; India, IP/C/M/40, para. 82; Norway, IP/C/M/39, para. 121; Peru, IP/C/W/447, IP/C/M/48, para. 94; Switzerland, IP/C/M/46, para. 73.

[432] Andean Community, IP/C/M/37/Add.1, para. 231; Brazil et al, IP/C/W/356; Brazil, IP/C/W/228, IP/C/M/37/Add.1, para. 236; Indonesia, IP/C/M/36/Add.1, para. 217.

[433] Brazil et al, IP/C/W/429/Rev.1; India, IP/C/M/45, para. 20.

[434] United States, IP/C/M/49, para. 160.

## ANNEX

## DOCUMENTS OF THE TRIPS COUNCIL WITH RESPECT TO THE REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B); THE RELATIONSHIP BETWEEN TRIPS AND THE CONVENTION ON BIOLOGICAL DIVERSITY; AND THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

The reports on the meetings of the TRIPS Council held during the period January 1999 to October 2005 (IP/C/M/21-35, 36/Add.1, 37/Add.1, 38-40 and 42-49) reflect the work done so far in the TRIPS Council with respect to three agenda items, namely, the review of the provisions of Article 27.3(b); the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD); and the protection of traditional knowledge and folklore (List A). The substantive discussions in the TRIPS Council on these issues have been recorded in the reports of the meetings held from August 1999 to October 2005 (IP/C/M/24-35, 36/Add.1, 37/Add.1, 38-40 and 42-49).

Other documents that have been made available include:

- Members' submissions relating to the three afore-mentioned agenda items. Over the period December 1998 to June 2005, 52 papers have been submitted by Members or groups of Members (List B).

- Information on national legislation, practices and experiences submitted by eight Members (List C).

- Responses to the questionnaire on Article 27.3(b) from 25 Members (List D).

- Information provided on work in six intergovernmental organizations (List E).

- Notes by the Secretariat on relevant issues under discussion in the TRIPS Council (List F).

| LIST A – Records of the work of the TRIPS Council | | | |
|---|---|---|---|
| | IP/C/M/21-35, 36/Add.1, 37/Add.1, 38-40 and 42-49 | Minutes of the TRIPS Council Meetings | 22 January 1999 – 25-26, 28 October 2005 |

| LIST B - Members' submissions relating to the three agenda items | | | |
|---|---|---|---|
| **2005** | | | |
| Bolivia, Brazil, Colombia, Cuba, India, and Pakistan | IP/C/W/459 | The Relationship between the TRIPS Agreement and the CBD, the Protection of Traditional Knowledge and Folklore – Technical Observation on US Submission IP/C/W/449 | 18 November 2005 |
| Peru | IP/C/W/458 | Analysis of Potential Cases of Biopiracy | 7 November 2005 |
| United States | IP/C/W/449 | Article 27.3(b) - Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 10 June 2005 |
| Peru | IP/C/W/447 | Article 27.3(b) - Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 8 June 2005 |
| Switzerland | IP/C/W/446 | The Relationship between the TRIPS Agreement and the CBD, the Protection of Traditional Knowledge and the Review of Implementation of the TRIPS Agreement under Article 71.1 | 30 May 2005 |
| Peru | IP/C/W/441/Rev.1 | Revised version of document IP/C/W/441 - Article 27.3(b) - Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 19 May 2005 |
| Brazil, India | IP/C/W/443 | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434) | 18 March 2005 |
| Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand | IP/C/W/442 | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Benefit-Sharing under the Relevant National Regime | 18 March 2005 |
| Peru | IP/C/W/441 | Article 27.3(b) - Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 8 March 2005 |
| Dominican Republic | IP/C/W/429/Rev.1/ Add.3 | Request of the Dominican Republic to be added to the list of sponsors of document IP/C/W/429/Rev.1 | 10 February 2005 |
| Colombia | IP/C/W/429/Rev.1/ Add.2 | Request of Colombia to be added to the list of sponsors of document IP/C/W/429/Rev.1 | 20 January 2005 |

