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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

FIRST DRAFT

Prepared by the Secretariat

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PART I: INTRODUCTION

Context of this document

1. This document examines a range of issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. It is one step in developing a response to the Conference of Parties (COP) of the Convention on Biological Diversity (CBD), which has (in Decision VII/19) invited the World Intellectual Property Organization (WIPO) to:

"examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:

(a) Options for model provisions on proposed disclosure requirements;

(b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;

(c) Options for incentive measures for applicants;

(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;

(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the CBD on its work, in particular on actions or steps proposed to address the above issues, in order for the CBD to provide additional information to WIPO for its consideration in the spirit of mutual supportiveness."

2. The WIPO General Assembly decided on a process to respond to the COP invitation. Briefly, this included (i) an invitation by WIPO Member States to submit comments and proposals by December 15, 2004; (ii) the preparation of a draft examination and its circulation for comments by the end of January 2005; (iii) observations and comments on the draft to be submitted by Member States and accredited observers by the end of March 2005; (iv) publication on the website and in a consolidated document of all comments and observations received; (v) convening of a one-day *ad hoc* intergovernmental meeting to consider and discuss a revised version of the draft which would be available at least 15 days before the Meeting; (vi) preparation of a further revised draft to be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.

3. The present draft is the document foreseen in step (ii) of this process. Further details of the background to the process are provided in the Annex.

Submissions received from WIPO Member States

4. The first step in the procedure agreed by the WIPO General Assembly was for the Director General of WIPO to invite all Member States 'to submit proposals and suggestions before December 15, 2004.' The invitation was accordingly circulated (C.7092 and C. 7093, November 10, 2004). By December 15, 2004, submissions had been received from the following Member States and groups of Member States: African Group, Australia, Belize, Brazil, Colombia, the European Community and its Member States, Ghana, the Islamic Republic of Iran, Japan, the Kyrgyz Republic, Peru on behalf of the Andean Community, the Russian Federation, Switzerland, Turkey, and the United States of America. These were posted on line at www.wipo.int/tk/en/genetic/proposals/index.html#proposals, and have been

circulated as a provisional collation. A further collation, in the working languages of the relevant bodies, will be circulated in advance of the planned meeting to consider the present draft.

Background to this draft examination

Contents and status of this document

5. This document is an initial draft only, as provided in the agreed process, and is intended to provide a basis for the continuing dialogue foreseen by the WIPO General Assembly. It attempts to provide a synthesized information resource, based as far as possible on existing material. It contains several summaries of the issues raised, and a table of disclosure mechanisms discussed; these are not intended to prejudge or prescribe any approach, but to provide a possible framework for this information to be presented in an accessible, concise and neutral manner. These draft summaries and table are most unlikely, however, to be acceptable in their present form and may be considered as placeholders for future development, if appropriate.

6. This initial draft examination draws as far as possible on the guidance directly provided by WIPO Member States in the agreed procedure, on the submissions and proposals made by WIPO Member States within WIPO and in other forums, on existing national and regional laws, and on the earlier study prepared by WIPO (publication 786(E); the text is also available in the six official languages of WIPO as document WO/GA/30/7 Add.1).

7. As this initial draft aims to follow these materials very closely, some relevant material is entirely duplicated from previous documents. These include specific Member State proposals, and relevant technical passages from the Technical Study (such as those setting out relevant provisions of WIPO treaties relevant to this examination, which aim to introduce no new material but to make available existing material in context).

8. The earlier WIPO technical study on this issue was transmitted to the CBD COP with the following clarification of its status:

> "The attached draft technical study has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive interpretation of any treaty. It is to be regarded as a technical input to facilitate policy discussion and analysis in the Convention on Biological Diversity and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States."

9. The present initial draft has been prepared in a similar vein, and it may be considered appropriate for it to be accompanied by a similar disclaimer. This would be consistent with the position put by a number of WIPO Member States on the current process (see comments cited below, in particular those of the Islamic Republic of Iran, which specifically proposes a similar disclaimer).

Background to the Invitation of the CBD COP

10. The most recent invitation from the CBD COP follows a series of invitations, which led *inter alia* to the preparation of the UNEP-WIPO Study on IP aspects of ABS, the earlier Technical Study on disclosure issues, and work on guidelines relating to IP and the mutually agreed terms established in ABS arrangements. These past invitations have included:

- inviting WIPO to 'analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for intellectual property rights, including patents' (V/26)
- requesting WIPO to 'take due account of relevant provisions of the CBD, including the impact of intellectual property rights on the conservation and sustainable use of biological diversity, and in particular the value of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity; (V/26)
- encouraging WIPO 'to make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation' (decision IV/24)
- inviting WIPO 'to take into account the lifestyles and the traditional systems of access and use of the knowledge, technologies and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity in its work and the relevant recommendations of the COP (VI/9)
- inviting WIPO 'to further strengthen the complementarity of its work programme with that of the Convention on intellectual property issues arising from access and benefit-sharing and Article 8(j) and related provisions and to provide appropriate information on these issues with a view to enhancing mutual supportiveness in the relevant work programmes that fall within the respective mandates of the Convention and the Organization.'(VI/20)

11. Accordingly, the most recent invitation from the CBD COP (including the preparation of this draft 'examination' of issues) may take account of these earlier invitations and the ongoing dialogue and cooperation that is envisaged. In addition, some distinct aspects of the most recent invitation, including those underscored by WIPO Member States (recalling also the context of the decision taken by the CBD COP), are as follows:

(a) WIPO is invited to 'examine' issues regarding the interrelation of access to genetic resources and disclosure requirements in IP rights applications and the five specific issues stipulated, and is only invited to 'address' them *where appropriate;*[1]

(b) The invitation signals the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD:[2] this suggests a focus on advancing the conservation of biological diversity, the sustainable use of its components, and fair and equitable sharing of benefits from the use of genetic resources;

(c) The five specific sets of issues that are enumerated are not necessarily exhaustive, suggesting that the invitation potentially considers a broader set of issues (as implied by the term '*inter alia*');

(d) The invitation appears potentially to relate to work within WIPO, but also foresees a reporting process to the CBD COP, to be followed by a continuing feedback process (so the CBD would 'provide additional information to WIPO for its consideration in the spirit of mutual supportiveness'). This raises, in principle at least, the possibility of WIPO forwarding to the CBD any specific questions concerning the implications and operations of the CBD for its guidance.

(e) In addition, the same COP decision requested the Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of

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1 See comments of Brazil

2 See e.g. comments of the African Group

GR and associated TK in applications for IP rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to WIPO. This suggests that, depending on the CBD's own procedures, there may be further input from the CBD that may be relevant to the current examination: this may apply especially to the fifth element of the CBD COP decision, concerning certification (see discussion in Part IV.E below), given that the Working Group was requested to consider certification in particular. The Working Group is currently due to meet from February 14 to 18 February, 2005, and March 13 to 17, 2006.

(f) The invitation refers to 'intellectual property' applications. This term seems to refer in particular to applications for registration of industrial property titles. The most often considered forms of industrial property are patents (and related forms such as utility models, plant patents and petty patents/innovation patents and the like), and plant breeder's rights or plant variety rights. The latter form of IP is not within the competence of WIPO, and is the province of the International Union for the Protection of New Varieties of Plants (UPOV). In response to a request of the Executive Secretary of the CBD, UPOV has developed a reply, based on the principles of the UPOV Convention, in order to provide some guidance on UPOV's views on the "process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing" (available at www.upov.int/en/news/2003/intro_cbd.html). Other forms of industrial property with potential bearing on access and benefit sharing include the law of distinctive indications (trade marks, collective and certification marks, and geographical indications) and trade names, but these are not covered in the present document.

(g) The relevant international legal framework includes multilateral environmental agreements (MEAs) such as the CBD, agreements dealing with access to and use of genetic resources (the FAO International Treaty and the CBD), and IP provisions both within WIPO and beyond it (including UPOV and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO). WIPO does not have competence to make definitive comment on these areas, apart from specific IP measures, legal and policy concepts, and legal instruments within its competence. Nonetheless, there is a strong expectation that WIPO should be guided by and seek to support the objectives and the legal provisions of this broader body of legal and policy materials. For instance, the African Group underlined 'the importance it attaches to the mutual supportiveness mentioned in the invitation between CBD and WIPO. This mutual supportiveness entails making the intellectual property system, and in particular the patent system, supportive of the protection [of] bio-diversity, through the introduction of legally binding measures…"[3]

12. The COP decision also refers to the previous WIPO technical study in the following terms:"*Noting with appreciation* the Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge prepared by World Intellectual Property Organization at the request of the Conference of the Parties in decision VI/24 C and considering the contents of the Technical Study to be helpful in the consideration of intellectual property-related aspects of user measures."[4] This suggests that elements of the technical study may also be usefully drawn upon in undertaking an examination that was subsequently proposed as a further step in this process.

Relationship with current WIPO activities

13. As noted above the CBD COP invited WIPO to 'examine and, where appropriate, address' certain issues relating to disclosure and access to genetic resources, and regularly to

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[3] See e.g. comments of the African Group:

[4] See document UNEP/CBD/COP/7/6, Annex, page 27.

provide reports to the CBD on its work. This document 'examines' these issues in four main ways:

- by citing Member State commentary on the issues
- by citing relevant proposals in WIPO and other forums
- by extracting material from the Technical Study that is relevant to the specific issues raised
- by summarizing or distilling key issues, without seeking to prejudge them, including through an illustrative table of disclosure mechanisms

The invitation from the COP suggests three steps on the part of WIPO – examining the issues, addressing them where appropriate, and reporting regularly to the CBD. As required by the WIPO General Assembly decision, this draft has been prepared as an initial draft 'examination' of substantive technical issues. This 'examination' may or may not be viewed by WIPO Member States as part of 'addressing' the issues, and as constituting the first (or the sole) regular 'report' as foreseen by the CBD COP Decision. Additionally, the 'report' that the CBD COP has invited may, potentially, cover more WIPO processes than simply the preparation of this draft examination. Accordingly, as a separate question, WIPO Member States may wish to consider further the relationship between the present examination and the invitation to inform the CBD regularly of relevant developments. It may also require consideration of how relevant parts of WIPO's work program may, 'where, appropriate, address' these issues may arise (notably in the SCP, the Working Group on PCT Reform, and the IGC). Options may include an annual update prepared for the WIPO General Assembly to be passed to the CBD, or a biennial report to be prepared in synchronization with the sessions of the CBD COP.

Memorandum of Understanding

14. This process of ongoing cooperation, information exchange and technical input 'in the spirit of mutual supportiveness' is also consistent with the Memorandum of Understanding (MoU) concluded between the CBD Secretariat and WIPO (see document WO/CC/48/2 of July 24, 2002). This MoU recalled COP Decision IV/9 which requested the Executive Secretary 'to seek ways … to enhance cooperation between the Convention on Biological Diversity and WIPO' and decision V/26 (B)(3) which 'requested the Executive Secretary to endeavour to undertake further cooperation and consultation with WIPO on issues regarding intellectual property rights and relevant provisions of the Convention.' It also recalled COP decision V/26 (A)(15)(e) inviting WIPO 'to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, and requested WIPO, among others, in its work on intellectual property rights issues, to take due account of relevant provisions of the Convention, including the impact of intellectual property rights on the conservation and sustainable use of biological diversity, and in particular the value of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity.'

15. The MoU also recalled 'the indication by the [IGC] that WIPO should address the intellectual property issues before the [IGC] in conjunction with the CBD Secretariat and the Secretariat of the Food and Agriculture Organization of the United Nations, to ensure that WIPO's work continues to be consistent with and complementary to the work being done by those Organizations' and recognized the 'need to enhance the mutually supportive relationship between WIPO and the [CBD] by establishing appropriate arrangements for cooperation between them on these issues.' The MoU provided, *inter alia*, that the 'CBD Secretariat and WIPO will, upon request and subject to the approval of their competent subsidiary bodies, undertake studies and provide other technical inputs in writing to the

governing or competent subsidiary bodies of the requesting Party on issues within their areas of competence, as necessary for the advancement of their respective programs of work' and will 'mutually support one another in the undertaking and promotion of activities and projects relevant to their respective mandates.'

16. It may be noted also that WIPO's Agreement with the United Nations includes (Article 2) an undertaking to 'co-operate in whatever measures may be necessary to make co-ordination of the policies and activities of the United Nations and those of the organs and agencies within the United Nations system fully effective.'

FAO International Treaty

17. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) under the auspices of the Food and Agricultural Organization (FAO) is another important element of the international framework for access to genetic resources and benefit-sharing, and may also need to be taken into account. The ITPGR provides for a multilateral approach to access and benefit-sharing, in which sovereign rights of States over their own genetic resources are recognized, and it is agreed, in the exercise of these rights, to establish an open multilateral system of exchange. Such a system is exemplified in the work and functioning of the Consultative Group on International Agricultural Research and is to be established under Part IV of the ITPGR in the form of a Multilateral System of Access and Benefit-sharing (MLS). The MLS will include the plant genetic resources for food and agriculture listed under Annex 1 of the ITPGR and which are under the management and control of Contracting Parties and in the public domain. The MLS will provide for facilitated access in accordance with certain conditions and benefit-sharing through mechanisms of information exchange, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization. Whereas the CBD defines the term "country of origin of genetic resources" (Article 2), the ITPGR uses the term "center of origin" of plant genetic resources (Article 2), reflecting the fact that for many such resources a single country of origin may not easily be determined. This may need to be taken into account when considering references to the source or origin of relevant genetic resources.

Objectives of the CBD

18. The invitation calls on WIPO to take 'into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD.' This draft examination does not purport to analyse or interpret the CBD and its objectives; and it should be noted that the invitation refers to a feedback process whereby the CBD would "provide additional information to WIPO for its consideration in the spirit of mutual supportiveness." This may provide an opportunity for input to WIPO on relevant aspects of the objectives of the CBD.

19. The objectives of the CBD (as expressed in Article 1) are threefold:

- the conservation of biological diversity,
- the sustainable use of its components, and
- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

20. While this examination seeks to take full account of each of these objectives, the emphasis in discussions within WIPO, and more generally concerning the relationship between the IP system and the CBD, has been on the third of these objectives, namely the fair

and equitable sharing of the benefits arising out of the use of genetic resources. For example, the CBD COP commented that the previous WIPO Technical Study was 'helpful in the consideration of intellectual property-related aspects of user measures.' User measures are mentioned in the CBD 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization' ('Bonn Guidelines'), decribed as 'appropriate legal, administrative or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing [genetic] resources and mutually agreed terms on which access was granted.'

21. Hence, while all three objectives are clearly of high importance, in practical terms the focus has been on the third objective, equitable benefit-sharing, and this current examination, with the guidance of Member States and other stakeholders, is likely to focus on this objective as well. That said, the impact on conservation of biological diversity (the first objective of the CBD) and the sustainable use of its components (its second objective) are clearly important, as is the impact on maintaining and respecting traditional knowledge (TK). For example, a study on this issue commissioned by UNEP and WIPO observed:

> Some associations of TK holders have maintained that the acknowledgment of contributions of local knowledge providers and innovators should be required for TK-based patent applications. They have maintained that such disclosure requirements are a form of acknowledgement of TK which would promote the conservation of TK systems, because through such acknowledgement of TK communities would learn more about the value of their own knowledge and thus may have increased incentives to conserve.[5]

22. In addition to the objectives formally specified in the CBD, the African Group also links the invitation to a need to support and not run counter to the 'objectives and principles of the CBD.' In this context, the African Group highlights the 'objectives and principles enshrined in Articles 3, 15 and 16 of the CBD.' These Articles refer respectively to the sovereign right of States to exploit their own resources and the responsibility of States to ensure that activities within their jurisdiction or control do not cause damage to the environment (Article 3); access to genetic resources (Article 15); and access to and transfer of technology (Article 16).

