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WORLD INTELLECTUAL PROPERTY ORGANIZATION

GENEVA

INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Fourteenth Session Geneva, June 29 to July 3, 2009

AFRICAN GROUP SUBMISSION ON DOCUMENT WIPO/GRTKF/IC/13/9

Document prepared by the Secretariat

- 1. In a *note verbale* dated June 22, 2009, the Permanent Mission of Senegal, on behalf of the African Group, submitted as working documents for the fourteenth session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee"), documents WIPO/GRTKF/IC/13/9 ("African Group Proposal on the Protection of Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources") and WIPO/GRTKF/IC/13/10 (comprising "Recommendations of the African Group on WIPO IGC Intersessional Work").
- 2. Furthermore, the African Group requested that three addendums be added to document WIPO/GRTKF/IC/13/9 as re-issued, namely (i) "Revised Provisions for the Protection of Traditional Cultural Expressions/Expressions of Folklore" as contained in document WIPO/GRTKF/IC/9/4, (ii) "Revised Provisions for the Protection of Traditional Knowledge" as contained in document WIPO/GRTKF/IC/9/5 and (iii) "Genetic Resources", being the contents of document WIPO/GRTKF/IC/11/8(a).
- 3. Accordingly, in response to this submission, document WIPO/GRTKF/IC/13/9 is hereby re-issued as a working document for the fourteenth session of the Committee, with the three addendums referred to, in the Annex to this document.

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- 4. In further response to the African Group's submission, document WIPO/GRTKF/IC/13/10 is separately re-issued as document WIPO/GRTKF/IC/14/10.
 - 5. The Committee is invited to take note of this document and the Annex to it.

WIPO/GRTKF/IC/14/9 ANNEX I

AFRICAN GROUP PROPOSAL ON THE PROTECTION OF TRADITIONAL KNOWLEDGE, TRADITIONAL CULTURAL EXPRESSIONS AND GENETIC RESOURCES

The African Group, in making this submission, is of the opinion that the ultimate objective of this process should be the development and adoption of a legally binding international instrument for the protection of traditional knowledge, traditional cultural expressions and genetic resources. The African Group also believes that much work has been done towards the review of legal and policy options for the protection of traditional knowledge, traditional cultural expressions and genetic resources which have been based on extensive international, regional and national experiences as highlighted in the "factual extractions".

It is important to bear in mind that the comments to the 10 issues currently under discussion, and of which the Members of the African Group has provided comprehensive responses, are complementary to the work done by the WIPO IGC in establishing parameters for defining and clarifying issues related to Objectives and Principles for the protection of traditional knowledge traditional cultural expressions and genetic resources.

In addition to this, the submission is made without prejudice to the establishment of a framework for the development and adoption of an instrument defining the scope, subject matter, rights conferred and related issues pertaining to the protection of traditional knowledge traditional cultural expressions and genetic resources.

Consideration of the factual extractions under the ten issues on the Traditional Knowledge (TK) and Traditional Cultural Expressions (TCEs) should be streamlined into the current work of the IGC so as to expedite deliberations in the IGC on substantive matters pertinent to the establishment of an international framework for the protection of traditional knowledge, traditional cultural expressions and genetic resources.

Pursuant to the above, the African Group would like to present its comments and recommendations on the factual extractions concerning Traditional Knowledge and Traditional Cultural Expressions. The African Group has studied the factual extractions, without attribution and has made the following observations on the points of convergence and divergences by Member States on the ten issues.

THE PROTECTION OF TRADITIONAL KNOWLEDGE

<u>Issue 1 - Definition of Traditional Knowledge</u>

The general consensus is that a working definition of Traditional Knowledge (TK) is important. The views vary from a broad definition to a more concise and narrower definition. Article 3 ("general scope of subject matter") in document WIPO/GRTKF/IC/11/5C would be a good starting pointing for discussions.

View 1:

The definition should:

- Include "knowledge systems, generated from local indigenous or traditional communities" as well those "generated, preserved and transmitted in different approaches, different people, including ethical (minorities) groups".
- "Be anthropological"
- "Be accumulated knowledge that was the result of intellectual activity and insight into a traditional context and included the know-how, skills, innovations ... embodied in the traditional lifestyle systems".