| LIST B - Members' submissions relating to the three agenda items | | | |
|---|---|---|---|
| **2004** | | | |
| Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, Venezuela | IP/C/W/438 | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Prior Informed Consent under the Relevant National Regime | 10 December 2004 |
| United States | IP/C/W/434 | Article 27.3(b) - Relationship between the TRIPS Agreement and the CBD and the Protection of Traditional Knowledge and Folklore | 26 November 2004 |
| Switzerland | IP/C/W/433 | Further Observations by Switzerland on its Proposals regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications | 25 November 2004 |
| Bolivia | IP/C/W/429/Rev.1/ Add.1 | Request of Bolivia to be added to the list of sponsors of document IP/C/W/429/Rev.1 | 14 October 2004 |
| Cuba, Ecuador | IP/C/W/429/Rev.1 | Revised version of document IP/C/W/429 and request from Cuba and Ecuador to be added to the list of sponsors | 27 September 2004 |
| Brazil, India, Pakistan, Peru, Thailand and Venezuela | IP/C/W/429 | Elements of the Obligation to Disclose the Source and Country of Origin of Biological Resources and/or Traditional Knowledge used in an Invention | 21 September 2004 |
| Switzerland | IP/C/W/423 | Additional Comments by Switzerland on its Proposal Submitted to WIPO Regarding the Declaration of Source of Genetic Resources and Traditional Knowledge in Patent Applications | 14 June 2004 |
| Bolivia | IP/C/W/420/Add.1 | Request of Bolivia to be added to the list of sponsors of Document IP/C/W/420 | 5 March 2004 |
| Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela | IP/C/W/420 | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) – Checklist of Issues | 2 March 2004 |
| **2003** | | | |
| Morocco on behalf of the African Group | IP/C/W/404 | Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement | 26 June 2003 |
| Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela | IP/C/W/403 | The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and Traditional Knowledge | 24 June 2003 |

| LIST B - Members' submissions relating to the three agenda items | | | |
|---|---|---|---|
| **2003 (cont'd)** | | | |
| Switzerland | IP/C/W/400/Rev.1 | Revised version of document IP/C/W/400 - Article 27.3(b) - The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and Traditional Knowledge – Revision | 18 June 2003 |
| Switzerland | IP/C/W/400 | Article 27.3(b) - The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and Traditional Knowledge | 28 May 2003 |
| **2002** | | | |
| Peru | IP/C/W/356/Add.1 | Request of Peru to be added to the List of Sponsors of Document IP/C/W/356 | 1 November 2002 |
| European Communities and Member States | IP/C/W/383 | Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore | 17 October 2002 |
| Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe | IP/C/W/356 | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity | 24 June 2002 |
| **2001** | | | |
| Australia | IP/C/W/310 | Communication from Australia: Review of Article 27.3(b) | 2 October 2001 |
| Norway | IP/C/W/293 | Communication from Norway: Review of Article 27.3(b) of the TRIPS Agreement: The Relationship between the TRIPS Agreement and the Convention on Biological Diversity | 29 June 2001 |
| Switzerland | IP/C/W/284 | Communication from Switzerland: Review of Article 27.3(b): The View of Switzerland | 15 June 2001 |
| United States | IP/C/W/257 | Communication from the United States - Views of the United States on the Relationship between the Convention on Biological Diversity and the TRIPS Agreement | 13 June 2001 |
| EC | IP/C/W/254 | Review of the Provisions of Article 27.3(b) of the TRIPS Agreement: Communication from the European Communities and their Member States | 13 June 2001 |

| LIST B - Members' submissions relating to the three agenda items | | | |
|---|---|---|---|
| **2001 (cont'd)** | | | |
| Peru | IP/C/W/246 | Communication from Peru: Peru's Experience of the Protection of Traditional Knowledge and Access to Genetic Resources | 04 March 2001 |
| **2000** | | | |
| Japan | IP/C/W/236 | Review of the provisions of Article 27.3(b) - Japan's view | 11 December 2000 |
| Singapore | JOB(00)/7853 | Non-paper by Singapore - Article 27.3(b) | 11 December 2000 |
| Brazil | IP/C/W/228 | Review of Article 27.3(b) – Communication from Brazil | 24 November 2000 |
| India | JOB(00)/6091 | Non-paper by India | 5 October 2000 |
| United States | IP/C/W/209 | Review of the Provisions of Article 27.3(b) - Further Views of the United States – Communication from the United States | 3 October 2000 |
| Mauritius | IP/C/W/206 | Communication from Mauritius on behalf of the African Group | 20 September 2000 |
| India | IP/C/W/196 | Communication from India | 12 July 2000 |
| India | IP/C/W/195 | Communication from India | 12 July 2000 |
| **1999** | | | |
| Kenya | IP/C/W/163 | Review of the Provisions of Article 27.3(b) – Communication from Kenya on behalf of the African Group | 8 November 1999 |
| Cuba, Honduras, Paraguay and Venezuela | IP/C/W/166 | Review of Implementation of the Agreement under Article 71.1: Proposal on the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities | 5 November 1999 |
| Norway | IP/C/W/167 | Review of the Provisions of Article 27.3(b) - Communication from Norway | 3 November 1999 |
| Andean Group | IP/C/W/165 | Review of the Provisions of Article 27.3(b) - Proposal on the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities – Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru | 3 November 1999 |
| India | IP/C/W/161 | Review of the Provisions of Article 27.3(b) - Communication from India | 3 November 1999 |
| Brazil | IP/C/W/164 | Review of the Provisions of Article 27.3(b) - Communication from Brazil | 29 October 1999 |
| United States | IP/C/W/162 | Review of the Provisions of Article 27.3(b) – Communication from the United States | 29 October 1999 |
| Canada, EC, Japan and USA | IP/C/W/126 | Review of the Provisions of Article 27.3(b) - Communication from Canada, the European Communities, Japan and the United States | 5 February 1999 |