User measures in the context of access and benefit sharing

23. The relevance and utility of disclosure requirements in patent applications forms part of a more general study of the ways in which laws and legal mechanisms in so-called 'user' countries (that is to say, those countries that are likely to make commercial and scientific use of genetic resources); as one recent study characterizes such measures:

> While most countries are both 'providers' and 'users' of genetic resources, there has been a tendency in the international debate on access to genetic resources and benefit–sharing (ABS) to view developing countries as primarily 'providers' of such resources, while more industrialized, developed countries— and, specifically, the private sector businesses and scientific research institutions within their jurisdictions—have been portrayed as 'users' of these genetic resources. Such generalizations are of course not absolutely true and in many cases industrialized countries, such as Australia, are also important providers, while some developing countries, such as Brazil, have highly developed biotechnology and agro–industrial capacities. This study is based on the

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[5] Professor A.K. Gupta, 'WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge,' p. 149 (at http://www.wipo.int/tk/en/publications/769e_unep_tk.pdf)

premise that user measures should at first instance be adopted primarily by countries with extensive biotechnology, pharmaceutical, and agro–industrial capacity to control use of genetic resources for scientific and commercial research and development activities in their jurisdictions. [6]

Member State views on the nature of this document

24. A number of Member State submissions provided guidance on the nature of this present document, in particular:

(a) The response should be fully mindful of all discussions on the interaction between genetic resources and disclosure requirements (in particular, the Standing Committee on Patent Law (SCP), the Working Group on PCT Reform, and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)).[7]

(b) It should set out, take full account of, and reflect all proposals and views regarding patent disclosure requirement and genetic resources that may have been made by WIPO Member States in different fora both within WIPO and beyond it, without prejudice to the positions of Member States on these matters;[8]

(c) WIPO should not pass judgment on different options nor seek to advocate specific approaches to the detriment of others.[9]

(d) Any response should be regarded as technical input to facilitate policy discussion and it should not be considered as a formal paper or a policy position on the part of WIPO, its Secretariat or its Member States.[10]

(e) WIPO should preferably limit its work on the comments made by delegations in various bodies rather than going to details before the decision of the WIPO General Assembly in 2005.[11]

(f) It is more suitable that the preliminary response be general and limited to the existing discussions in different bodies of WIPO in the context of CBD objectives.[12]

(g) The concept that the work should be supportive and should not run counter to the objectives and principles of the CBD 'must be a fundamental guiding principle in WIPO's work.' This entails 'making the IP system, and in particular the patent system, supportive of the protection [of] bio-diversity, through the introduction of legally binding measures such as the disclosure of the source and country of origin of the biological resources and associated traditional knowledge used in the invention and evidence of compliance with national access and benefit sharing laws of the country of origin of the genetic resources, as requirements for the granting of patents.'[13]

(h) The matter 'has an interdisciplinary nature with technical, political, economical and social aspects.'[14]

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6 User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity, UNU/IAS Report, March 2003, at 16.

7 See comments of Brazil

8 See comments of the African Group and Brazil

9 See comments of the African Group and Brazil

10 See comments of the Islamic Republic of Iran

11 See comments of the Islamic Republic of Iran

12 See comments of the Islamic Republic of Iran

13 See comments of the African Group

14 See comments of the Kyrgyz Republic

Subject matter

25. This section briefly reviews the subject matter that may be relevant to the five limbs of the CBD invitation. The various proposals and measures differ significantly in the subject matter covered; there are various references, for example, to biological materials, biological resources, genetic material and genetic resources. Member State submissions have used a range of terms, with potentially diverse implications. So as not to prejudge the scope of the examination, these will be referred to collectively as 'GBMR' (genetic or biological materials or resources). Several of these terms are defined in the CBD itself:

> "*Biological resources"* includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
>
> *"Genetic material"* means any material of plant, animal, microbial or other origin containing functional units of heredity.
>
> "*Genetic resources"* means genetic material of actual or potential value.

26. The chief points of difference appear to be that 'genetic' subject matter must contain the functional units of heredity, whereas 'biological' subject matter need not; and 'resources' have actual or potential value (or 'use' in the case of biological resources). Logically, 'genetic' is a more limited category than 'biological,' as is 'resources' as against 'material.' These distinctions may be relevant in determining the scope of disclosure requirements and their implications for the patent system. For example, if a disclosure requirement is limited to genetic resources, could it suggest that an invention is relevant if it makes use of the functional units of heredity present in a resource? Equally, does a disclosure requirement limited to 'resources' only apply if the invention makes use of 'actual or potential value' of the resource? These questions are simply intended to highlight the possible implications, not to suggest any legal interpretation.

27. Concerning relevant knowledge, various proposals and mechanisms either refer to TK as such, not necessarily linked with biological or genetic material; or they are limited to TK in some way associated with biological or genetic material or resources. Traditional knowledge is defined in the draft provisions on TK protection currently under consideration within WIPO as follows:

> [T]he content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.
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> Protection should be extended at least to that traditional knowledge which is:
>
> (i) generated, preserved and transmitted in a traditional and intergenerational context;
>
> (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and

(iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility, such as a sense of obligation to preserve, use and transmit the knowledge appropriately, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive; this relationship may be expressed formally or informally by customary or traditional practices, protocols or laws.[15]

28. Some mechanisms are limited to TK that is 'associated' or otherwise linked with genetic resources. Article 8(j) of the CBD defines an important link between TK and genetic resources, when it refers to 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.' This potentially could be taken into account when considering the scope of disclosure of TK that would be pertinent to the objectives of the CBD.

Relevance to ABS

29. The provisions of the CBD relating to ABS may be relevant in clarifying the choice of term and subject matter for disclosure requirements and related mechanisms. For instance, concerning GBMR, the third objective of the CBD (Article 1) refers to 'the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.' Detailed CBD provisions concerning ABS (such as Article 16) refer to genetic resources as such. Concerning benefit-sharing relating to TK, the CBD (Article 8(j)) provides for an obligation (subject to national legislation) to, inter alia, 'encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.'

[15] WIPO/GRTKF/IC/7/5, Annex I, page 6

PART II: OVERVIEW OF EXISTING PROPOSALS AND MECHANISMS

30. This initial draft examination is intended to illustrate as far as possible and be shaped by the full range of options currently considered or implemented by WIPO Member States, or put forward in regional and international policy and legislative forums, in line with the guidance received from Member States concerning the scope of this examination. This section therefore sets out, for illustrative purposes only, a range of such mechanisms and proposals. Apart from the most recent proposals (those concerning the PCT and SPLT), each of these examples was also cited in the Technical Study. This is not intended to be an exhaustive list, but does aim to reflect the full scope of proposals and mechanisms. If the revised form of this document is to retain this section and the examples provisionally included in it, it would doubtless benefit considerably from a wider range of Member State inputs, and corrections and deletions as appropriate. Translations and other citations, where provided in this section, are not necessarily official and are not intended to interpret legal provisions. The selection of national measures is intended only to be illustrative and makes use of publicly available materials.

International measures and declarations

Bonn Guidelines

31. Within the framework of the CBD, the Bonn Guidelines provide for 'measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights.'

32. The COP decision (VI/24) adopting the Bonn Guidelines also contained related material on the role of IP rights in the implementation of access and benefit-sharing arrangements (Part C), in which the COP invites Parties and Governments to encourage the disclosure of:

- the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted;
- the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development.

33. Among the proposed elements for an international regime according to CBD COP Decision VII/19 is 'disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights.'

WTO TRIPS Council

34. The Doha Ministerial declaration[16] instructed 'the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the [CBD], the protection of traditional knowledge and folklore, and other

[16] WT/MIN(01)/DEC/1, adopted on 14 November 2001

relevant new developments raised by members pursuant to Article 71.1.' In document IP/C/W/368 (The Relationship between the TRIPS Agreement and the CBD: Summary of Issues Raised and Points Made), the WTO Secretariat summarized proposals made within the WTO TRIPS Council up to August 2002. Concerning disclosure requirements, it summarized the proposals as follows:

> It has … been suggested that the TRIPS Agreement should be amended so as to require, or to enable, WTO Members to require that patent applicants disclose, as a condition to patentability: (a) the source of any genetic material used in a claimed invention; (b) any related traditional knowledge used in the invention; (c) evidence of prior informed consent from the competent authority in the country of origin of the genetic material; and (d) evidence of fair and equitable benefit sharing.[37] It has been suggested that such provisions could be incorporated into the TRIPS Agreement by amending Article 27.3(b)[17] or Article 29.[18]
>
> In response, the view has been expressed that such a provision is neither necessary nor desirable for implementing the prior informed consent and benefit-sharing provisions of the CBD. The point has been made that intellectual property rights do not aim to regulate the access and use of genetic resources, to regulate the terms and conditions for bio-prospecting or the commercialization of IPR-protected goods and services.[19] It has been said that this could best be done through contracts between the authorities competent for granting access to genetic resources and any related traditional knowledge and those wishing to make use of such resources and knowledge. In accordance with the CBD, countries could incorporate in their national legislation requirements for the conclusion of such contracts. It has been suggested that, to be effective, such contracts should spell out in detail the terms and conditions under which access and use is granted, including any requirements for joint research and development or for the transfer of technology that might result from the use of genetic resources and traditional knowledge to which access is to be granted. For instance, those seeking access to genetic resources for research and development could be required to share the benefits of any patents that might be granted for inventions developed from those genetic resources, including by providing access to the technology. Questions of jurisdiction of courts and conditions required to be included in contracts with third parties licensed to make use of genetic resources or traditional knowledge obtained would have to be spelled out. Criminal and/or civil remedies could be provided for in the event of a breach of obligations on either side and contracts can be litigated in the specified jurisdiction and judgements enforced around the world under international agreements regarding the recognition of judgements.[20]

35. Specific proposals and submissions to the WTO TRIPS Council have addressed this issue further. In particular, documents IP/C/W/356, IP/C/W/403, IP/C/W/420, IP/C/W/429Rev.1, IP/C/W/438 and IP/C/W/434 have been cited in various Member State submissions under the current process.[21] Specifically, for example, IP/C/W/356, submitted on behalf of the delegations to the WTO of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe proposed that:

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17 Brazil, IP/C/W/228, IP/C/M/32, para. 128, IP/C/M/33, para. 121. [footnote in original]

18 India, IP/C/W/195, IP/C/M/24, para. 81. [footnote in original]

19 EC, IP/C/W/254. [footnote in original]

20 United States, IP/C/W/257. [footnote in original]

21 For example, the submissions of Brazil and the United States of America

the TRIPS Agreement should be amended in order to provide that [WTO] Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:

(i) disclosure of 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 through approval of authorities under the relevant national regimes; and

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

Draft Substantive Patent Law Treaty

36. The question of disclosure of origin of genetic resources and TK has been raised in the WIPO SCP, which is working on a draft Substantive Patent Law Treaty (SPLT).

37. The current draft text of the SPLT (document SCP/10/10) contains three drafting proposals that are potentially relevant to this issue. They are each supported by a number of delegations but are not agreed by all delegations, and are each subject to the annotation '[t]he SCP agreed at its eighth session to include this paragraph in square brackets, but to postpone substantive discussions on this provision.' The drafting proposals include the following (directly relevant text only cited here):

[2(2) 'Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to … comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.]

[13 (4) and 14(3) (identical text): 'A Contracting Party may also require compliance with the applicable law on … environment, access to genetic resources, protection of traditional knowledge…]

Rule 4(2) may also be relevant (as per paragraph 114 of SCP/9/8).

38. The United States of America, Japan and the European Patent Office submitted a joint proposal to the tenth session of the SCP, which took place between May 10 and 14, 2004, designed to limit the draft SPLT to the provisions relating to the definition of prior art, the grace period, novelty and inventive step.

39. This proposal obtained the support of numerous delegations, in particular those from industrialized countries. A number of delegations, however, opposed this proposal and emphasized the need to examine all the provisions of the current draft as a whole, taking into account their interdependent nature and recalling the importance they attached to other matters, such as the disclosure of the origin of genetic resources and traditional knowledge, public health, patentability criteria and the general exceptions. Nevertheless, other delegations considered that the SCP should not deal with matters relating to disclosure and the protection of genetic resources and traditional knowledge, at least until the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC), as the Committee competent to deal with such matters, had completed its consideration of the issues in question. Certain delegations did not share this point of view and considered that the SCP was the appropriate forum to consider such matters.

40. In view of the diversity of opinions expressed, the SCP at its 10th session was unable to reach a consensus on whether it should give priority to a first set of provisions or on whether it should examine the draft SPLT as a whole. The Committee furthermore failed to reach

agreement on the suggestion put forward by the Chair of the session that the question of the SCP's future work be submitted to the WIPO General Assembly.

41. Following these developments, the United States of America and Japan submitted a proposal to the Director General of WIPO with the request that it be added to the agenda for the WIPO General Assembly's 40th series of meetings in September-October 2004. This proposal corresponded, in essence, to the one they had already submitted, together with the European Patent Office, to the tenth session of the SCP. After a lengthy discussion among Member States, during which the positions and concerns expressed were similar to those that had been voiced at the 10th session of the SCP, the WIPO General Assembly adopted the following statement:

> "(i) The General Assembly considered the proposal submitted by the Delegations of Japan and the United States of America (document WO/GA/31/10). No consensus has been reached thereon.
>
> "(ii) It was decided that the dates of the next Standing Committee on the Law of Patents (SCP) should be determined by the Director General following informal consultations that he may undertake."

Patent Cooperation Treaty

Proposal by Switzerland to amend the PCT Regulations

42. Switzerland has submitted a proposal to the Working Group on Reform of the PCT to amend the Regulations under the PCT to explicitly enable Contracting Parties to require patent applicants to declare the source of genetic resources and traditional knowledge, if an invention is directly based on such resources or knowledge. More specifically, Switzerland proposes to amend the Regulations to explicitly enable Contracting Parties to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.

43. By reference, the proposed amendment to the PCT would also apply to the PLT. Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications. Based on the PLT, national law may foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention.

44. The specific proposals are as follows:

- introduction of a new paragraph (g) in Rule 51*bis*.1 of the PCT Regulations so as to enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge; such new paragraph could read as follows:

"(g) Subject to Rule 51bis.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish:

(i) a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource;
(ii) a declaration as to the source of traditional knowledge related to genetic resources, if the inventor knows that the invention is directly based on such knowledge;
(iii) a declaration that the source referred to in (i) or (ii) is unknown to the inventor or applicant, if this is the case."[22]

– a complementary change with the introduction of a new item (vi) in Rule 4.17 of the PCT Regulations so as to afford applicants the possibility of satisfying any disclosure requirements under the national laws of designated States already at the time of filing an international patent application or later during the international phase, as follows:

["The request may, for the purposes of the national law applicable in one or more designated States, contain one or more of the following declarations, worded as prescribed by the Administrative Instructions:]

"(vi) a declaration as to the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in Rule 51bis.1(g)."[23]

– several other amendments to the PCT-Regulations, namely, a proposal to amend Rule 48 so as to ensure that a declaration is published together with the international application; a proposal to amend Rule 51*bis*.2 so as to limit the circumstances in which designated States are entitled to require documents or evidence from applicants in the national phase in relation to declarations contained in the international application; and a proposal to amend Rule 51*bis*.3 so as to require designated Offices to invite applicants to comply with the respective requirements of the national laws concerning declarations where those requirements have not already been fulfilled by the time of entry of the application into the national phase.

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[22] The Swiss proposal explains that Rule 51bis.1(g) would only apply if the national law of a Contracting Party of the PCT requires patent applicants submitting an international patent application to declare the source of genetic resources and/or knowledge, innovations and practices, in their patent applications. It is thus the national legislator who decides whether such a declaration is required or not. In case an application does not contain the required declaration, the national law may foresee that the application is not processed any further until the patent applicant has furnished the required declaration; the national law may also foresee that non-declaration will not affect the processing of patents.

[23] The Swiss proposal explains that this proposal would give patent applicants the possibility of satisfying the declaration requirement under national patent law in accordance with the proposed new Rule 51bis.1(g) at the time of filing an international patent application or later during the international phase. This would further simplify procedures related to the declaration of the source of genetic resources and/or knowledge, innovations and practices, with regard to international patent applications. The standard wording in the Administrative Instructions for such a declaration would have to be amended accordingly.

Regional measures

The Andean Community

45. Andean Community Decision 486 (Common Intellectual Property Regime), provides that applications for patents shall contain, inter alia, "a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries" and "if applicable, a copy of the document that certifies the license 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 was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations" (Article 26).

European Community

46. Recital 27 in the preamble of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions states that: "whereas 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; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

47. The European Community and its Member States have also submitted a specific proposal in relation to the current process, which is described as an 'attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications.' This proposal is summarized as follows:

(a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;

(b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible;

(c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;

(d) the invention must be directly based on the specific genetic resources;

(e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of "traditional knowledge" is necessary;

(f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;

(g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;

(h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

National proposals and measures

Costa Rica

48. The Biodiversity Law of Costa Rica (in an unofficial translation) provides in Article 78 that the State "shall grant the protection indicated in the previous article, among other ways, by means of patents, trade secrets, plant breeders' rights, sui generis community intellectual rights, copyrights and farmers' rights. These rights shall not apply to: … Inventions essentially derived from knowledge which is associated with traditional or cultural biological practices in the public domain…" In Article 80, it provides that "the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation."

Egypt

49. The Patent Act of Egypt (Article 13) provides, *inter alia*, that "[w]here the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner."

India

50. India's Biological Diversity Act 2002 provides that (article 6(1)) "[n]o person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application … provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned [and] provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof." It also provides (article 6(2))that the 'National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.'