View 2:

- Questions whether the definition be formal or rigid? The definition should consider the evolving nature of TK.

View 3:

- Precise definition important in order for a common understanding.
- Definition required to obtain legal certainty so that it's clearly identifiable and described. A single definition is not appropriate.
- Look at the purposes of protection, whether that protection is by legal, non-legal, national and international means.

Way Forward:

The IGC should have a concise and flexible working definition which is complemented by a list of examples of TK.

The definition of TK should also include innovative aspects. The term should not be limited to a single technical field and be inclusive of all knowledge systems.

<u>Issue 2 - Who Should Benefit From Any Such Protection Or Who Should Hold The Rights To Protectable Traditional Knowledge</u>

The view is that Article 4 ("beneficiaries of protection"), and Article 5 ("eligibility for protection") of the document WIPO/GRTKF/1C/11/5(c) is an adequate basis for further work.

View 1:

- Article 4 ("beneficiaries of protection"), Article 5 ("eligibility for protection") in document WIPO/GRTKF/IC/11/5(C) provides a good basis for identifying beneficiaries for further discussion.
- "Developments on this issue should follow developments in relevant international fora."
- "Protection of TK should benefit the communities who generated, preserved and transmitted the knowledge in a traditional and intergenerational context, who were associated with it and who identified with it."
- "Rights-holders and beneficiaries of any benefits flowing from the use or exploitation of TK and TCE's should be the traditional knowledge holders and TCEs creators themselves and their community (ies)."
- "Considering existing human rights instruments...protection of TK should benefit the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context."

View 2:

- "The scope of a community etc. should be clarified and would be necessary to set guidelines in order to clarify relations between the interested parties."

Way Forward:

That Article 4 ("beneficiaries of protection"), Article 5 ("eligibility for protection") in document WIPO/GRTKF/IC/11/5(C) be considered as a basis in identifying the beneficiaries for protection. The overall views identify beneficiaries to include, amongst others, knowledge holders and practitioners from local communities.

The State will act as custodians of the TK taking into due consideration the interests of the local communities concerned.

Ownership of transnational TK should be treated as a special category as it is not a norm.

<u>Issue 3 - What Objective Is Sought To Be Achieved Through According Intellectual Property Protection (Economic Rights/Moral Rights)</u>

The general view as to the objective sought to be achieved looks at the principles of fair and equitable benefit-sharing, prior informed consent, the recognition of knowledge holders and the protection of their economic and moral rights. There is general agreement for the need for economic and moral rights policy objectives in varying degrees. One view, however, recognises the moral rights but not the economic rights. Overall consistency and complimentarity to existing IP regimes is articulated.

Few were yet unclear as to specifying the objective to be achieved.

View 1

- Article 6 ("fair and equitable benefit-sharing and recognition of knowledge holders") and Article 7 ("principle of Prior Informed Consent") in WIPO/GRTKF/1C/11/5(C) is a good basis for discussion.
- The link between TK and biodiversity, established under the Convention on Biological Diversity (CBD) and its Bonn Guidelines, indicate that economic rights and objectives are also relevant.
- To ensure proper attribution of rights through recognition of TK's contribution to creative endeavors
- It was both the economic and moral rights that were to be protected as a means of rewarding the holders of TK

View 2

- The "intellectual property" mentioned would not be limited to the existing systems, but also include the new system related that may come into being in the future.

View 3

- The key initial step in the development of any approach to the protection of TK as it intersects with IP is to first determine the relevant policy objectives and general guiding principles. Measures should be consistent with, complimentary to, existing IP regimes.
- The IGC has made substantial progress in identifying and articulating a wide range of specific policy objectives for the protection, preservation and promotion of TK.
- The argument to extend IP protection to TK for economic rights does not clearly contain or identify a justifiable reason why traditional knowledge is eligible for such protection.

Way Forward:

That prior informed consent (PIC), mutually agreed terms (MAT) and benefit-sharing are the means to achieve moral and economic rights through IP protection.

<u>Issue 4 - What Form Of Behaviour In Relation To The Protectable Traditional Knowledge Should Be Considered Unacceptable/Illegal</u>

The general view looks at, and elaborates, certain elements contained in Article 1 of ("protection against misappropriation") of WIPO/GRTKF/1C/11/5C.