| LIST B - Members' submissions relating to the three agenda items | | | |
|---|---|---|---|
| **1998** | | | |
| Mexico | Job No. 6957 | Non-paper from Mexico: Application of Article 27.3(b) | 8 December 1998 |

| LIST C - Information on national legislation, practices and experiences | | | |
|---|---|---|---|
| **2005** | | | |
| Norway | IP/C/M/49, paras. 81-84 | Minutes of Meeting of the Council for TRIPS | 26 and 28 October 2005 |
| Peru | IP/C/M/49, paras. 81-84 | Minutes of Meeting of the Council for TRIPS | 26 and 28 October 2005 |
| Peru | IP/C/W/458 | Analysis of Potential Cases of Biopiracy | 7 November 2005 |
| India | IP/C/M/48, paras. 43-45 | Minutes of Meeting of the Council for TRIPS | 14-16 June 2005 |
| Norway | IP/C/M/48, para. 67 | Minutes of Meeting of the Council for TRIPS | 14-16 June 2005 |
| Peru | IP/C/W/447 | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 8 June 2005 |
| Peru | IP/C/W/441/Rev.1 | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 19 May 2005 |
| Peru | IP/C/M/47, paras. 16-23 | Minutes of Meeting of the Council for TRIPS | 8-9 and 31 March 2005 |
| Peru | IP/C/W/441 | Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD and protection of Traditional Knowledge and Folklore | 8 March 2005 |
| **2004** | | | |
| Australia | IP/C/M/46, para. 63 | Minutes of Meeting of the Council for TRIPS | 1-2 December 2004 |
| Peru | IP/C/M/45, para. 31 | Minutes of Meeting of the Council for TRIPS | 21 September 2004 |
| EC | IP/C/M/43, para. 39 | Minutes of Meeting of the Council for TRIPS | 8 March 2004 |
| Norway | IP/C/M/43, para. 54 | Minutes of Meeting of the Council for TRIPS | 8 March 2004 |
| **2003** | | | |
| United States | IP/C/M/42, para. 110 | Minutes of Meeting of the Council for TRIPS | 18 November 2003 |
| EC | IP/C/M/42, para. 108 | Minutes of Meeting of the Council for TRIPS | 18 November 2003 |
| Norway | IP/C/M/40, paras. 87-88 | Minutes of Meeting of the Council for TRIPS | 4-5 June 2003 |
| Norway | IP/C/M/39, para. 121 | Minutes of Meeting of the Council for TRIPS | 18-19 February 2003 |
| United States | IP/C/W/393 | Access to Genetic Resources Regime of the United States National Parks | 28 January 2003 |