51. The Patents (Amendment) Act of 2002 amended the Patents Act, 1970, to provide that, in certain defined circumstances (see s. 10(4)(d)(ii)), a patent application should be completed by fulfilling the condition that it 'disclose the source and geographical origin of the biological material in the specification, when used in the invention.' (s. 10(4)(d)(ii)(D))

Various mechanisms within existing patent law

52. The WIPO Technical Study outlined a large number of applicable mechanisms within existing patent law that are relevant to the current examination. Further details of these were provided in WIPO Member States' responses to questionnaire WIPO/GRTKF/IC/Q.3, which formed the basis of the Technical Study. For the sake of brevity, they are not repeated here, but can be briefly summarized as follows:

- requirements to disclose known TK when it is relevant prior art (i.e. relevant to the assessment of the invention's novelty and inventiveness);
- requirements to disclose a TK holder who may be considered the or an inventor;
- requirement to disclose source or origin of GBMR when access to the GBMR is required for to enable the carrying out of the invention;
- disclosure of GBMR per se (or microorganisms in particular) when this is relevant to disclosure of the invention (including deposit of actual microorganisms or other biological materials for the purposes of patent procedure, in line with the Budapest Treaty);
- the effect of obligations under access and benefit-sharing laws or agreements on the entitlement to apply for, be granted or to maintain ownership of a patent (for instance, the Bonn Guidelines indicate that one issue to be considered in concluding ABS material transfer agreements is 'whether intellectual property rights may be sought and if so under what conditions');
- obligations to disclose relevant TK or GBMR in a patent application when disclosure of this information is required under other legal obligations, arising under contracts or access regulation.

Document WIPO/GRTKF/IC/2/15 ("Patents Using Biological Sources Material and Mention of the Country of Origin in Patents Using Biological Source Material, submitted by the Delegation of Spain) contains a number of examples.

PART III: TECHNICAL AND LEGAL BACKGROUND

53. The CBD Ad Hoc Open-ended Working Group on Access and Benefit-sharing has noted that "there is a need for accurate technical intellectual property information and explanation concerning methods for requiring the disclosure within patent applications of, inter alia: (a) Genetic resources utilized in the development of the claimed inventions; (b) The country of origin of genetic resources utilized in the claimed inventions; (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions; (d) The source of associated traditional knowledge, innovations and practices; and (e) Evidence of prior informed consent,"[24] and accordingly recommended the development of the WIPO Technical Study. A recent UNU-IAS study on the issue commented that "even though there is a growing body of law and policy which establishes either mandatory or voluntary requirements to disclose the origin of genetic resources and traditional knowledge in patent applications, there still remains significant and wide spread uncertainty as to even the legality of such measures, to say nothing about their effectiveness."[25]

54. In the light of these comments, this section provides a technical-level discussion of some of the core concepts that arise in this examination, to provide background to the following specific surveys. This is not new material. It distils the contents of the Technical Study which was earlier provided to the CBD COP. It then cites a checklist that was submitted in 2004 to the WTO Council for TRIPS as a recent overview of issues that are currently under consideration and may therefore be considered relevant to the present examination.

55. Proposals for enhanced disclosure relating to GBMR or TK seek to bridge between two legal regimes and policy systems:

- Regulation of the access to, use of, and sharing of benefits from GBMR and TK; and
- Laws governing the grant of patent rights for eligible inventions.

56. Proposals for enhanced disclosure relating to GBMR and TK range over the interface between these two legal regimes in various ways, including clarifying or modifying existing patent law, extending the reach of patent law doctrines, creating new doctrines in patent law, and applying and harnessing patent processing as a means of indirectly enforcing regulations on access and benefit-sharing. The debate is often expressed in terms of 'disclosure requirements' relating to the claimed invention and the creation of new disclosure requirements as a condition of 'patentability'.

57. The range of patent law potentially involved extends beyond well beyond requirements to disclose information, and covers legal issues beyond the patentability of an invention as such. So as not to prejudge the scope of consideration of the issues, this draft examination goes beyond requirements to disclose information as such, and encompasses other related measures that have been identified in the debate as being relevant to ABS. Analyzing disclosure requirements can lead to such underlying questions as:

- who is the true inventor of a claimed invention, when the invention uses TK directly or substantially?
- what external circumstances affect the entitlement of the applicant to apply for and to be granted a patent, especially the circumstances that surround the

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[24] UNEP/CBD/COP/6/6, p. 35.

[25] UNU Study, note 6 above, 27-28

obtaining and use of inputs to the invention, and any broader obligations that arise?

- is the claimed invention truly new and inventive (non-obvious), having regard to already known TK and GBMR?
- has the applicant disclosed all known background knowledge (including TK) that is relevant to the claim that the invention is patentable?
- apart from the applicant, are there other interests that should be recognized: ownership interests (e.g. arising from benefit-sharing obligations), licensing or security interests, or interests arising from a TK holder's role in an invention?
- how can the patent system be used to monitor and sanction compliance with laws governing access to GBMR and compliance with the terms of laws or regulations governing ABS, mutually agreed terms, permits, licenses or other contractual obligations, especially when these obligations arise under foreign jurisdictions?

Disclosure under patent law

58. Disclosure is part of the core rationale of patent law. Unless an invention is fully disclosed, a patent on that invention is invalid. Patent law concerns more than whether a given invention is patentable or not, even though this determination is the prime task of a patent examiner. To receive and sustain a valid patent, applicants may be required to disclose the claimed invention itself, how to carry it out (including the best known mode), any known technology ('prior art') relevant to assessing whether the claimed invention is patentable, the identity of the true inventor, and the legal basis for entitlement to be granted a patent. Each of these may be relevant to disclosing relevant GBMR or TK, but their effect is likely to vary in different jurisdictions. The full operational context of the patent system ranges beyond the standard distinction between 'substantive' or 'formality' requirements, and beyond the technical patentability of an invention as such; given that the focus is on the broader context of the inventive process and the actions of the inventor, it may be relevant to consider the broader law of patent ownership, the applicant's entitlement to apply for and be granted a patent, and the recognition of security and other interests in a patent; commentators have also referred to broader principles of equitable behaviour.

Patentability of invention and entitlement to apply for and be granted a patent

59. 'Patentability' concerns characteristics of the invention as such. As observed above, other substantive legal requirements for receiving and maintaining a valid patent may be relevant to disclosure and compliance with access and benefit-sharing – in particular, the law that governs the entitlement to apply for and be granted a patent. In view of the range of submissions, proposals and existing measures in place, there may be no one single 'disclosure' scenario that captures all the existing concerns about GBMR and TK relevant to patented inventions, nor all the current proposals for enhanced forms of disclosure that feature in the current debate. One way of clarifying and ordering disclosure scenarios is to consider what relationship would need to exist between the claimed invention and certain GBMR/TK to trigger a specific requirement to disclose relevant information. For instance, the nature and reach of disclosure may be very different depending on whether the GBMR/TK was incidental or fundamental to the development of the invention; whether the GBMR/TK contributed to one earlier step to a chain of innovations that over time culminated in the invention, or was a direct input to the claimed inventive step; whether particular qualities of a GBMR were essential to the invention, or the GBMR was in effect only a vehicle for a separate innovative concept; or whether a GBMR was used in a particular embodiment or one example in the description of the invention, but was not indispensable to arriving at (or replicating) the invention as claimed.

Use of existing patent law and disclosure of GBMR/TK

60. Established patent law requirements have been used to require disclosure of GBMR/TK:

- Where access to the GBMR is required to enable a person skilled in the art to carry out the invention (or to carry out the best known mode where applicable), and the GBMR is not readily available to that person (for instance, as a plant variety well known to researchers in the field); the patent applicant may be obliged to disclose its source so that third parties can carry out the invention.
- Where the GBMR is already readily available to third parties already skilled in the relevant art, then the disclosure requirements may still require that the GBMR be fully described.
- Where the TK is an inventive contribution to the invention as claimed, then the applicant may be required to disclose the provider of the TK as a joint or sole inventor.
- Where the TK (known to the applicant) is so close to the claimed invention that it has bearing on the assessment of the validity of the application (e.g. in assessing whether the invention is truly novel and nonobvious), or so that it is necessary for the understanding of the inventive concept, then some patent laws will already require its disclosure.

61. Such conventional disclosure requirements may not apply if the TK is more remote from the claimed inventive concept (for example, if the TK is in the background but not relevant in assessing whether the invention is new, inventive or useful), or if a GBMR does not in itself give rise to an inventive concept – such as when an inventive genetic modification is introduced into a specific variety of wheat (in effect, a relevant GBMR), but the claimed invention extends to any variety of wheat). In some of these cases, the enquiry seems to be more about the legal relationship between the inventor and the access to GBMR or TK, rather than about the link between the invention as such and GBMR or TK. The concern may be that prior informed consent was not obtained when GBMR or TK were accessed, yet this access led in time to the claimed invention. For example, prior informed consent may include a contractual obligation to share ownership of any IP rights resulting from the access (similarly to agreements concerning other non-inventive contributions to a research process, such as financial backing or provision of other resources); in this case, the core legal questions may concern ownership of the patent and compliance with contractual obligations, rather than validity of the invention. In other cases, prior informed consent has entailed contractual agreement for the source of GBMR to be acknowledged in the patent. The diversity of prior informed consent arrangements may also include licensing and security interests, which may be recorded in various ways under patent laws.

62. Entitlement to apply for a patent, inventorship, rights to ownership, obligations arising from non-inventive contributions, enforcement of contractual obligations, and the formal recognition of ownership, licensing and security interests, are all legally significant issues in acquiring, holding and enforcing patent rights – and thus may play a role in access and benefit-sharing. They are typically considered distinctly from the patentability of the invention as such (a narrower concept, as contrasted with the validity of a patent on that invention, and the entitlement to own and exercise the patent right).

Disclosure as such or a bar on entitlement to a patent?

63. There is a fundamental issue of whether a legal requirement relating to GBMR or TK would concern disclosure as such, or whether it would actually function as an effective

prohibition on securing a patent if certain preconditions are not met. For instance, if there is a requirement to file evidence of prior informed consent of GBMR/TK holders, this may simply be to provide information about the circumstances in which the GBMR/TK was obtained in the interests of transparency, or it may be a means of implementing an obligation to obtain prior informed consent before a patent application may be filed or a patent is validly granted. Consideration of disclosure requirements has also focused on whether disclosure is considered a 'substantive' requirement in patent law or as a 'formality,' and what sanctions should apply if the disclosure requirement is not met.

64. The Technical Study reviewed these issues with a view to clarifying the context and impact of disclosure requirements. The focus has been on whether failure to meet disclosure requirements would or should lead to refusal or invalidation of a patent, but other experiences indicate that failure to make true declarations can have serious implications, whether or not the patent is invalidated on substantive patentability grounds. For example, different jurisdictions provide for severe consequences in the event of failure to declare the true inventor (or to include a co-inventor), failure to disclose known prior art, or failure to establish an entitlement derived from the inventor. Failure to comply with some formality requirements, such as payment of maintenance fees or good faith errors in naming inventors, can be remedied once the failure is identified.

65. The Technical Study also noted that questions of how to deal appropriately and fairly with unintentional errors and omissions need to be considered in any disclosure requirement. The study noted that disclosure scenarios many raise questions of what circumstances create an obligation, and what steps are considered sufficient to discharge the obligation. The complex pattern of inputs into a research program over time that may in turn yield a series of interrelated inventions may create a degree of uncertainty as to what is required for disclosure in any particular patent application, and on what basis. These questions are illustrated by two scenarios:

- where there are diffuse or diverse inputs leading to the invention (for instance, when an invention draws on an extensive plant breeding program based on successive generations of breeding lines from numerous sources): which inputs, and how many, should be identified and reported; and,
- an extended chain of provenance (such as when an invention may draw on a novel use of an active compound that had been separately, earlier isolated from a biological sample): how far back along the chain of provenance from the precise inventive step should the disclosure requirement reach?

66. The study set out a structured approach to reviewing the range of possible disclosure requirements, based on the following questions:

(i) What would be the relationship between the claimed invention and the GBMR/TK; or what would be a sufficient link between the two to trigger a disclosure requirement?
(ii) What legal principle would form the basis of the requirement?
(iii) What would be the nature of the obligation placed on the applicant?
(iv) What would be the consequence of failure to comply with the requirement?
(v) How would the requirement be implemented, verified or monitored?

(i) Trigger for the disclosure requirement

67. Three broad functions have been considered for disclosure methods relating to GBMR/TK:

(a) to disclose any GBMR/TK actually used in the course of developing the invention (a descriptive, enabling or transparency function, pertaining to the GBMR/TK itself and its relationship with the invention); in the case of biological resources, this may extend to actual deposit of samples as part of the essential patent disclosure obligation;

(b) to disclose the actual source or origin of the GBMR/TK (a disclosure of provenance function, relating to where the GBMR/TK was obtained, geographically and in what jurisdiction) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed, so as to ensure the invention can be duplicated or reproduced, or so they can be traced to a specific community or custodian); and,

(c) to provide an undertaking or evidence of prior informed consent and/or of equitable benefit-sharing (a compliance function, relating to the legitimacy of the acts of access to GBMR/TK source material and demonstration of the legitimacy of legal provenance) – this may entail showing that GBMR/TK used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; that lawful arrangements have been established for equitable benefit-sharing; or that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.

68. Possible linkages that may trigger disclosure requirements include:

Drawing on existing patent law principles:

- access to GBMR is necessary to carry out or replicate the invention as claimed;
- access to GBMR is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent;
- the TK is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious;
- TK was provided by a TK holder and is directly used in developing the invention, to the extent that the TK holder is a potential co-inventor.

Further forms of linkage:

- the GBMR or TK were used in the course of research that led to the invention, and were essential to deriving the invention;
- the GBMR or TK were used in the course of research leading to the invention, but were only incidental to the attainment of the invention;
- the research leading to the invention, the attainment of the invention itself, or the act of filing the patent application, falls within the scope of an obligation incurred under an access agreement or access legislation.

(ii) The legal principle forming the basis of the requirement

69. A disclosure requirement may be derived from existing patent law, or may be based in other legal systems. In the first category, the possibilities include:

(a) The obligation to disclose the invention sufficiently for it to be carried out by a person skilled in the art, and where appropriate to disclose the best mode for carrying out the invention known to the inventor;

(b) The requirement that patent claims be supported sufficiently by the technical disclosure in the patent;

(c) The requirement to provide information concerning known prior art relevant to the assessment of the patent claims;

(d) The requirement to establish entitlement to apply for or be granted a patent;

(e) Requirements concerning the registration of licenses and security interests; and

(f) A requirement derived from the interaction between patent law and principles of *ordre public* and morality.

70. Non-patent law principles underpinning a disclosure obligation could be drawn from laws concerning access to GBMR/TK, and related benefit-sharing obligations, including:

(a) international standards, notably the CBD and the FAO ITPGR;

(b) applicable national laws in the country of origin, the country of research/invention, or the country where the patent application is lodged, especially concerning access to and use of GBMR and related TK and laws giving domestic legal effect to the CBD; and

(c) contract law may provide the legal basis, in its own right or when contracts or licenses are used as a legal mechanism for implementing access and benefit-sharing regulations.

(iii) The nature of the obligation placed on the applicant

71. The obligation placed on the applicant can range from an exhortation or encouragement to a potential ground of refusal or revocation of a patent. Disclosure requirements concerning GBMR/TK have formal or procedural aspects (such as format and documentation requirements, and deadlines for compliance), as well as meeting substantive tests (for instance, in disclosing enough about genetic resources used in the invention to ensure a skilled person can replicate the invention). Therefore a disclosure requirement may be analyzed as having both aspects, and both may be significant.

72. While the impact of a disclosure obligation may best be determined with reference to the consequences of failure to comply, it is equally important to clarify what it means to comply: for instance, should the applicant go beyond information that is readily available, and should the applicant actively trace the origins of GBMR/TK and investigate the circumstances of its acquisition. The intent of the applicant may also be considered: was a failure to provide relevant information in good faith, or fraudulent in intent? And where should the burden of proof lie: is the applicant is obliged positively to prove that access to GBMR/TK met a certain standard, or can legitimacy of access be assumed in absence of evidence to the contrary?

(iv) The consequences of failure to comply

73. Since disclosure requirements generally have both formal and substantive aspects, the consequences of failure to comply with either aspect may differ. Failure to comply in formal terms may not necessarily have serious consequences, provided it is not fraudulent and is remedied in a timely manner. Failure to comply in substantive terms (such as requirement to disclose sufficient material to sustain patent claims) may have major consequences for the fate of a patent application or granted patent. The consequences of failure to comply with a particular disclosure obligation may, in principle, flow from the reason for the imposition of the requirement. A failure to disclose genetic resources necessary to carry out the invention may lead to the refusal, narrowing or invalidation of claims that would depend for their legitimacy on that disclosure. A failure to provide adequate information to substantiate entitlement to apply for or be granted a patent may lead to the loss of the patent.