Other comments provide suggestions as to how to identify these forms of behaviour that should be considered unacceptable/illegal.

View 1:

- Article 1 ("protection against misappropriation") of WIPO/GRTKF/1C/11/5 (c) provided an adequate basis for discussions
- More specifically to those who use TK that has already been accessed, to disclose the origin of the TK in an appropriate way and not disguise, distort or tamper the fact.
- Unauthorized reproduction, adaptation and commercialization with no sharing of benefits (economic or otherwise) with the relevant TK and/or TCE's holders.
- TK should be protected, against misappropriation which consists of any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means

View 2:

- Convergence on the draft policy objectives would be an important first step to addressing concerns raised in the IGC
- Important to have a set of clear and agreed objectives before delineating forms of behaviour that might be considered to be unacceptable.
- Suggest the conducting of a fact-finding survey to find out what damage is incurred by what acts.

Way Forward:

That Article 1 ("protection against misappropriation") of WIPO/GRTKF/1C/11/5(c) and Article 10bis of the Paris Convention relating to unfair competition be considered as a basis to identify unacceptable/illegal forms of behaviour.

There is convergence of views on various elements regarding unacceptable/illegal forms of behaviour.

<u>Issue 5 - Should There Be Any Exception Or Limitations To Rights Attaching To Protectable Traditional Knowledge</u>

Although the general views on issue of exceptions and limitations are similar with consideration for further analysis, there is still the view that this issue should not be discussed at this stage.

View 1:

- Article 8 (1) ("exceptions and limitations") represents adequate basis for discussion.
- The rights of TK holders should have lesser limitations and exceptions than in the case of other IPRs

View 2:

- Further analysis is required in order to determine what should be considered unacceptable or illegal, and where limitations can be drawn.
- Exceptions and limitations dependent on kind of protection accorded to TK

View 3:

- Important to have a set of clear and agreed objectives before delineating exceptions and limitations.
- Premature for the IGC to discuss exceptions and limitations.
- Any justifiable reasons for IP right protection to be extended to TK are not clearly identified and sufficiently explained.

Way Forward:

We are of the view that there should be some limitations and exceptions taking into account, inter alia, public interest and the continuing customary use and practice of the community.

Issue 6 - For how long should protection be accorded?

The comments under this issue look at perpetual protection versus limited period of protection. Overall, the views agree on perpetual protection, however, in view of existing IP laws, the limitation on the period still needs to be considered.

View 1:

- Protection should be in perpetuity, not limited to a fixed term.
- Protection last as long as the TK fulfills the criteria for eligibility for protection.

View 2:

 No objection to protection limited in time, however, discussions are necessary to determine duration of protection to last as long as the distinctive association and protected subject remains intact

View 3:

- The term of IP right for TK should be limited to balance the interest of investors and the public.
- The length of protection would depend on what is being protected and objectives being pursued.

Way Forward:

We are of the view that the duration of protection should be in perpetuity however, the duration of protection should be viewed under the provisions of exceptions and limitations.

<u>Issue 7 - To what extent do existing IPRS already afford protection? What gaps need to be filled?</u>

View 1:

- The current IP system does not offer protection to the stock of TK owing to the holistic
 and expansive nature of the knowledge. However, in some specific cases elements of TK
 could be protected within the existing IP system
- IPR rules have so far proved insufficient to safeguard TK holders against misappropriation
- Although the existing IPR system could afford protection for TK to some extent, it is not enough
- The key issue is that the IP system is limited to the protection of economic and commercial rights. It was not designed to protect cultural values and identity associated with TK

View 2:

- Exploring the use of the current IP systems on TK as long as criteria are met (i.e. Trademarks; Article 10bis of the Paris convention, geographical indications, label of origin)
- Explorations of national and community use of IPR will help the IGC to identify gaps in existing international frameworks. These perceived gaps could then be considered and addressed.
- Mandatory system of disclosure of TK is a gap in the current IP system

View 3:

 At this stage there is no perceivable gap between the current system and the necessary forms/level of protection. Under limited cases TK can be protected under current IP system

Way Forward:

There are some areas where IP systems are applicable to some facets of TK. Therefore there is a need for a holistic legal instrument for TK. Consideration should include the development of a sui generis system.