| LIST C - Information on national legislation, practices and experiences | | | |
|---|---|---|---|
| **2002** | | | |
| Peru | IP/C/M/38, para. 245 | Minutes of Meeting of the Council for TRIPS | 25-27 and 29 November and 20 December 2002 |
| India | IP/C/M/37/Add.1, para. 253 | Minutes of Meeting of the Council for TRIPS | 17-19 September 2002 |
| New Zealand | IP/C/M/37/Add.1, para. 248 | Minutes of Meeting of the Council for TRIPS | 17-19 September 2002 |
| Peru | IP/C/M/36/Add.1, para. 204 | Minutes of Meeting of the Council for TRIPS | 25-27 June 2002 |
| United States | IP/C/W/341 | Technology transfer practices of the US National Cancer Institute's Departmental Therapeutics Programme – Communication from the United States | 25 March 2002 |
| **2001** | | | |
| Australia | IP/C/W/310 | Communication from Australia: Review of Article 27.3(b) | 2 October 2001 |
| Peru | IP/C/W/246 | Communication from Peru: Peru's Experience of the Protection of Traditional Knowledge and Access to Genetic Resources | 14 March 2001 |
| **2000** | | | |
| India | IP/C/W/198 | Protection of Biodiversity and Traditional Knowledge – The Indian Experience | 14 July 2000 |

| LIST D - Information on Review of the Provisions of Article 27.3(b) | | | |
|---|---|---|---|
| **2004** | | | |
| Moldova | IP/C/W/125/Add.24 | Review of the Provisions of Article 27.3(b) - Information from Members – Addendum | 26 January 2004 |
| **2002** | | | |
| Lithuania | IP/C/W/125/Add.23 | Review of the Provisions of Article 27.3(b) - Information from Members – Addendum | 22 July 2002 |
| **2001** | | | |
| Czech Republic | IP/C/W/125/Add.8/Suppl.1 | Review of the Provisions of Article 27.3(b) - Information from Members - Supplement | 18 September 2001 |
| Hong Kong, China | IP/C/W/125/Add.21 | Review of the Provisions of Article 27.3(b) - Information from Members – Addendum | 10 August 2001 |
| Thailand | IP/C/W/125/Add.22 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 10 July 2001 |
| Estonia | IP/C/W/125/Add.20 | Review of the Provisions of Article 27.3(b) - Information from Members – Addendum | 2 July 2001 |

| LIST D - Information on Review of the Provisions of Article 27.3(b) | | | |
|---|---|---|---|
| **2000** | | | |
| Iceland | IP/C/W/125/Add.19 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 17 July 2000 |
| **1999** | | | |
| Slovak Republic | IP/C/W/125/Add.18 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 27 July 1999 |
| South Africa | IP/C/W/125/ Add.16/Corr.1 | Review of the Provisions of Article 27.3(b) – Information from Members – Addendum - Corrigendum | 25 May 1999 |
| Norway | IP/C/W/125/Add.17 | Review of the Provisions of Article 27.3(b) – Information from Members – Addendum | 19 May 1999 |
| South Africa | IP/C/W/125/Add.16 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 21 April 1999 |
| Morocco | IP/C/W/125/Add.14 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 20 April 1999 |
| US | IP/C/W/125/Add.5 | Review of the Provisions of Article 27.3(b) – Information from Members – Addendum | 20 April 1999 |
| Switzerland | IP/C/W/125/Add.15 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 13 April 1999 |
| Australia | IP/C/W/125/Add.13 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 16 March 1999 |
| Canada | IP/C/W/125/Add.12 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 12 March 1999 |
| Poland | IP/C/W/125/Add.11 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 12 March 1999 |
| Japan | IP/C/W/125/Add.7 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 12 March 1999 |
| Slovenia | IP/C/W/125/Add.10 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 16 February 1999 |
| Korea | IP/C/W/125/Add.9 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 16 February 1999 |
| Czech Republic | IP/C/W/125/Add.8 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 16 February 1999 |
| Romania | IP/C/W/125/Add.6 | Review of the Provisions of Article 27.3(b) – Information from Members – Addendum | 16 February 1999 |
| **1999 (cont'd)** | | | |

| LIST D - Information on Review of the Provisions of Article 27.3(b) | | | |
|---|---|---|---|
| Hungary | IP/C/W/125/Add.1 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 16 February 1999 |
| New Zealand | IP/C/W/125/Add.2 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 12 February 1999 |
| EC | IP/C/W/125/Add.4 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 10 February 1999 |
| Zambia | IP/C/W/125/Add.3 | Review of the Provisions of Article 27.3(b) – Information from Members - Addendum | 10 February 1999 |
| Bulgaria | IP/C/W/125 | Review of the Provisions of Article 27.3(b) – Information from Members | 3 February 1999 |