74. There is an uncertain area where disclosure requirements are not derived from substantive requirements relating to patentability of the invention or the entitlement of the applicant to receive a patent. Some disclosure requirements may be linked to distinct legal mechanisms, including in foreign jurisdictions, and may be aimed at monitoring or enforcement of regulations or specific contracts. One way of characterizing the relationship may be to draw a link between inequitable behavior in one context or jurisdiction, and entitlement to exercise patent rights in another, where the patented invention is in some way a consequence of the inequitable behavior. Another way of defining the link would be to view the denial or invalidation of a patent right in one jurisdiction as a form of sanction for non-compliance with other laws. Some uncertainty surrounds this kind of mechanism in international policy debate, and further study may be necessary of approaches to enforcing non-patent legal requirements through the patent system.

General issues

75. The essence of the patent system is transparency and disclosure (the concept of laying open for public inspection is the source of the English word ‘patent’). Patent law has developed a set of exacting standards for information disclosure which have deep policy and legal foundations within the patent system. The grant of a patent, and the effective exercise of patent rights, are founded on the principle of sufficient disclosure. The very operation of the patent system involves making publicly available a great detail of legal, administrative and technological information, in a harmonized and accessible format. Some patent applications do, as a matter of existing practice, disclose significant information concerning GBMR and TK. Disclosures even in existing patent applications are currently used by concerned parties to monitor the use (and potential misappropriation) of GBMR or TK. This monitoring function of the international patent system has been enhanced by the increasing searchability and availability on-line of patent information.

76. The Technical Study suggests an underlying, key issue is how to characterize the necessary relationship between GBMR and TK on the one hand, and the claimed invention on the other. Discussion of possible disclosure requirements has already covered many ways of expressing this linkage. Better characterizing this linkage should also clarify the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions, and how far these obligations ‘reach through’ subsequent inventive activities and ensuing patent applications. General patent law principles provide more specific ways of expressing this relationship, even if the objective of the requirement is not conceived in traditional patent terms. Patent law may also be drawn on to clarify or implement more generally stated disclosure requirements: for example, a general requirement to disclose genetic resources used in the invention may be difficult to define in practice, and may implemented through a more precise test that requires disclosure only when access to the resources would be necessary to reproduce the invention.

77. Another key issue is the legal basis of the disclosure requirement in question, and its relationship with the processing of patent applications, the grant of patents and the exercise of patent rights. This raises also the legal and practical interaction of the disclosure requirement with other areas of law beyond the patent system, including the law of other jurisdictions.

78. Some of the legal and policy questions identified in the Technical Study were:

(a) the potential role of the patent system in one country in monitoring and giving effect to contracts, licenses, and regulations in other areas of law and in other jurisdictions, and the resolution of private international law or ‘choice of law’ issues that arise in

interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of GBMR/TK;

(b) the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with non-patent laws and regulations, or whether it incorporates compliance mechanisms;

(c) the ways in which patent law and procedure can take account of the circumstances and context of inventive activity that are unrelated to the assessment of the invention itself and the eligibility of the applicant to be granted a patent;

(d) the situations in which national authorities can impose additional administrative, procedural or substantive legal requirements on patent applicants, within existing international legal standards applying to patent procedures, and the role of non-IP international law and legal principles in this regard;

(e) the legal and operational distinction (to the extent one can be drawn) between patent formalities or procedural requirements, and substantive criteria for patentability, and ways of characterizing the legal implications of such distinctions;

(f) clarification of the implications of issues such as the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, differing approaches to setting and enforcing conditions for access and benefit sharing in the context of patent disclosure requirements, and coherence between mechanisms for recording or certifying conditions of access and the patent system.

79. A further area for clarification is what actions of the inventor or patent applicant are to be monitored or regulated through a disclosure requirement – the actual use of the GBMR/TK (including its use in inventive activities), or the act of filing a patent application as such. The policy concern may relate to the legitimacy of the research or commercial behavior that makes use of the GBMR/TK (including prior informed consent of TK or GBMR holders). In this case, the patent application has a secondary role in providing evidence of such behavior. The concern may relate to the very filing a patent application or holding a patent (for instance, where prior informed consent is given to research but not seeking IP, or prior informed consent includes agreement on assignment, coownership or similar disposition of ensuing IP).

80. The Technical Study notes that the core issues raised are the subjects of ongoing international policy debate. They may involve specific policy choices, such as the distinction between formal requirements or 'form or contents' and substantive patent law and how to certify the basis of prior informed consent or legitimacy of access to GBMR/TK. It observed that some key legal concepts and approaches raised in the debate are so far untested, are the subject of policy development, or are in the early stages of implementation and practical experience, and thus cannot be definitively analyzed. Accordingly, the study was offered as a resource to facilitate the continuing debate, not to prescribe any particular approach.

TRIPS Council Checklist of Issues

81. The Doha Ministerial declaration[26] instructed 'the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1.' Part II of this document (above) contains a summary of this process. With reference to this decision, in 2004, a number of WTO Members submitted to the WTO TRIPS

[26] WT/MIN(01)/DEC/1, adopted on 14 November 2001

Council a checklist of issues relevant to this work.[27] The purpose of the checklist was 'to assist and expedite the process and not to limit the ambit of the discussions'. The checklist was 'drawn up on the basis of the issues raised and points made by various delegations in their communications and statements to the Council for TRIPS since 1999 and, in particular, in the post-Doha period. It is provided here as it may be relevant to the issues under consideration.

Disclosure of source and country of origin of the biological resource and of the traditional knowledge used in the invention

- How would an obligation for disclosure of country and source of origin of biological resource and associated traditional knowledge used in an invention help in better examination of patents and in preventing cases of bad patents?

- What is the meaning of disclosure of source and country of origin of biological resource and of the traditional knowledge used in the invention?

- What would be the legal effect of wrongful disclosure or non-disclosure?

- On whom should the burden of proof lie?

- In what manner should the proposed obligation of disclosure of source and country of origin and associated traditional knowledge be introduced in the TRIPS Agreement?

Disclosure of evidence of prior informed consent under the relevant national regime

- How would furnishing the above evidence facilitate achieving the objectives of the CBD of ensuring prior informed consent and harmonious relationship between the CBD and the TRIPS Agreement? Could contractual arrangements for ensuring prior informed consent and benefit-sharing suffice to achieve the objectives of the CBD in this regard?

- How should the evidence of prior informed consent through approval of authorities under the relevant national regime be provided for?

- What should be the nature of obligation on the patent applicant that should satisfy the requirement of prior informed consent?

- What should be the obligation if there is no national regime in the country of origin?

- What should be the legal effect of not providing evidence of prior informed consent through approval of authorities under the relevant national regime?

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[27] The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD): Checklist of Issues, IP/C/W/420 and IP/C/W/420/Add.1 (March 2004), submitted by Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela.

Disclosure of evidence of benefit sharing under the relevant national regime

– What should be the meaning of evidence of benefit sharing under the relevant national regime?

– When is this evidence to be introduced by the patent applicant?

– What should be the obligation if there is no relevant national regime in the country of origin?

– What should be the legal effect of not providing evidence of fair and equitable benefit sharing under the relevant national regime?

PART IV: SPECIFIC ISSUES IN THE CBD COP INVITATION

82. This Part sets out material on the five specific elements of the CBD invitation, briefly (a) model provisions; (b) trigger mechanisms; (c) incentives; (d) treaty implications; and (e) implications of certification. The content of each section draws mainly on the submissions by Member States, the material set out above, the Technical Study and several other studies cited above, including the UNEP-WIPO study.

A. OPTIONS FOR MODEL PROVISIONS

83. The first specific element of the CBD COP invitation concerns 'options for model provisions on proposed disclosure requirements.' Certain Member State submissions (set out below) express caution about the development of model provisions, citing various reasons. Given that other Member States made substantive submissions on this element of the invitation, one possible way of taking this concern into account could be to observe firstly that the examination of options for model provisions in the course of the current exercise should not prejudice the position of those Member States who wish to establish internationally binding rules in WIPO or in other fora; and secondly that the examination of options for modelprovisions may be seen as a supplementary mechanism for advancing understanding and international consensus on the substance of disclosure requirements rather than necessarily an end in itself.

Form or status of model provisions

84. The form or status of model provisions would depend on their intended function. 'Model provisions' would normally suggest standard text to be drawn on to guide either national legislation or agreements, but without any legally binding quality (even though there may be other incentives to comply). Model provisions may be intended to give practical guidance (including for coordinating technical assistance to countries who elect to introduce disclosure requirements and other measures at the national level). Non-binding recommendations may take the form of model provisions (an example would be more detailed elaboration of the recommendations regarding disclosure already present in the Bonn Guidelines). Model provisions may serve as a menu to illustrate the range of options available for national legislation. Model provisions may also serve to illustrate the range of options available to facilitate international debate, policy coordination or textual negotiations. Model provisions may be intended to evolve into draft provisions that would provide the basis for coordination and negotiation on a future binding legal instrument or provisions within a revised international legal instrument. There may of course be a range of other options concerning the form and status of model provisions, depending on their purpose and context.

85. Based on the submissions already made, a likely concern is that any formulation of model provisions should not prejudice national positions on the development of legally binding international law, including prejudice on substantive policy or legal points, but also potential prejudice to the procedural opportunities and the allocation of resources.

Substance of model provisions

86. Concerning the substance of potential model provisions on disclosure requirements, there appear to be two general options: (i) elaborating or extending existing patent law mechanisms and adapting them specifically to TK and GBMR as appropriate, and (ii) entirely new or specific disclosure and related mechanisms. Based on existing studies and surveys, the first category (adapting or extending existing mechanisms) could include provisions on recognition of TK as prior art; requirements to disclose any known TK relevant to the

invention; provisions on entitlement to apply, ownership and other interests as a consequence of access and benefit-sharing obligations incurred by the applicant; provisions on disclosure of inventors ensuring the recognition of inventive contributions by TK holders; provisions for deposit and notification of samples of GBMR relevant to the invention; other provisions ensuring the identification and location of GBMR relevant to the invention; and provisions concerning requirements to supply further evidence to substantiate inventorship or entitlement to apply.

87. Measures or proposals in the second category (new or specific measures) can be variously characterized as follows:[28]

(a) *Origin or source:* disclosure of the source and/or country of origin of GBMR and/or TK or associated traditional knowledge, where the GBMR or TK is connected to the claimed invention in a defined way;
(b) *Prior informed consent:* declaration, submission of specific documentation, or furnishing of other evidence of compliance with prior informed consent under the relevant national regime (relating to GBMR and possibly associated TK); and
(c) *Equitable benefit-sharing:* declaration, submission of specific documentation, or furnishing of other evidence of compliance with fair and equitable benefit sharing under the relevant national regime (relating to GBMR and possibly associated TK).

In addition, at least one national law requires that certain inputs to a claimed invention have been obtained in a lawful manner. Such a requirement could, for example, have relevance to prior informed consent or compliance with ABS regulations.

88. Ghana characterizes the general options as "(i) mandatory requirements for disclosure of origin and legal access (this takes into account prior informed consent and mutually agreed terms); (ii) disclosure requirements without legal consequences in cases of non-compliance; and (iii) stand alone disclosure requirements linked to public law – access legislation etc." Ghana notes that "most developing countries prefer the first option. What has not been clarified is whether to make the disclosure mandatory as a formality in the patent procedure or as substantive patentability criterion."

Some possible functions of disclosure requirements

89. The submission of Brazil summarized the functions of an enhanced disclosure and ABS compliance requirement as follows:

> It is envisaged that the establishment of a mandatory, universal disclosure of origin requirement will contribute to the attainment of the following objectives:
>
> 1. Improve the substantive examination of patent applications, by (i) helping to ensure that all relevant prior art information is available to the patent examiner; (ii) helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under, for example, Article 27, paragraphs 2 and 3, of the TRIPS Agreement, as well as related provisions of other international agreements; (iii) helping to systematize available information on biological resources and associated traditional knowledge that will continuously build the prior art information available to patent examiners and the general public.

[28] E.g. Brazil; TRIPS Council proposal noted above.

2. It is foreseen, furthermore, that the disclosure requirement will also be relevant to the determination of inventorship or entitlement to the claimed invention, and would be useful in cases relating to challenges to patent grants, including disputes on inventorship or entitlement, as well as infringement cases.

3. In some cases, disclosure of origin may also facilitate or permit the actual execution of the invention, such as where a biological material is endemic to a specific location;

4. Disclosure of origin would, moreover, constitute a necessary and effective incentive measure for patent applicants to comply with the access and benefit sharing legislation of countries of origin of the biological resources, in a manner that would contribute to the realization of the principles and objectives enshrined in provisions of international IP treaties, such as Articles 7 and 8 of the TRIPS Agreement. More generally, it would constitute an important realization of the principle of *equity*.

5. As a transparency measure, disclosure of origin would help keep track of the commercial exploitation of biological materials for the purposes of benefit sharing.

Other guidance on options for disclosure requirements

90. On element (a) of the invitation, the Kyrgyz Republic comments that the process 'does not at present allow time to give a uniform answer to the first question. It is necessary to analyze this matter deeper. However … matters related to access to genetic resources have no direct legal links to the protection of GR and associated TK. The CBD provides for the right of each member state to make independent decisions related to genetic resources on the national level. Disclosure requirements or designation of the biological material used in the process of the subject matter creation on which protection is claimed are purely technical in nature and do not ryb contrary to the CBD provisions and objectives. We deem that disclosure requirements as to the biological materials, could allow developing national-level provisions to regulate matters related to the access to genetic resources and equitable sharing arising from the use of genetic resources.'

91. Concerning the possible options for provisions, the submission of Brazil proposes that 'disclosure of origin, prior informed consent and fair and equitable benefit sharing (henceforward, "disclosure of origin") should be a mandatory requirement, to be imposed on patent applicants in all jurisdictions, preferably through an amendment to relevant international intellectual property treaties, such as the WTO TRIPS Agreement.' It stipulates that a 'patent application will be deemed to comply with a disclosure of origin requirement if it contains a declaration, in a prescribed form, indicating the source and country of origin of the biological resources and/or associated traditional knowledge used in an invention, as well as a declaration that prior informed consent and fair and equitable benefit sharing have been complied with under the relevant national regime. These declarations should be accompanied, where relevant, by the actual evidence of prior informed consent and benefit sharing, for example, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin.'

92. The Australian submission suggests that any disclosure requirements should:

- be easy to implement;
- not impose undue burdens and costs on IP right owners and administrators;
- encourage research and commercialisation;

- not affect the integrity of IP rights, especially since lack of disclosure should not be a bar to a patent, although there may be other legal ramifications outside the IP system (for example, transfer of ownership) for failing to disclose traditional knowledge and/or genetic resources;
- have a minimum impact on current IP systems;
- encourage creators to disclose the relevant inputs into their inventive process, while recognising there may be circumstances in which disclosure is not possible or appropriate; and
- provide useful information and be easily accessible to access providers.

93. Turkey observes that disclosure mechanisms should provide for compliance with access and benefit sharing regulations, penalties for provisions of false information, refusal of grant on formality grounds, invalidation of patent after grant, narrowing or invalidation of patent claims that would have been supported by information not disclosed and prior informed consent.

94. Belize submitted that the model provisions 'must include clauses relating to the fair and equitable sharing of benefits including profit sharing, royalty payments, access to and transfer of technologies, the granting of free licenses to the community, and the development of local human resources. Also, the model provisions must outline enforcement measures that are expeditious and preventive, and constitute a deterrent to further infringements. Such enforcement measures must cover civil judicial procedures, provisional measures, border measures, and criminal procedures. However, such enforcement measures must not create barriers to free trade and must meet the basic principles of due process.'

95. Belize also proposed that 'related provisions must be included in a wide array of intellectual property legislation such as patents and plant variety legislation. Patent applicants must be required to disclose the source and geographical origin of the biological material in their specifications and to demonstrate that they have secured prior informed consent to use the material. The traditional knowledge of indigenous communities should qualify as prior art that is capable of anticipating an invention that is claimed in a specification. The traditional knowledge holder must also be treated as a person 'skilled in the art' in order to determine the obviousness of an invention. Such model patent law provisions must also cover the area of opposition and revocation. Belize proposes that an invention should be refused or revoked if the invention is anticipated by traditional knowledge or if the complete specification does not disclose or wrongly mentions the source of the biological material used for the invention. Similar provisions must be included in the model provisions for plant varieties legislation.'