<u>Issue 8 - What sanctions or penalties should apply to behaviour or acts considered to be unacceptable/illegal?</u>

The general agreement is that there should be application of sanctions and penalties.

View 1:

- Appropriate civil and criminal sanctions and penalties should be applied.
- Formulation in Article 8 (a) ("sanctions, remedies and exercise of rights") under the TCEs document WIPO/GRTKF/IC/12/4C was found appropriate.
- Criminal penalties or a combination of criminal and civil may be more appropriate
- "Any acts that contravene the laws could be subject to effective sanctions"

View 2:

- Discussions would not advance the work of the IGC at this time
- Any justifiable reasons for IP right protection to be extended to TK are not clearly identified and sufficiently explained
- It is only once when an understanding of objectives and possible measures is developed further that fruitful and detailed discussions could be undertaken further

Way Forward:

Any acts that contravene the laws should be subject to effective sanctions.

Currently sanctions and penalties are being applied.

<u>Issue 9 - Which issues to be dealt with internationally and which nationally, or what division should be made between international regulation and national regulation?</u>

View 1:

- WIPO had the responsibility to develop an international framework for norms and standards leading to a legally binding international instrument
- International instrument applicable to (i) requirements for prior informed consent and benefit sharing (ii) acts of misappropriation (iii) need for effective enforcement measures
- To solve the problems of access and misappropriation of TK abroad
- Protection of TK is needed at the international level to prevent misappropriation, misuse and misrepresentations

View 2:

 Requires a careful consideration of both the national and international aspects of the complex issues

View 3:

- Premature to discuss but supports a flexible approach. Either leaving to national legislators or non-binding legal outcome at the international level.
- Favors solutions in the form of non-binding mechanisms as this provides greater flexibility and choice of implementation at the national level.'

Way Forward:

There is general consensus for the need of an international instrument(s) or framework.

However the legal status of the instrument(s) at the international level is still under consideration.

Issue 10 - How Should Foreign Rights Holders/Beneficiaries be treated?

The principle of national treatment is the general view on treatment of foreign rights holders/beneficiaries.

View 1:

- "the principle of national treatment should apply"

View 2:

- "Any justifiable reasons for IP right protection to be extended to TK are not clearly identified and sufficiently explained."
- "Further work is needed to determine how foreign rights holders/beneficiaries should be treated given that many cultures have common wellsprings."

Way Forward:

The principle of national treatment should apply in compliance with other international legal obligations and provisions.

PROTECTION OF TRADITIONAL CULTURAL EXPRESSIONS

It is instructive to note that most countries have welcomed the ten issues as allowing the IGC to focus more on the substantive issues at stake; or as an opportunity for members to engage in the kind of focused discussion needed to reach a consensus on these important questions.

The ultimate goal of the ten issues should therefore be to bring about a more focused and constructive discussion of the issues towards attaining a positive outcome.

Issue 1 – Definition of Traditional Cultural Expressions that should be protected.

View 1:

- Various countries gave illustrative lists of TCEs as contained in their respective legislations.
- Any artistic or traditional expressions that are the results of individual or communal creativity.
- Should be determined by the relevant customary laws.
- The terms are unclear at the moment.
- The working definition provided in Article 1 ("subject matter for protection") document WIPO/GRTKF/IC/11/4C is a good basis for further work.

View 2:

- Formal or rigid definition may not be needed
- Clear definition is a prerequisite

Way Forward:

While there is yet no clear and acceptable definition, the formulation in document WIPO/GRTKF/IC/11/4C is a good basis for further improvement of the definition of TCEs.

While this is viewed as a good working definition, the definition should not be rigid and remain flexible and descriptive. The definition should take into account the element of the community and that it is passed one from generation to generation. Cultural expressions differ from community to community

The Berne Convention definition is limited to copyright forms. While it is suitable for certain forms of TCEs (literary and artistic) it does not extend to protecting the universe of TCEs

Issue 2 – Who should benefit from such protection or hold the rights to protectable TCEs?

View 1:

- Local communities only.
- Local communities and recognized individuals.

View 2:

Concerns exist for inter-communal and cross-border issues.