| LIST E - Information on the work of intergovernmental organizations | | | |
|---|---|---|---|
| **2002** | | | |
| World Bank | IP/C/W/347/Add.4 | Review of the Provisions of Article 27.3(b) - Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 21 October 2002 |
| UPOV | IP/C/W/347/Add.3 | Review of the Provisions of Article 27.3(b) - Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 7 June 2002 |
| UNCTAD | IP/C/W/347/Add.2 | Review of the Provisions of Article 27.3(b) - Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 7 June 2002 |
| CBD | IP/C/W/347/Add.1 | Review of the Provisions of Article 27.3(b) - Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 7 June 2002 |
| FAO | IP/C/W/347 | Review of the Provisions of Article 27.3(b) - Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 7 June 2002 |

| LIST E - Information on the work of intergovernmental organizations | | | |
|---|---|---|---|
| WIPO | JOB(02)/15 | WIPO Activities of Relevance to the Work of the Council for TRIPS | 4 March 2002 |
| **2001** | | | |
| WIPO | IP/C/W/242 | Statement by the World Intellectual Property Organization (WIPO) on intellectual property, biodiversity and traditional knowledge | 6 February 2001 |
| **2000** | | | |
| UNCTAD | IP/C/W/230 | Document prepared by the UNCTAD Secretariat for the expert meeting on systems and national experiences for protecting traditional knowledge, innovations and practices which took place from 30 October to 1 November 2000 in Geneva: Outcome of the expert meeting | 14 December 2000 |
| WIPO | IP/C/W/218 | Document prepared by the International Bureau of WIPO for the meeting on intellectual property and genetic resources, which took place on 17 and 18 April 2000 in Geneva: Intellectual Property and Genetic Resources – An Overview | 18 October 2000 |
| WIPO | IP/C/W/217 | Document prepared by the International Bureau of WIPO for the round table on intellectual property and traditional knowledge, which took place on 1 and 2 November 1999 in Geneva: Protection of Traditional Knowledge: A Global Intellectual Property Issue | 18 October 2000 |
| **1999** | | | |
| FAO | IP/C/W/130/Add.2 | Review of the Provisions of Article 27.3(b) – Information from Intergovernmental Organizations - Addendum | 12 April 1999 |
| CBD | IP/C/W/130/Add.1 | Review of the Provisions of Article 27.3(b) – Information from Intergovernmental Organizations - Addendum | 16 March 1999 |
| UPOV | IP/C/W/130 | Review of the Provisions of Article 27.3(b) – Information from Intergovernmental Organizations | 17 February 1999 |

| LIST F – Notes by the Secretariat | | |
|---|---|---|
| **2003** | | |
| IP/C/W/273/Rev.1 | Review of the Provisions of Article 27.3(b): Illustrative List of Questions Prepared by the Secretariat – Revision | 18 February 2003 |
| **2002** | | |
| IP/C/W/370 | The Protection of Traditional Knowledge and Folklore – Summary of Issues Raised and Points Made | 8 August 2002 |
| IP/C/W/369 | Review of the Provisions of Article 27.3(b) of the TRIPS Agreement – Summary of Issues Raised and Points Made | 8 August 2002 |
| IP/C/W/368 | The Relationship between the TRIPS Agreement and the Convention on Biodiversity – Summary of Issues Raised and Points Made | 8 August 2002 |
| JOB(02)/60 | The Protection of Traditional Knowledge and Folklore – Summary of Issues Raised and Points Made | 18 June 2002 |
| **2002 (cont'd)** | | |
| JOB(02)/59 | Review of the Provisions of Article 27.3(b) – Summary of Issues Raised and Points Made | 18 June 2002 |
| JOB(02)/58 | The Relationship between the TRIPS Agreement and the CBD – Summary of Issues Raised and Points Made | 18 June 2002 |
| **2001** | | |
| IP/C/W/273 | Review of the Provisions of Article 27.3(b): Synoptic Tables of Information provided by Members – Informal Note by the Secretariat | 5 June 2001 |
| **2000** | | |
| JOB(00)/7517 | The Relationship between the Convention on Biological Diversity and the TRIPS Agreement: Checklist of Points Made – Note by the Secretariat | 23 November 2000 |
| **1999** | | |
| Job No. 2627 | UPOV-WIPO-WTO joint symposium on the protection of plant varieties under Article 27.3(b) of the TRIPS Agreement: Texts of presentations | 7 May 1999 |
| **1998** | | |
| IP/C/W/122 | Illustrative Questions: Review of the Provisions of Article 27.3(b) | 22 December 1998 |
| Job No. 6955 | Review of the Provisions of Article 27.3(b): Lifting of Reserve | 16 December 1998 |

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