96. The proposal of the EC and its Member States suggested that "in order to provide patent applicants with a clear idea of what needs to be disclosed, the language used here should be the same as in the CBD definitions of country of origin, genetic resources and genetic material. First, the material that would be the subject of the requirement: Article 15 (7) of the CBD states that access and benefit-sharing objectives must be met with regard to "genetic resources." It is therefore coherent to use the universally accepted CBD language. "Genetic resources" is defined in Article 2 CBD as "genetic material of actual or potential value". The same provision states that "genetic material" includes "any material, of plant, animal, microbial or other origin containing functional units of heredity". In this context, human genetic resources are excluded, and this exclusion should be carried over to the proposed system. Second, the origin of the genetic resource: a disclosure of origin requirement would assist countries providing access to genetic resources to monitor and keep track of compliance with national access and benefit-sharing rules. On this basis, the applicant should be required to declare the country of origin of genetic resources, if he is aware of it. No additional

research on his part would be required. It is the disclosure of the country of origin that paves the way for monitoring the respect of the rules on access and benefit-sharing, where such rules are in place. Third, the connection between the material and the patented invention: the applicant must have used the genetic resources in the claimed invention. A notion should be applied that makes it possible for the applicant to disclose the material used in the invention in an adequate way, without having the obligation to make further research on the origin of the resource, taking into account the interests of the applicant, the patent office and other stake holders. A good balance can be found by requiring that the invention must be "directly based on" the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource. The inventor must also have had physical access to the genetic 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."

97. Colombia considers that 'the grant of patents which relate to inventions developed from biological and genetic resources, and their products, derived from a country of origin which is a party to the CBD, should be subject to access being granted thereto in accordance with the requirements of Article 15 of the CBD, and the national and international standards specific to the subject. The disclosure should state clearly the place, quantity and date of collection of the material.' Colombia endorsed the Swiss proposal concerning the PCT (set out above in Part II), noting the following principles:

- transparency measures must be effective and efficient;
- transparency measures should guarantee legal security, be practical, and avoid major charges and costs for patent applicants, as well as for patent authorities;
- the measures should allow States to introduce solutions to take effect at the national level, and which relate to national interests and needs;
- transparency measures should be consistent with the relevant international agreements.

98. Colombia added that the requirement of disclosure should in all cases be compulsory, so that 'a declaration to the effect that the origin of the genetic resource is unknown would not suffice for the purposes of fully satisfying the disclosure requirement.' In addition, the proposed text should not refer to the "national law applied by the designated Office", but to any Member State, thereby confirming the binding nature of the requirement of disclosure.

Concerns about or limits to the development of model provisions

99. As noted above, several submissions raise concerns about the role of model provisions. The African Group cautions against model provisions on the basis that 'only internationally legally binding measures could effectively contribute to combating the misappropriation of genetic resources and the traditional knowledge associated with these resources. The Group therefore considers that 'model provisions would not constitute an effective measure for combating the misappropriation of genetic resources.' The 'effective solution to this global problem should be a mandatory universal disclosure requirement implemented in all countries.' The Group accordingly observed that it would not be appropriate for WIPO to examine (a) in the CBD invitation, and that the response to the CBD invitation should take this opinion into account.

100. Switzerland proposes several amendments to the PCT Regulations 'in order to explicitly enable the Contracting Parties of this treaty to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications' and observes that the

'wording of the proposed new provisions … in particular the proposed new subpara. (g) in Rule 51*bis*.1 and subpara. (vi) in Rule 4.17, is sufficiently specific and clear to be directly implemented at the national level. Accordingly, Switzerland sees no need for model provisions on proposed disclosure requirements.'

101. The United States advised that it supported the goals of ensuring appropriate access and prior informed consent to genetic resources and equitable benefit sharing agreements and principles, but that it strongly believed that new disclosure requirements in the patent system were not an effective means of achieving these goals: "new disclosure requirements in the patent system would create uncertainties in the patent application process and in any patent rights granted without achieving the desired goals stated above. New disclosure requirements would create additional obstacles for patent applicants, increase uncertainties in patent examination, as examiners could not verify the provided information, increase administrative costs for patent offices and generate more post-grant litigation on patent rights. These increased burdens and uncertainties are not warranted in the patent system, especially since the new disclosure requirements would not achieve the desired outcome of appropriate prior informed consent and benefit sharing and, indeed, could lead to significant negative consequences." The United States observed that 'there can be no model provisions for new disclosure requirements, as new disclosure requirements would only frustrate the objectives that they are intended to achieve.'

Specific elements of model provisions

102. The Technical Study identified a range of disclosure scenarios, which may be correlated with the possible substantial content of model provisions; the content of each of these can be found in existing Member State submissions, proposals or laws:

- specific mechanisms created to address GBMR and TK, in particular relating to disclosure of origin or source, such as the proposals and existing measures set out in Part II above: these may relate to declaration of origin or source, evidence of prior informed consent, and/or evidence of fair and equitable benefit sharing);
- identifying TK and/or GBMR explicitly as prior art vitiating the novelty of a claimed invention;
- provisions requiring the disclosure of known TK and/or GBMR as prior art relevant to the assessment of the patentability of a claimed invention;
- provisions requiring a TK holder as the inventor or as one inventor when TK is a specific component of the claimed invention;
- when the origin of GBMR is required for to enable the carrying out of the invention;
- when the disclosure of actual GBMR, or even the physical deposit of a sample, is required for enablement;
- when obligations under access and benefit-sharing laws or agreements affect the entitlement to apply for a patent; and
- when disclosure of other information is required under other legal obligations, arising under contracts or access regulation.

'Lawful' as against 'rightful' obtaining of resources

103. A recently published independent study commissioned by UNEP and WIPO draws a distinction between lawful and rightful obtaining of resources used in inventions, raising a potential supplementary option for model provisions for ethical guidance in the absence of applicable legislation:

Every patent office should insist that a patent applicant declares that the knowledge and resources used in the relevant invention have been obtained "lawfully" and "rightfully". This last point may require legislation in both developed and developing countries to ensure proper disclosure by a corporation or individual seeking patent protection. "Lawful" acquisition will, of course, depend upon the laws and regulations in place in the source country, and may, for instance, require the need to consider whether prior informed consent of relevant local communities and creative individuals has been obtained. "Rightful" acquisition may involve consideration of ethical issues. For instance, even if a local community had not originally required monetary compensation for sharing biological material or associated knowledge, might a potential applicant for a patent be bound by ethical conduct to set up a trust fund or other forms of monetary reciprocity for an affected local community? If a country does not have any applicable legislation in place … then material and knowledge may be acquired lawfully but not rightfully.[29]

Summary of options for model provisions

Concerning the form or status of model provisions, specific options include:

(a) model provisions for practical guidance (including for coordinating technical assistance to countries who elect to introduce disclosure requirements and other measures at the national level),

(b) non-binding recommendations in the form of model provisions (such as more detailed elaboration of the recommendations already present in the Bonn Guidelines),

(c) model provisions that serve to illustrate the range of options available for national legislation,

(d) model provisions that serve to illustrate the range of options available for international debate, policy coordination or textual negotiations, or

(e) draft provisions intended to serve as the basis for coordination and negotiation on a future binding legal instrument or provisions within a revised international legal instrument.

There may be other options concerning forum and status depending on the purpose of the model provisions. A key concern is that the development or promulgation of any model provisions should not prejudice the position or interests of Member States in terms of

Options on the substance of model provisions interact with each of the other elements of the examination which are discussed below (IV.B to IV.E). These options include enhanced use of existing patent law and principles, and new or *sui generis* mechanisms. A number of Member States have stressed that new mechanisms specific for TK and GBMR are required, but other mechanisms are mentioned as well for the sake of completeness.

One way of organizing options would be to use the following categories:

(i) Nature of mechanism

(ii) Subject matter of disclosure

(iii) Required linkage with claimed or patented invention (or substantive trigger)

(iv) Procedural trigger for disclosure requirement

(v) Legal principle forming the basis of the requirement

[29] UNEP-WIPO study, footnote 5 above, 57-58

(vi) Nature of the obligation on the applicant

(vii) Consequences of failure to comply and incentives to comply

(viii) Implementing, verifying or monitoring the requirement

The following table has been developed to illustrate some of these options. It is stressed that this means of summarizing information is not intended to interpret, limit or promote any particular mechanism; nor does it reflect on the consistency or otherwise of any approach with existing treaty standards.

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ILLUSTRATIVE TABLE OF OPTIONS FOR DISCLOSURE AND RELATED MECHANISMS[*]

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Acknowledgement of inventorship	Traditional knowledge	Part or entirety of the claimed inventive concept	Entitlement to apply derived from actual inventor(s); Paris Convention obligation to identify inventor	If TK holder contributes to claimed inventive concept, requirement to disclose identity. Possible requirement to identify TK holder as co-applicant/co-owner, or as sole applicant/owner.	Application may be refused	Office may request further information in the event prima facie doubt exists re identity of inventor Administrative or judicial proceedings for opposition, revocation or full/partial transfer of patent to TK holder
Declaration of TK as relevant prior art	Traditional knowledge that meets legal criteria for prior art [and that is known to applicant]	Relevant to the patentability of the claimed invention (e.g. novelty and inventiveness/ non-obviousness	Patentability of invention includes novelty and inventive step (or non-obviousness). Obligation to inform office of known relevant information.	Applicant is obliged to disclose all known prior art relevant to patentability of claimed invention, including traditional knowledge.	'Fraud on the office' or similar offence; sanctions for inequitable behaviour; Failure to disclose known TK may render patent unenforceable.	Failure to disclose may become apparent during examination or enforcement of patent, or in opposition or revocation proceedings
Definition of prior art	Traditional knowledge	TK explicitly designated as prior art that vitiates novelty and/or non-obviousness	Clarification of existing law of patentable inventions	Invention must be novel and non-obvious	Claims may be narrowed, refused or revoked.	Relevant to examination, opposition or revocation proceedings.
Definition of patentable invention	Traditional knowledge and/or GBMR	Invention cannot consist of existing TK or certain GBMR	Law defining scope of patentable subject matter	Claimed invention must fall within permitted subject matter	Claims may be narrowed, refused or revoked.	Relevant to examination, opposition or revocation proceedings.

[*] This table is to illustrate mechanisms that have been discussed or proposed. It is not intended to suggest, interpret or promote any particular mechanism, nor to limit choices available. It does not imply that any specific choice is consistent or otherwise with treaty obligations.
Sources: Member State submissions and responses to WIPO/GRTKF/IC/Q.3, Technical Study, and measures in Part II above.

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Specific disclosure of TK or GBMR, or related ABS-compliance measure	(i) TK (ii) TK associated with GR (iii) genetic resources (iv) biological resources and/or (v) biological material Where (i) source/origin of TK/GR is already known to applicant; or (ii) applicant can determine its source/origin through reasonable effort; or (iii) TK/GR is not subject to any such qualification] TK/GR may be in public domain [or may be hitherto undisclosed]	Invention (i) directly based on TK/GBMR (ii) [essentially] derived from TK or GBMR (iii) uses biological material (iv) makes immediate use of GR (depends on its specific properties) (v) resulted from research using GBMR or TK, which were - essential/necessary - incidental - necessary to deriving the invention (vi) partly or entirely comprises TK/GBMR or there is an obligation or responsibility under ABS law, regulation, permit, licence or agreement relating to TK or GBMR that covers (i) the research or related activities that lead to the invention, or (ii) the attainment of the invention, or (iii) the act of filing for patent on the invention.	Compliance with ABS laws in the country of origin, with the terms of an ABS licence or permit, or with specific contractual obligations to provider of GBMR or TK. Ownership rights established on the basis of an ABS law or specific ABS agreement. Expanded conception of patent law disclosure principles. Principles governing equitable behaviour.	Patent applicant is obliged to: (i) disclose the origin or source of the GBMR or TK (ii) provide a declaration, evidence or certification of prior informed consent relating to access (iii) provide a declaration, evidence or certification of an agreement to share benefits, or of actual sharing of benefits and/or (iv) ensure TK or GMBR used in invention are legitimately sources (v) ensure applicant has derived proper title from the inventor and third party interests (e.g. provider of TK or GBMR) are reflected in identification of applicant.	(i) Application considered incomplete upon filing without required declaration or documentation (ii) Application rejected during formality examination (with/without procedure for rectifying) (iii) Application rejected during substantive examination (with/without procedure for rectifying) (iv) Patent not granted or sealed until/unless required material is provided (v) Patent opposed or revoked if required material is lacking. (vi) Patent ownership transferred in whole/in part to beneficiary of ABS law or agreement. (vii) Patent is not enforceable on basis of equity.	(i) routine step during formal/substantive examination (ii) grounds for opposition, revocation, or unenforceability of patent (iii) basis for claim of assignment or transfer of patent in whole or part to ABS beneficiary.

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Obligation outside patent law to disclose details of access/use, or to cede/share ownership	GBMR and/or TK provided under an ABS or related law, or within the terms of a specific ABS agreement.	Defined by obligations under the ABS or related law, or the specific ABS agreement.	ABS or related law in country of origin Contract obligation in country of origin, to be recognized in patenting country.	Obligation to disclose TK or GMRM Obligation to include ABS beneficiary as applicant or co-applicant	Breach of obligation under law or contract Transfer of ownership in whole or part.	Counterclaim during patent enforcement Challenge by interested party
Deposit of microorganisms or biological material	Microorganisms, or biological material	Relevant to patent procedure (e.g. invention cannot be fully disclosed or enabled without access to microorganism or biological material)	Obligation to disclose invention under basic patent law principles cannot be fulfilled without deposit of actual sample. Budapest Treaty arrangements for international recognition of deposit.	Disclosure of actual sample; Provision of certification regarding deposit to patent authorities.	Patent may be found inadequately disclosed, resulting in	Certification provided during patent procedure.

B. TRIGGERS FOR DISCLOSURE REQUIREMENTS

104. The second specific element of the CBD invitation relates to 'practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements.' The 'trigger' for disclosure requirements has been construed in a substantive sense (what is the required relationship between the claimed or patented invention and the relevant GBMR or TK to trigger the obligation to disclose) and in a procedural sense (at what stage of processing an application would the obligation be triggered.[30]) Similarly, the comment has been made that the 'disclosure requirement would have both substantive and formal implications.'[31] The need to clarify the trigger of the disclosure obligation was identified in the Technical Study and examined in detail (see V.1 of the Study, and the brief summary above in Part III).

105. Belize comments on the trigger requirement in the context of patent processing. It suggests that 'the most effective way of triggering the disclosure requirement will be to require industrial property offices to conduct searches for 'traditional prior art'. However, this requirement will never be effective unless certain practical steps are taken. Firstly, technically uniform digital databases will have to be created of existing traditional knowledge. Secondly, such documentation must be recognized for national and international prior art searches. This entails the incorporation of such data in international classification systems such as the International Patent Classification (IPC), and the recruiting of traditional knowledge experts by International Search Authorities (ISA).' Separate steps are in train within various WIPO fora to implement measures along these lines.[32]

106. Ghana indicates that if the invention is 'essentially derived' from the GR/TK, then it should trigger the disclosure requirement, whether or not the 'material used is well known (public domain) or not (undisclosed information).'

107. Colombia suggests that the analysis of a patent application, insofar as it is based on a genetic resource, and the study of legal access thereto should be incorporated in the guidelines for patent examiners. This would mean that the following elements should be disclosed when a patent application is filed with the patent office:

(a) the biological and genetic resources and their derived products as used, together with the individual certificate of legal provenance;

(b) the country of origin of said resources; and

(c) proof of the prior informed consent of the country of origin with regard to (b).

108. The national intellectual property authorities should include, in the determination of the prior art, information referring to biological and genetic resources and their derived products belonging to the Parties. 9. In addition, the documented information which has been submitted on these subjects by the competent intellectual property authorities of the other Party should be taken into account in the corresponding examinations. 10. The information referred to in the previous paragraph will be intended for the exclusive use of the national intellectual property authorities for the purposes of examining patent applications.

109. Colombia proposes two options for activation of the disclosure requirement:

(a) During the formal examination, when the office could send a notification in the event that the applicant has not produced the access contract or the certificate of origin of the

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30 See, for example, comments by Colombia

31 Comments by Brazil

32 Details are set out, for example, in documents WIPO/GRTKF/IC/6/8 and WIPO/GRTKF/IC/5/6

genetic resource. Further stages in the application procedure would not proceed until the required disclosure was made.

(b) During substantive or patentability examination, when it would be viable to notify the applicant of failure to disclose, but this would be less beneficial, since processing would be at a more advanced stage.

110. Commenting on triggers of disclosure requirements, Brazil noted that the disclosure requirement would have both substantive and formal implications. 'Any use of biological resources and associated traditional knowledge, the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention, would be sufficient to trigger the disclosure obligation. Even where the use was only incidental, it would be sufficient to trigger the obligation, if the disclosure were relevant for prior art, inventorship or entitlement determinations, the scope of the claim and/or for understanding or carrying out the invention. Among others, the uses that would be relevant for prior art, inventorship or entitlement determinations, the determination of the scope of the claims and/or for understanding or carrying out the invention could include, among others, where the biological resources and/or traditional knowledge is used:

(a) to form part of the claimed invention;
(b) during the process of developing the claimed invention;
(c) as a necessary prerequisite for the development of the invention;
(d) to facilitate the development of the invention; and
(e) as necessary background material for the development of the invention.

While there will be administrative implications and there may be cost implications for applicants as they are expected to at least employ all reasonable measures to determine the country of origin and source of the material to meet this obligation, it is not foreseen that administrative procedures and costs related to meeting the obligation would be in any way burdensome."

111. Ghana proposes that the trigger for the application of disclosure requirements 'should be based on the relationship between the invention and the GR/TK. If the invention is essentially derived from the GR/TK, then it should trigger the application of disclosure requirement. This should be made independent of whether the material used is well known (Public domain) or not (undisclosed information).'

112. The United States of America advises on the current substantive requirements that trigger disclosure requirements in its jurisdiction: "filing a patent application in the United States would trigger an obligation on behalf of the an applicant to disclose the claimed invention and the manner and process of making and using it, in full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains to make and use the invention. Upon filing, the inventor is also required to disclose the best mode, or embodiment, of the invention that he or she is aware of at the time of filing. Finally, the possession of any information that is material to patentability, during the pendancy of the patent application, would trigger an obligation on behalf of the applicant to disclose this information to the USPTO."

113. The proposal of the EC and its Member States comments on the substantive linkage requires as follows: "a good balance can be found by requiring that the invention must be "directly based on" the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource. The inventor must also have had physical access to the genetic 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."

114. The Kyrgyz Republic points out concerning the trigger of a disclosure requirement that 'it is necessary to develop relevant legal basis to regulate genetic resources and associated TK protection on the national and international levels, and develop legislation with regard to the access to genetic resources.'

Summary of triggers for disclosure requirements

Possible triggers for disclosure that draw on or adapt existing patent law principles:

(a) access to the GBMR is necessary to carry out or replicate the invention as claimed;

(b) access to the GBMR is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent;

(c) the TK is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious;

(d) TK was provided by a TK holder and is directly used in developing the invention, to the extent that the TK holder is a potential co-inventor;

(e) The circumstances of access to the GBMR or TK are sufficient to establish a claim of ownership or entitlement to apply for a patent.

Further forms of linkage, beyond existing patent law principles:

(a) The invention makes immediate use of the genetic resource, that is, it depends on the specific properties of the resource (in particular, the functional units of heredity and the actual or potential value that define it *as* a genetic resource);

(b) The GBMR or TK were used in the course of research that led to the invention, and were essential to deriving the invention;

(c) The GBMR or TK were used in the course of research leading to the invention, but were only incidental to the attainment of the invention;

(d) The GBMR or TK forms part of the claimed invention;

(e) The GBMR or TK was a necessary prerequisite for the development of the invention;

(d) The GBMR or TK was used to facilitate the development of the invention;

(e) The GBMR or TK was necessary background material for the development of the invention;

(f) The research leading to the invention, the attainment of the invention itself, or the act of filing the patent application, falls within the scope of an obligation incurred under a national biodiversity law or other access legislation, or under a specfic access permit, licence, agreement or contract.

Procedural options

The procedural trigger creating an obligation for disclosure may in theory include:

(a) initial filing of the application (a minimum documentation requirement);

(b) a specific deadline after filing the application;

(c) formal examination of the application;

(d) substantive examination;

(e) prior to grant or sealing of the patent;

(f) during patent opposition or revocation proceedings (including counterclaims during enforcement proceedings); or

(g) when the patent right is asserted or enforced.

(see table above for further summary)

C. INCENTIVE MEASURES FOR APPLICANTS

115. The third element of the CBD COP invitation concerned options for incentive measures for applicants. The 'incentives measures' discussed include legal, economic, social and moral incentives. The possible objectives of incentives were variously construed as promoting:

- compliance with disclosure requirements as such,
- ensuring prior informed consent and equitable benefit sharing,
- conservation and sustainable use of genetic resources, and conservation of TK,[33]
- innovation related to conservation and sustainable use, and
- disclosure of new information to the public.

116. Article 11 of the CBD provides that each 'Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.' The general context of incentives may be illuminated by past COP decisions and continuing CBD work on incentive measures, whether or not they have direct bearing on the present examination. The COP has acknowledged 'the importance of incentive measures in achieving conservation and sustainable use of the components of biodiversity' and recognized that 'biodiversity provides global services to humankind that are not captured and adequately recognized by current economic relations, patterns and policies' (Decision V/15). COP Decision VI/15 endorsed a set of practical principles and guidelines for the design and implementation of incentive measures which, for instance, clarified 'goals of the incentive measures' as follows: 'consistent with decision V/15, the purpose of incentive measures is to change institutional and individual behaviour in order to achieve in whole or in part the following objectives of the CBD: the conservation of biodiversity, the sustainable use of the components of biodiversity and the fair and equitable sharing of benefits arising out of the utilization of genetic resources.'

117. Incentives may need to be distinguished from consequences or outcomes – such as an increased or decreased use of the patent system – or from positive or negative externalities, which are defined as "a side-effect or consequence (of an industrial or commercial activity) which affects other parties without this being reflected in the cost of the goods or services involved; a social cost or benefit" (Oxford English Dictionary).

118. The UNEP-WIPO case study, in considering incentives relating to conservation, value-addition and innovation, identifies four kinds of incentives, according to whether the nature of the benefit is material or non-material, and the target of the incentive is individual or collective.[34] It comments:

- Incentives could be in cash or kind, conditional (linked to research) or unconditional;

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[33] See the observation of the UNEP-WIPO study footnote 5 above, Part I.

[34] See Gupta, footnote 5 above, at 41-42.

- Community incentives could be of a direct nature, or they could be indirect. They could be provided at a single point in time, or over an extended period of time;
- Incentives could be provided by external agencies or by the local communities themselves. The improved status of the innovators on account of social recognition may, or may not, be associated with a greater say in decision making at the societal level; and
- Incentives may focus on empowerment of local communities so that they may have better negotiating skills and better knowledge for conservation of local resources. Alternatively, the incentives may be targeted directly at conservation. Incentives targeted at the community may lead to action either at the community level or even at the individual level."

119. Comments and discussion also cover both 'positive'and 'negative' incentives – referring respectively, to measures that reward desired actions, and measures that deter undesired actions. A number of both positive and negative incentive measures are discussed in the Member State submissions. Some submissions, and the work of CBD processes, also invoke the concept of 'perverse incentives.' This term strictly refers to measures that bring about the opposite effect from what they are intended to promote. A number of comments refer to the possible creation of perverse incentives in the context of promoting the objectives of the CBD within the patent system. In the context of the CBD, the COP has noted proposals concerning perverse incentives that stipulate that a "*perverse incentive* emanates from policies or practices that encourage, either directly or indirectly, resource uses leading to the degradation and loss of biological diversity. The removal of such policies or practices or the mitigation of their perverse effects is therefore an important element in promoting the conservation and sustainable use of biological diversity."

120. The submission of Belize is one that highlights both positive and negative incenstives. For instance, it proposed fee reductions at national patent offices and under the PCT system 'in order to encourage applicants to disclose the origins of the genetic material that is contained in their complete specifications.' But Belize also considered that the 'most effective incentive measure for applicants' would be the 'negative incentive invoked by the threat of revocation of a patent that was granted based on the non-disclosure or misleading disclosure of the source of the origins of the genetic material that is contained in the complete specification.'

121. The USA noted that 'patents provide a strong incentive for innovation' and 'an incentive to disclose new, useful and unobvious information to the public.' It cautioned that 'new disclosure requirements would detract from this incentive by making it more difficult for applicants to obtain a patent and by introducing uncertainties into patents.'

122. Brazil's submission outlines the legal effects of non-compliance with a proposed new requirement as follows:

> The proposed disclosure of origin requirement will have both formal and substantive components and implications. The nature of the legal effect of insufficient, wrongful or no disclosure of origin, and of evidence of prior informed consent and fair and equitable benefit sharing, will depend on whether one is dealing with a formal or substantive component of the disclosure and whether it is at the level of pre or post-grant. In this context, where the insufficient, wrongful or no disclosure is discovered before the examination or grant of a patent, the legal effect could be that the application would not be processed any further until the submission of the necessary disclosure declarations and evidence. This could be accompanied with penalties and time limits within which

the proper disclosure declarations and evidence should be provided, otherwise the application could be deemed withdrawn. In essence, the insufficient, wrongful or no disclosure of the source and country of origin of the biological resources and/or traditional knowledge, as well as failure to provide evidence of prior informed consent and fair and equitable benefit sharing, should justify the non-processing of the application.

Where the insufficient, wrongful or lack of disclosure of source and country of origin is discovered after the grant of a patent, the legal effect could include:

– Revocation of the patent where it is determined that the proper disclosure 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 and where there is fraudulent intention for the insufficient, wrongful or lack of disclosure. In addition to revocation, criminal and/or administrative sanctions may also be imposed, for example, where the insufficient, wrongful or lack of disclosure amounts to a false representation;

– Full or partial transfer of the rights to the invention where full disclosure would have shown that another person or community or governmental agency is the inventor or part inventor or would otherwise be entitled to all or part of the claimed invention; and,

– Narrowing the scope of the claims where parts of the claims are 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.

Similarly, where the failure to provide evidence of prior informed consent is discovered after the grant of a patent, the legal effect could include:

– Revocation of the patent. In addition to revocation, criminal and/or administrative sanctions may also follow, outside the patent system, in particular, to ensure adequate compensation where it is eventually determined that no prior informed consent was obtained;

– Criminal and/or civil sanctions, including the possibility of punitive damages, could follow, again outside the patent system, where it is determined that the patent holder in fact obtained prior informed but did not provide the evidence in the application.

Additionally, sanctions should also apply in cases of failure to provide evidence of fair and equitable benefit sharing. These shall be elaborated upon at a later time. While a certain level of leeway may be given here on the exact legal effect for each infraction, every State should nevertheless have an obligation to ensure that the effect of insufficient, wrongful or lack of disclosure, and/or of failure to provide evidence of prior informed consent and fair and equitable benefit sharing, is effective in terms of its deterrent, compensatory and equity value.

123. The EC and its Member States comment that ‘meaningful and workable sanctions should be attached to the provision of incorrect or incomplete information. Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on

the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers. It must be left to the individual Contracting State to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.'

124. Colombia proposes that the main incentive for timely disclosure is that 'without the fulfillment of this requirement the patent may not be granted. Even where the patent is granted, it would be likely to be invalidated.' A further incentive would be more rapid treatment of the application. In addition, 'the applicant would have legal security for his patent' since 'the patent application will be much clearer and more precise, and consequently so will the subject matter of the applicant's right.' Colombia indicates that recognition would be given to 'the legal work done and to that which benefits nature, with mechanisms including those whereby the applicant and/or holder has the opportunity to promote his invention as biodiversity friendly.' In the event that an applicant or patent owner has made 'unlawful use of the genetic resources of a Party, without satisfying the requirements of Article 15 of the CBD, each Party will establish compensation mechanisms such as the following, in order to legalize use in the countries which are party to the CBD: (a) the applicant must pay royalties from the date on which the patent application was submitted for the use of the inventions derived from said genetic resources; and (b) the applicant shall recognize the use of the genetic resource and the place of origin in the description of the patent application and/or on the label attached to the product, claimed in said application and/or patent, for marketing purposes.

Cooperation-based incentives:

125. Japan reports that on the basis of CBD-related cooperation with other countries and variuos scientific and commercial projects, it has found that "companies have a sense of responsibility and conduct fair and equitable benefit sharing with providers of genetic resources. Moreover, companies are willing to promote and undertake genetic resource-based research projects with providers of genetic resources with whom conditions can be arranged for the proper implementation of contracts based on mutual understanding and trust … the steady progress of these approaches will help to materialize access to genetic resources and fair and equitable benefit-sharing based on the spirit of CBD."

Possible undesirable or perverse incentives

126. Japan observes that "huge risks and increases of cost adversely affect business. This is particularly true in business sectors that require very substantial monetary expenditures and long-term R&D to earn profits, and, if stringent regulations to take out genetic resources are introduced and unpredictable procedures caused cost increases, the business sector will hesitate to use genetic resources. As a result, there is little, by way of benefits, to share with providers of genetic resources." Japan further specifies that "if the disclosure the source/country of origin of genetic resources in a patent application should be made an obligation, it would increase the burden of applicants applying for a patent for an invention based on genetic resources because there would be an additional risk where a patent would be invalidated only on the grounds that disclosure requirements were not met. In cases in which an applicant could not immediately specify the source/country of origin of a genetic resource (e.g. a corporation directly purchased the resource from a genetic resource traders or

researchers exchanged genetic resources through a network of researchers), an applicant would have to directly investigate the source/country of origin of the genetic resources. Such a burden might discourage inventors from conducting research into inventions based on genetic resources due to the huge expense or from obtaining a patent for such inventions. As a result, fewer and fewer genetic resources would be utilized, and, in the end, access to genetic resources as well as fair and equitable benefit-sharing would not be facilitated."

127. Australia observes that 'if these broad parameters (see paragraph 89 above) are not met in relation to proposed patent disclosure regimes then it is possible that unintended consequences may arise that would discourage research and innovation and risk undermining the objectives of a patent disclosure regime. For example, the invalidation or non-grant of patent rights could directly undercut any capacity to share benefits, as without the benefits that can accrue from strong patent rights the benefits to potential access providers could be dramatically reduced or nullified. Similarly without a valid patent right, individuals can still commercialise their IP without any obligation to disclose their invention to the public or to share the benefits unless there is an underlying regime ensuring benefit sharing.'

128. Bearing in mind the objectives of the CBD, a broader conception of incentives may involve consideration of how the IP system would contribute to the objectives of conservation, sustainable use and equitable benefit-sharing holistically. For example, an independent study commissioned by UNEP and WIPO observed that 'increased erosion of biodiversity and associated TK will clearly not be halted by documentation. This is particularly true for genetic resources, which co-evolve with human societies over a long period of time. The in-situ conservation of wild, as well as agro-biodiversity suddenly becomes important. In the absence of various incentives, it is unlikely to take place. My suggestion is that IP provide an important means for strengthening the range of incentives that local communities need for conserving genetic resources and associate TK. In fact, IP can also provide incentives for augmenting this knowledge and resource base. The Honey Bee Network has documented many examples of plant varieties being developed by local farmers, using traditional methods and knowledge systems. In the absence of adequate mechanisms to provide protection for such efforts, proper incentives are not yet available to encourage more people to pursue such innovations. The ultimate test of any incentive system is whether it can nurture and augment the spirit of experimentation, exploration and sharing, so evident in traditional communities over the years. We need to find ways of ensuring that the value system of many of these communities does not become a reason for their remaining poor, and thus, ultimately, eroding their vitally important knowledge and resource base.'

Summary of incentives

Nature of incentives: legal, economic, social and moral.

Behaviour that may be encouraged by incentives:

- conservation and sustainable use of genetic resources, and conservation of TK
- equitable sharing of benefits
- obtaining prior informed consent
- confidence in equitable basis for sharing TK or GBMR
- greater cooperation and partnership with custodians of TK and GBMR
- innovation related to conservation and sustainable use
- compliance with laws or contractual obligations in country of origin

- conformity with guidelines or other standards
- incentives to disclose new information to the public.

Positive incentives:

- benefits an applicant obtains from greater legal security concerning the legitimacy of the application and granted patent
- enhanced and less burdensome avenues for further cooperation and access
- enhanced basis for dealing with the patented technology
- reduced fees
- recognition that an invention is biodiversity-friendly
- benefits from a positive public perception concerning the use of the GBMR or TK

Negative incentives

- fines, imprisonment or criminal penalties for false declarations
- refusal or invalidation of patent, or incapacity to enforce patent rights
- full or partial transfer of ownership of patent
- applicant's original use of GMRM or TK would infringe the patent once ownership transferred

'Perverse' or undesirable incentives

- discouraging disclosure of invention through patent system, favouring use of trade secrets
- discouraging sustainable use of GR
- invalidation leading to more widespread use of invention by third parties, without equitable benefit-sharing with provider
- costs of legal unpredictability or uncertainty
- disclosure of exact origin prejudicial to conservation of rare but valuable species
- disclosure of secret or sacred TK that is constrained by customary law or confidentiality constraints

D. IMPLICATIONS FOR WIPO TREATIES

129. Element (d) of the CBD invitation concerned 'identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties.' WIPO-administered treaties that may be relevant to such measures include the Paris Convention, the PLT, and the Patent Cooperation Treaty. Some relevant provisions are set out and discussed in the Technical Study (Section VII). The Technical Study also mentioned relevant provisions in the WTO TRIPS Agreement, although WIPO is not legally competent to interpret that agreement. Current treaty-related proposals within WIPO that are of direct relevance to this examination include the negotiations on a draft Substantive Patent Law Treaty (SPLT) and the Swiss proposal to amend the Regulations under the PCT; brief details of these proposals are set out in Part II above. The question of specific disclosure requirements was also considered in the preparations for the conclusion of the PLT.

130. One question that arises in considering the treaty implications of any disclosure or other ABS-relevant legal measures is their status as either 'formal' or 'substantive' measures. This is relevant for the PLT and the PCT, as these aim to regulate formalities only. The discussion of this question in the Technical Study is summarized briefly here:

131. Patent applications contain a combination of technical, legal and administrative information. Under national and regional patent law and related laws (and in line with established international standards), patent applicants are typically required to furnish information in four general areas:

(a) Information that enables a person skilled in the art to carry out the claimed invention, and in some laws the disclosure of the best mode of carrying out the invention known by the inventor at the relevant date.[35] For inventions involving a new microorganism, the disclosure obligation may also entail deposit of the microorganism itself;[36]

(b) information that defines the matter for which protection is sought (a claim or claims);

(c) other information relevant to the determination of novelty, inventive step or non-obviousness, and capability of industrial application or utility of the claimed invention, including search reports, and other known prior art;[37]

(d) administrative or bibliographic information relevant to the claimed patent right, such as the name of the inventor, address for service, details of priority documents, etc.

132. These requirements are generally characterized as 'formal' or 'substantive,' and there is a distinction in the PCT and PLT systems between substantive patent law and requirements concerning the 'form or contents' of an application. This is an important distinction in the context of the current discussion, and a distinction that is not always clearly articulated. A reference to 'formality requirements' may apply to the need to disclose information (such as names of inventor(s) and addresses) or to the need to submit certain documents (such as priority documents – i.e. copies and translations of foreign patent applications that form the basis of a claim to priority); 'formality requirements' may also refer to the physical format (layout on the page, size of paper, etc.). 'Substantive requirements' generally refers to the actual nature of the invention as such, and whether it meets the standards set for patentability ('substantive' law may also be relevant, however, in determining such questions as inventorship, entitlement to apply for or to be granted a patent, and other interests in a patent right, quite apart from the qualities of the invention as such). The distinction between substantive and formal requirements is often considered in terms of consequences of non-compliance (in particular, failure to comply with substantive requirements such as novelty renders a patent invalid), failure to meet certain formality requirements may nonetheless be fatal for a patent application, especially if it is not rectified in time.

133. The obligation on an applicant to provide information can therefore be considered under two aspects – compliance with formal requirements, and compliance with substantive

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35 For example, TRIPS Article 29.1 provides that: "[WTO] Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."

36 See the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977); this requirement applies in some countries to biological resources in general – see the discussion below in paragraph 45.

37 TRIPS Article 29.2 provides that "Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

requirements. For example, where a patent application is required to identify the inventor or inventors, this may be considered as a formality requirement (in that an application will generally not be accepted if there is no mention of a claimed inventor), but determining the identity of the inventor also entails a substantive legal judgement, and indeed forms the basis of the entitlement to a patent right. An incorrect or incomplete indication of the inventor may lead to transfer or invalidation of the patent right. Similarly, it is also a formal requirement that a patent application should include a description of the invention, but this description must also meet specific substantive standards if the patent application is to be accepted (or if a granted patent is to be valid).

134. International standards that apply to the patent system have bearing both on formalities and substantive aspects of the requirements placed on an applicant. This distinction can be illustrated by reference to the requirements specified for applications to be accorded a filing date by the patent authority receiving the application. Such requirements are considered to be 'formalities' rather than substantive requirements. For instance, it is generally mandatory to submit an apparent description of the invention before a filing date is accorded to a patent application; at this stage no judgement is made as to the substantive content of the description, but the application is accepted for processing because it meets the formality requirement when it simply appears that a description has been submitted. Patent applications may subsequently be examined to assess whether the application accords with substantive requirements, such as the requirement that the invention as claimed be novel, involve an inventive step (or be non-obvious), and be industrially applicable,[38] and the requirement that the description be sufficient and the claims be supported by it. At this stage, the description may be assessed as to its substantive compliance with legal requirements, as against formal compliance.

135. For instance, in relation to descriptions, the PLT (Article 5(1)(a)) identifies, as a formality requirement, 'a part which on the face of it appears to be a description' as one of the elements that forms part of an application sufficient to establish a filing date. The PCT Article 3(2) similarly requires that an international application shall contain a description, among other elements required for establishing a filing date, but it also sets a substantive standard for the description, specifying that it "shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." (Article 5) This substantive requirement is mirrored in TRIPS, Article 28, which makes it mandatory for WTO Members to "require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art…" Some international standards are permissive rather than mandatory, in other words clarifying optional requirements that may be imposed on a patent applicant. Hence TRIPS indicates that WTO Members "may require the applicant to indicate the best mode for carrying out the invention known to the inventor," leaving this in effect as an optional additional requirement for a patent application to meet. The PCT Regulations (Rule 5.1(v)) provides that the description should: "set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State."

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[38] PCT Article 33(1) and TRIPS Article 27(1).

Provisions of WIPO treaties

Paris Convention

136. The Paris Convention lays down certain core principles that apply to national patent laws. For instance, Article 2 has the effect of applying the principle of national treatment to patent law:

> "Nationals of any country of the [Paris] Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with."

This means that no disclosure requirement should be applied more advantageously to domestic nationals who are applying for or who hold patent rights, as compared to foreign nationals.

137. Article 4*bis* of the Paris Convention provides for the independence of patents obtained for the same invention in different countries "in an unrestricted sense," which includes independence "as regards the grounds for nullity and forfeiture." Article 4*ter* establishes the right of the inventor "to be mentioned as such in the patent," a disclosure mechanism that may be relevant to the present issue.

138. Article 4 *quater* requires that the basis for refusal or invalidation of a patent should not include "the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law." For instance, whether or not a particular technology has been approved for use should not be the basis for refusal. This expresses a distinction between the authorization to market a product, and the determination of the validity of a patent relating to the product, a distinction that may be a background consideration for some disclosure requirements that effectively create new substantive grounds for patent validity.

Patent Law Treaty

139. The PLT establishes standards for formalities and procedure with respect to national (regional) patent applications filed with national (regional) offices, and to international applications under the PCT once they enter the so-called "national phase." The PLT "does not establish a completely uniform procedure for all Contracting Parties, but provides assurance for applications and owners that, for example, an application that complies with the maximum requirements permitted under the Treaty and Regulations will comply with formal requirement applied by any Contracting Party."[39] Article 2(2), entitled "*No Regulation of Substantive Patent Law*," provides that "(n)othing in this Treaty or the Regulations is intended to be construed as prescribing anything that would limit the freedom of a Contracting Party to prescribe such requirements of the applicable substantive law relating to patents as it desires."

140. The PLT does nonetheless contain several provisions that may be relevant to the formality or procedural aspects of disclosure requirements. For instance, this may apply to

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[39] Paragraph 2.01, Explanatory Notes on the PLT and Regulations under the PLT, WIPO Publication No. 258, 2000: prepared "for explanatory purposes only."

the establishment of a filing date of an application. Article 5(1), entitled "*Elements of Application*" effectively requires that an applicant should be accorded a filing date if he or she has submitted to a patent office: "(i) an express or implicit indication to the effect that the elements are intended to be an application; (ii) indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office; (iii) a part which on the face of it appears to be a description." For instance, patent claims, which are fundamentally important both to the validity and to the legal effect of the patent right, need not be filed in the first instance for a patent application to be accorded a filing date. Similarly, the identity of the inventor, the disclosure of which may be required, need not be provided at the time of filing.

141. While this is essentially a question of filing formalities, it may have significant implications for some disclosure requirements. For example, discussion of disclosure requirements has suggested a strong form or requirement that would seem to entail failure to accord a filing date to an application unless it was submitted already with evidence of compliance with GBMR/TK access laws: "Applications unaccompanied by such documentation [official documentation from provider countries proving that genetic resources and associated TK] would automatically be *returned to the applicants for re-submission* with the relevant documentation."[40] This approach would suggest that the application would not be received and given a filing date without detailed documentation proving that GBMR/TK with some relationship with the patent application had been legitimately obtained. Such a requirement would be at odds with provisions such as those in the PLT that set standards for securing a filing date. Practically, it is also difficult to see how a determination could be made as to whether a declaration of GBMR/TK might be relevant without a claim of the patented invention (assuming some form of relationship must be established between the GBMR/TK and the invention as claimed to trigger the disclosure requirement), and yet an application can initially be accepted without submission of claims altogether – the claims forming the crucial element of interpreting the effective scope of the invention.

142. As noted above, the PLT also makes provision for the form and contents of patent applications and aligns these with the requirements of the PCT. WIPO document SCP/6/5 gives a detailed account of the interface between the PLT and PCT. The explanatory notes on the PLT[41] comment that Article 6(1) of the PLT applies the requirements relating to the form and contents of international applications under the PCT to national and regional applications. The wording of this provision is modeled after that of PCT Article 27(1). It is implicit that the expression form and contents of an application is to be construed in the same way as the expression in that Article. The Notes to that Article in the [relevant diplomatic records] contain the following explanation:

> "The words *form or contents* are used merely to emphasize something that could go without saying, namely that requirements of substantive patent law (criteria of patentability, etc.) are not meant."

143. The explanatory notes give illustrative examples as follows: "(t)he requirement, allowed under Article 29.2 of the TRIPS Agreement, that an applicant for a patent provide information concerning the applicant's foreign applications and grants, is not a requirement as to the "form or contents of an application" for the purposes of this provision. Similarly,

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40 Dutfield, Graham, "Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation," http://www.ictsd.org/unctad-ictsd, 2002, p. 25 (emphasis added).

41 Paragraphs 6.01 and 6.02, Explanatory Notes on the PLT and Regulations under the PLT, WIPO Publication No. 258(E), also provided as Annex I to WIPO document SCP/6/5.

requirements in respect of duty of disclosure, indications as to whether an application was prepared with the assistance of an invention marketing company and, if so, indications of the name and address of that company and requirements in relation to the disclosure of search results on related applications and patents, are also not requirements as to the "form or contents of an application" for the purposes of this provision. Further, requirements as to the "form or contents of an application" do not include any requirements relating to foreign investments, public concessions or public contracts under national laws and bilateral and multilateral agreements."[42]

144. Given that "in practice, different Contracting States have differing views"[43] on the issue of the distinction between substantive requirements and requirements as to form and contents, there is a degree of uncertainty and ambiguity as to how to draw this line. However, since the question has been avoided in the context of the PCT, it is deemed inappropriate for the PLT to strictly define a matter under the PCT which has intentionally been left ambiguous in the context of the PCT itself.[44] Equally, the nature of substantive standards is not prescribed within the PLT. There are two general areas of substantive law that are directly related to the grant of a patent: the eligibility of the disclosed invention itself for patent protection (its conformity with the definition of a patentable invention and with other patentability criteria), and the entitlement of the applicant to be granted the patent (inventorship, nature of the assignment of the right, etc.) Other areas of substantive law may not be directly relevant to the grant or validity of the patent as such – examples of such other areas are noted in the extract above, for instance foreign investment, public concessions or public contracts.

145. Article 10 of the PLT, entitled "Validity of Patent; Revocation" is also relevant to the present draft study, and has already been discussed above, particularly in relation to the nature of consequences of non-compliance with formal requirements. Article 10(1) provides that "non-compliance with one or more of the formal requirements referred to in Articles 6(1), (2), (4) and (5) and 8(1) to (4) with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention." Article 10(2) provides that "a patent may not be revoked or invalidated, either totally or in part, without the owner being given the opportunity to make observations on the intended revocation or invalidation, and to make amendments and corrections where permitted under the applicable law, within a reasonable time limit."

The Patent Cooperation Treaty

146. Because of the linkage between the two treaties that was consciously adopted during the PLT negotiations, the PCT itself is significant both in terms of determining the standards that apply to international applications (including the processing of international applications within national jurisdictions), and in terms of interpreting the PLT.

147. The PCT system is a patent filing system, not a patent granting system. It provides for an *international phase*, comprising filing of the international application, international search, international publication and international preliminary examination; and a subsequent *national phase* before designated national or regional patent offices, which process international applications as national or regional patent applications. The decision on granting or refusing patents is taken exclusively by national or regional offices in the national

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42 *op. cit.* paragraph 6.03 and Annex I to WIPO document SCP/6/5.

43 Document SCP/6/5, paragraph 8.

44 *Ibid.*

phase. Nonetheless, the PCT has the effect of harmonizing procedural and administrative matters, including the form and contents of patent applications.

148. PCT provisions may therefore be relevant to disclosure issues both in the international phase and in relation to national requirements concerning the form or contents of international applications. The requirements for the form or contents for the international application are set out in the Treaty itself, and the Regulations established under the PCT – these were discussed above in the review of disclosure obligations generally. In brief, the PCT specifies that an "international application shall contain … a request, a description, one or more claims, one or more drawings (where required), and an abstract." The nature of each of these elements is specified in some detail in the Treaty and Regulations.

149. Concerning the national phase, Article 27 of the PCT provides that "(n)o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations" but that this does not "preclude any national law from requiring, once the processing of the international application has started in the designated Office, the furnishing … of documents not part of the international application but which constitute proof of allegations or statements made in that application…" The same Article provides that nothing in the PCT or its Regulations "is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires" and that "national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law."

150. PCT Rule 51 *bis* elaborates on Article 27 and specifies (at 51 *bis*(i)(a)) that "the national law applicable by the designated Office may … require the applicant to furnish, in particular: (i) any document relating to the identity of the inventor, (ii) any document relating to the applicant's entitlement to apply for or be granted a patent," as well as information in certain circumstances concerning priority documentation, oath or declaration of inventorship, and evidence concerning non-prejudicial disclosures or exceptions to lack of novelty.

151. Potentially, and depending on the applicable national law, "any document relating to the applicant's entitlement to apply for be granted a patent" could concern issues such as whether the applicant is party to a legal agreement (such as a materials transfer agreement) concerning inputs to the inventive process that affected the applicant's legal entitlement to apply or to hold a granted patent. A PCT applicant may be required under national law to provide a declaration concerning their entitlement to apply for and be granted a patent (in the case of the majority of designated States): this can be complied with already upon filing or at a later stage during the international phase (by providing the appropriate declaration), or upon or after entry into the national phase before the designated Offices concerned. Where the designated Office "may reasonably doubt the veracity of the indications or declaration concerned" it can require documents or evidence concerning the applicant's entitlement and concerning the identity of the inventor.

152. The PCT system has specific provisions relevant to disclosure requirements in the form of deposit of biological materials and nucleotide or amino acid sequence listings. Rule 13*bis*.1 defines "reference to deposited biological material" as "particulars given in an international application with respect to the deposit of biological material with a depositary institution or to the biological material so deposited." Rule 13*bis*.2 stipulates how such references should be made (as discussed above, paragraph 103) and provides that "if so made, [a reference] shall be considered as satisfying the requirements of the national law of each designated State." Rule 13*ter*, concerning nucleotide and/or amino acid sequence listings, effectively requires that such listings be provided according to the standards set out in the

PCT Administrative Instructions, including submission in machine readable form. The consequence of failing to submit the listing within a certain time limit is that the international search would not be required to cover that application to the extent that failure to submit the information in the prescribed form prevents a meaningful search from being carried out. During the national/regional phase, a designated Office cannot require a sequence listing other than a listing in accordance with the standards provided in the Administrative Instructions.

153. The PCT currently does not have a mechanism for a distinct declaration concerning source of GBMR/TK as a separate element of the form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is not "intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires." This clearly applies to patentability of the invention as such. However, the entitlement of the applicant to apply for and be granted a patent is also a matter of substantive law, distinct from the technical patentability of the invention as such, but potentially at least as important in terms of the ultimate ownership and exercise of the patent.

154. As set out in detail in Part II above, Switzerland has proposed an amendment to the PCT Regulations to provide explicitly for the entitlement to impose a disclosure requirement.

General guidance on indentifying the implications for WIPO treaties

155. The Islamic Republic of Iran observed that 'it is not clear which body or bodies have the main responsibility for the identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties' and that the 'method of identifying the implications … should be decided upon by the Member States.'

156. Brazil observes that 'the proposals for a mandatory, universal, disclosure of origin requirement may have implications for WIPO-administered treaties, as well as treaties under negotiation. Many of these implications have not yet been fully discussed by WIPO Member States. Discussions, nevertheless, have taken place on the matter in the context of the PLT, the PCT and the draft SPLT. Brazil has made specific proposals with respect to the draft SPLT in the SCP and has, moreover, expressed itself on the issue of disclosure of origin, in the context of the PCT, in past sessions of the Working Group on Reform of the PCT, as well as in the WIPO General Assembly.'

157. The EC and its Member States comment that 'the introduction of [a disclosure requirement] should take place in an efficient and timely way, and be related to the existing international legal framework for patents. In order to achieve such a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements such as the EPC will be necessary. The disclosure requirement then applies to all international, regional and national patent applications at the earliest stage possible.'

158. Colombia indicates that 'national intellectual property authorities will cooperate with the WIPO Secretariat in the exchange of information on patent applications and patents granted for inventions, based on the use of biological and genetic resources, and their derived products, with a view to appropriate fulfillment of the requirement of disclosure, to be established in the PCT, PLT and draft SPLT. Disclosure mechanisms in these treaties 'would

provide an incentive for greater participation by the megadiverse countries in the treaties … there would be a greater flow of biotechnology applications, and above all there would be greater confidence in the system on the part of developing countries, since there would no longer be a sense of exploitation but of cooperation.'

159. Concerning the PLT, the EC and its Member States note that the PLT is 'aimed at the streamlining and harmonizing the procedures in the patent examination process, and in Article 5, stipulates the following.

> "A Contracting Party shall provide that the filing date of an application shall be the date on which its Office has received all of the following elements, filed, at the option of the applicant, on paper or as otherwise permitted by the Office for the purposes of the filing date:
> (i) an express or implicit indication to the effect that the elements are intended to be an application;
> (ii) indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office;
> (iii) a part which on the face of it appears to be a description."

From the aspect of formality, therefore, disclosure the source/country of origin of genetic resources is not necessary.'

160. Concerning the TRIPS Agreement (not a WIPO-administered treaty), Japan comments that Article 27.1 of TRIPS 'stipulates that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology…." Therefore, if disclosure requirements are made applicable only to genetic resource-related inventions, and invalidation of patents for such inventions is made allowable on the basis of lack of disclosure requirement, the adoption of these requirements could be considered as falling under the scope of "discrimination as to the field of technology."

161. Switzerland comments on the relevant treaties administered by WIPO, and the context of its own proposals to revise the PCT Regulations, as follows:

> The policy objective of the disclosure requirement is to increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization. To achieve this policy objective, the disclosure requirement has to be examined for the purposes of determining if a complete patent application has been filed. However, this policy objective neither requires nor justifies that the disclosure requirement is linked to the search, examination or grant of patents, or to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement.
>
> Due to the formal nature of the disclosure requirement, Switzerland considers the PCT and the Patent Law Treaty (PLT) to be in the foreground with regard to the disclosure of the source of genetic resources and traditional knowledge in patent applications. Both treaties are administered by WIPO and deal with the formal aspects of international (PCT) and national and regional (PLT) patent applications.
>
> According to Art. 27.1 of the PCT, "[n]o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this treaty and the regulations." In this regard, Rules 4.1 and 51*bis*.1 of the Regulations under the PCT are of particular importance:

Rule 4.1 enumerates the mandatory and optional contents of the request of an international patent application. According to Rule 4.1(c)(iii), such request may contain "declarations as provided in Rule 4.17." Rule 4.17 deals with certain declarations that are required by national laws in accordance with Rule 51*bis*.1(a). Rule 4.17 permits applicants to include in the request certain declarations corresponding to the matters set out in Rule 51*bis*.1(a)(i) to (v), relating to which designated Offices may require evidence or documents. According to Rule 4.18(a), "[t]he request shall contain no matter other than that specified in rules 4.1 to 4.17 [...]"; furthermore, Rule 4.18(b) requires the receiving Office to delete ex officio any such additional matter.

Present Rule 51*bis*.1 lists in subparas. (a) to (f) a number of matters relating to which the applicant may be required to furnish documents or evidence under the national law applicable by the designated Office. This rule provides clarity for both applicants and designated Offices that such items may be required to be furnished by the applicant under the national law applicable by the designated Office.

The current Rule 4 of the Regulations under the PCT does not require the declaration of the source of genetic resources and/or traditional knowledge in international patent applications. Furthermore, Rule 4 prevents patent applicants submitting an international patent application from voluntarily including any such information as part of the PCT procedure, except in the specification, that is, the description, of the invention. Furthermore, Rule 51*bis*.1, as currently worded, does not expressly mention the possibility of designated Offices to require the applicant to furnish information on the source of genetic resources and/or traditional knowledge under the national law applicable by the designated Office.

Art. 6.1 of the PLT, which deals with the form and contents of national patent applications, states that "[e]xcept where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:

> (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;
> (ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started[.]"

In this context, Rules 4.1 and 51*bis*.1 of the Regulations under the PCT are of particular importance.

Art. 10 of the PLT states that "[n]on-compliance with one or more of the formal requirements referred to in Articles 6(1) [...] with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the noncompliance with the formal requirement occurred as a result of a fraudulent intention." The validity of granted patents is thus not affected should the patent applicant not comply with the formal requirements enumerated in Art. 6.1. The only exception to this general rule is where such non-compliance results from fraudulent intention. Art. 10 of the PLT, however, only applies once a patent is granted, whereas it does not apply to the national patent granting procedure as such. Art. 10 does therefore not prevent Contracting Parties of the PLT from introducing sanctions for non-compliance with formal requirements prior to the granting of a patent (see Art. 6.8 of the PLT).

162. Concerning various WIPO-administered treaties and the TRIPS Agreement, the United States of America advises that these treaties "require disclosure requirements that are material to the determination of basic patentability standards (e.g., novelty, non-obviousness, enablement, utility). PCT Article 5 requires that a patent description disclose the invention in a manner sufficiently clear and concise for the invention to be carried out by a person skilled in the art. PLT Article 5 requires a submission, which on its face appears to be a description of the invention, in order to obtain a filing date. Under TRIPS Article 29 WTO Members must require that patent applicants disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. WTO Members may also require that applicants indicate the best mode for carrying out the invention known to the inventor at the filing date, or where priority is claimed, at the priority date of the application. On the other hand, we believe that new disclosure requirements may be inconsistent with, or may conflict with, WIPO administered treaties such as the PCT and PLT, as well as the WTO-administered TRIPS Agreement."

163. Ghana highlights a number of other issues, including national treatment under the Paris Convention and attribution of ownership; these are:

(a) disclosure requirements will need to account for multiplicity of sources;

(b) extent of obligation could place undue burden on the applicant to disclose the origin of all genetic resources and TK used in the invention - reasonable effort may be necessary;

(c) establishment of disclosure requirements minimum standards; and

(d) enforcement mechanisms required to deal with GR/TK of multicultural nature and those that cut across national boundaries.

Summary of possible implications for WIPO-administered treaties

Paris Convention: provisions concerning the right of the inventor to be mentioned as such in a patent, the independence of patents and national treatment.

PCT and PLT: provisions concerning documentation and formal requirements, potentially also concerning requirements for evidence of entitlement to apply; no effect on substantive conditions of patentability.

Current relevant proposals concerning the SPLT and revisions to the PCT Regulations

E. INTERNATIONAL CERTIFICATION

164. The fifth element of the CBD COP invitation refers to the 'intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.' This proposed system of certification (including within the context of the International Regime under development under the aegis of the CBD) potentially has bearing on specific requirements concerning evidence of prior informed consent and of equitable benefit sharing. However, it is notable that this issue is under active consideration within the CBD, as the following summary reports:

> COP VII 'stressed the need to … examine [inter alia] an international certificate of origin/source/legal provenance, in particular the operational functionality and cost effectiveness of such an international certificate. On the basis of information provided by Parties and other relevant stakeholders, the Conference of the Parties requested the

> Executive Secretary to further compile information on existing complementary measures and approaches, and experiences with their implementation, to disseminate such information and to prepare a report on the issue of additional approaches, on the basis of submissions received.[45]

Further updates on developments from the CBD may be valuable for WIPO's future work, consistent with the feedback process envisaged in the CBD COP invitation to WIPO. Brazil observed that 'discussions on certificates of origin/source/legal provenance are still ongoing in other fora,' but that 'Brazil would approach this matter in the context of the positions expressed with respect to items (a), (b) and (c) above.' A number of national experiences are reported concerning this issue, however. (The requirements of the Andean Community Decision 486 quoted above in Part II may also provide a valuable analogy).

165. The following general description of such certificates was prepared by the Secretariat in a document for the third meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing:

> The certificate has generally been described as a type of passport or permit which accompanies the genetic resource(s) along its life cycle and can be verified at various points of its life cycle and more importantly once the genetic resource(s) has left the provider country. As stated in the European Community submission, "it could accompany the genetic resources from the collection phase until the marketing of the product which makes use of them and therefore increase transparency and traceability".
>
> The certificate could provide a guarantee that requirements related to the legal acquisition of genetic resources in the country of origin or provider country have been met. The certificate would hence ensure legal certainty for users and ensure providers that their resources are used in conformity with legal obligations.
>
> The certificate of origin/source/legal provenance could contribute to building trust among users and providers of genetic resources. It may, on the one hand, reduce pressures in the provider countries to adopt restrictive legislation on access and benefit-sharing and, on the other hand, provide users with greater legal certainty and provide evidence that users are meeting access and benefit-sharing requirements.[46]

Implications for the operation of patent systems

166. As noted above, certification may be relevant to any specific requirement concerning evidence of prior informed consent and of equitable benefit sharing, or more broadly to comply with any requirement to demonstrate that relevant materials have been acquired lawfully. A specific issue has concerned how administrative or legal authorities in one jurisdiction are legally or practically capable to make a judgment about an individual's conformity with laws and regulations (including ABS laws and regulations) in another jurisdiction. The issues that arise may depend on the nature of any underlying obligation to provide evidence or specific documentation relating to the legal circumstances of access to and use of genetic resources (and associated TK).

167. To assist in the consideration of this issue, but without prejudging policy or legal questions, it may be helpful to consider two broadly analogous arrangements – (i) the use of 'priority documents,' the copies of original patent (or other IP) applications filed in a foreign

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[45] UNEP/CBD/WG-ABS/3/5 (10 December 2004), p. 16.
[46] UNEP/CBD/WG-ABS/3/5, 10 December 2004, p. 18.

jurisdiction, which are used to establish a legal entitlement to the 'right of priority' under national patent law in accordance with Article 4 of the Paris Convention; and (ii) the certification that is required by a patent office in one country to establish that a deposit of a microorganisms for the purposes of patent procedure in an international depositary authority is sufficient under domestic law, in accordance with the system established by the Budapest Convention (see discussion of this system in the Technical Study). On the other hand, it should be noted that these two analogues relate to conformity with patent law standards in the granting country, for which the documentation (Paris priority document or Budapest certification) provides factual evidence or support.

Comments on certification issues

168. Turkey advised that a draft law on the "Registration of Genetic Resources" is in preparation. When the law enters into force, Turkey's genetic resources would be registered, but only in Turkey under this law. Consequently, Turkey supported 'all attempts for an international certification system of genetic resources. In this context, all genetic resources registered in member states may be collected in a central database, a system similar to CBD's biosafety clearing house mechanism. In this context, international minimum standards and components should be determined, international legal binding mechanisms should be formed, systems should be in compliance within each member state in this matter.'

169. The proposal of the EC and its Member States comments that "an indispensable measure that makes the disclosure requirement outlined in the previous sections an effective incentive to comply with access and benefit-sharing rules is the introduction of a simple notification procedure to be followed by the patent offices. The latter, every time they receive a declaration disclosing the country of origin or source of the genetic resource and/or associated TK, should notify this information to a centralised body. This could be done, for instance, by means of a standard form. That would facilitate the monitoring – by countries of origin and TK holders – of the respect of any benefit-sharing arrangements they entered into. The relevant information must be made available in accordance with the present rules on the confidential nature of applications. The notification should be as simple as possible and must not lead to an unnecessary administrative burden for patent offices. The exchange of information should also be managed in a cost-effective way and without unnecessary additional charges imposed on patent applicants. This could be achieved, for example, by using electronic means. It would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the information available from the declarations on disclosure.

170. The United States of America comments that 'any proposed certificate of origin, source or legal provenance should be separate from intellectual property protection. As noted in our paper, any new systems to promote access and adequate benefit sharing should be developed outside of the patent system to maximize their effectiveness and to avoid a negative impact on patents.'

171. The Kyrgyz Republic observes that 'international certificate of origin/source/legal provenance could be used to monitor the use of certain genetic resources as well as during the process of creation of the terms and conditions on access to genetic resources and equitable sharing arising from the use of genetic resources. Matters related to the scope of IPRs on biological subject matter have to be considered on the national level, taking into account all advantages and risks associated with implementation of such legal measures.'

Summary of IP-related issues concerning certification of genetic resources

Certification (e.g. proposed international certificate of origin/source/legal provenance) may be relevant in:

– establishing factual or legal circumstances of access to the GBMR or TK;

– providing *prima facie* evidence for national authorities that relevant laws of a foreign jurisdiction have been complied with within that distinct jurisdiction

– providing information for monitoring purposes

– complying with any obligation to provide evidence or documentation relating to the obtaining of GBMR or TK

Other issues may also include:

- substantive or formality requirements relating to certification

- 'enablement' or other procedures relating to the disclosure of inventions which involve the use of certain GBMR, where documentation provides information on the deposit of microorganisms or GBMR more enerally.

[Annex follows]

ANNEX

PROCEDURAL BACKGROUND TO THIS DOCUMENT

1. The Secretariat of the CBD reported to the IGC at its second session (WIPO/GRTKF/IC/2/11) on the outcome of the first meeting of the CBD Ad-Hoc Open-ended Working Group on Access and Benefit-sharing ("the Working Group"). The report indicated that the Working Group had developed the draft Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Use, and had recommended "that the Conference of the Parties [COP] at its sixth meeting invite [WIPO] to prepare a technical study on methods [for requiring disclosure within patent applications of certain information] which are consistent with obligations in treaties administered by [WIPO]" (WIPO/GRTKF/IC/2/11 and UNEP/CBD/COP/6/6).

2. The Working Group's Report was considered by the COP at its sixth meeting (held from April 7 to 19, 2002), and as part of its decision on this matter (decision VI/24), the COP invited WIPO to:

> "prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:
>
> (a) Genetic resources utilized in the development of the claimed inventions;
>
> (b) The country of origin of genetic resources utilized in the claimed inventions;
>
> (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
>
> (d) The source of associated traditional knowledge, innovations and practices; and,
>
> (e) Evidence of prior informed consent."

3. This invitation was transmitted to the IGC at its third session (WIPO/GRTKF/IC/3/12), which agreed to respond positively and adopted a work schedule which would allow for the completion and transmission of the study in time for the seventh meeting of the COP, then scheduled to be held in Kuala Lumpur from March 9 to 20, 2004. Between the IGC's third and fourth sessions, a questionnaire was developed in consultation with Member States (WIPO/GRTKF/IC/Q.3) and then circulated to Member States regarding the intellectual property issues identified for study in the invitation contained in Decision VI/24.

4. At its fourth session, the IGC considered and commented upon a draft technical study (WIPO/GRTKF/IC/4/11), which was based on questionnaire responses from WIPO Member States. The IGC invited further comments for incorporation into a revised version of the draft study, which was then prepared and submitted to the IGC at its fifth session (WIPO/GRTKF/IC/5/10). The IGC agreed to transmit this draft technical study to the WIPO General Assembly for consideration and possible transmission to the seventh meeting of the COP.

Transmission of the study to the CBD, and further steps

5. At its Thirtieth Session, the WIPO General Assembly adopted the draft revised technical study for transmission to the seventh meeting of the COP. This decision was subject to the following understanding:

> "The [Study] has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive interpretation of any treaty. It is to be regarded as a technical input to facilitate policy discussion and analysis in the CBD and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States."

Following the General Assembly decision, the Technical Study was transmitted to the Secretariat of the CBD together with this understanding.

6. The Technical Study was subsequently considered by the Working Group at its second meeting, held from December 1 to 5, 2003 (UNEP/CBD/COP/7/6, paragraphs 10 to 12, and 81). This led to the adoption of recommendations to the COP on the issues addressed in the Technical Study (UNEP/CBD/COP/7/6, paragraphs 75 to 85). The seventh COP met in Kuala Lumpur from February 9 to 20, 2004, and duly considered these recommendations. COP Decision VII/19 on '[a]ccess and benefit-sharing as related to genetic resources' included a reference to the Study and invited further work on this issue. Among other things, this decision:

- noted the technical study with appreciation;
- requested the CBD Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to WIPO and other relevant forums; and
- invited WIPO to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia:

  (a) Options for model provisions on proposed disclosure requirements;

  (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;

  (c) Options for incentive measures for applicants;

  (d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;

  (e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the CBD on its work, in particular on actions or steps proposed to address the above issues, in order for the CBD to provide additional information to WIPO for its consideration in the spirit of mutual supportiveness.

[End of Annex and of document]