Way Forward:

The local communities should be the primary beneficiaries of any protection but the relevant customary laws and protocols should be a determinant. Provisions should be put in place to address inter-communal and cross-border cases.

Originating community should be the beneficiary.

Since the definition of a community has been problematic it is important to offer general guidelines as to what constitutes a community. We should not be forced into a adopting a narrow legal definition. Where the origins are indeterminable, or beneficiaries are not easily identified, the State becomes the custodian.

<u>Issue 3 – What Objective is sought to be achieved through IP protection (economic/moral rights)?</u>

View 1:

- Many countries have listed various objectives to be achieved
- At this stage it did not appear to be amenable to protection, at the international level, as a form of IP. Not eligible for protection

View 2:

- The object of protection is unclear and need further discussion.
- The broadest overall objective of providing intellectual property rights is to promote creativity and innovation. Policy objectives might include, among others, promoting an environment of respect for TCEs/EoF, contributing to the preservation and safeguarding of TCEs/EoF, and encouraging, rewarding, and protecting authentic tradition-based creativity and innovation.

View 3:

- The objective should be the protection of moral rights for the preservation of culture and not economic rights.

Way Forward:

The objective of IP protection should be positive and defensive. It should cover both the economic and moral rights as they are interlinked. All TCEs should be IP protected at both national and international level.

<u>Issue 4 – What forms of behavior in relation to the protectable TCEs should be considered unacceptable/illegal</u>

View 1:

The following are identified as reprehensible:

- Derogatory use
- Unauthorised exploitation
- Unauthorized commercial exploitation
- Misappropriation
- Distortion and disrespect/denigration
- Unauthorised disclosure of secret TCEs

View 2:

- Doubts exist on the need for additional protection.

Way Forward:

Although a few countries expressed concerns over the use of the term "misappropriation" the majority agree that abuses should be prohibited. A minimum standard of protection should therefore be agreed upon, working from Article 3 ("acts of misappropriation (scope of protection)") of document WIPO/GRTKF/IC/11/4C.

The list should include

- violation of rules regarding the confidentiality and sacredness which govern practices and observances of traditional knowledge
- Suppression of the rights of knowledge holders in any form
- Derogatory use
- Unauthorized commercial exploitation
- Misappropriation
- Distortion, disrespect and denigration
- Unauthorised disclosure of secret TCEs

Issue 5 – Should there be any exceptions or limitations to rights attaching to protectable TCEs?

View 1:

- Many think Article 5 ("exceptions and limitations") of document WIPO/GRTKF/IC/11/4C is a good basis for discussion.
- There is, in principle, need for appropriate exceptions and limitations.
- Countries are not fully agreed on what should be included in the list of exceptions and limitations.

View 2

- Some countries are not ready to fully engage on this issue before the clarification of the substantive provisions.

Way Forward:

The list of possible exceptions should not be closed as negotiations on this continues and may bring up new issues; but document WIPO/GRTKF/IC/11/4C is an acceptable benchmark.

As there is no conclusion as to the objectives and the rights granted, it is important to leave the exceptions open. It is dependent on what rights are to be granted.

<u>Issue 6 – For how long should protection be accorded?</u>

View 1:

- Protection should not be limited in time so long as the TCE satisfies the requirements of protection

View 2:

- Reservations on the discussion of this issue at this point
- It is premature to discuss this issue.

Way Forward:

The determination of duration should be linked to the provisions on qualification (so long as the TCEs meet the requirements of protection). Many agree that the document WIPO/GRTKF/IC/11/4C is a good stating point.

Protection should not be limited in time for as long as the TCE satisfies the requirements of protection, as long as they remained integral to their collective identity and subject to the exceptions and limitations.

<u>Issue 7 – To what extent do existing IPRs already afford protection? What gaps need to be filled?</u>

View 1:

- The present protection available under IPR is limited and not adequate.
- General support for a gap analysis to be carried out.

Way Forward:

While some of the existing IP regimes may apply to TCEs, this will not always be the case and there is need to fill the gaps that currently exist.

The Intellectual Property regime was not designed to with TCEs in mind and there are several TCEs that would not be eligible for the exising protection offered by the IPRs system. There is a need to come up with a sui generis system of protection to address gaps left by the IPR system.

<u>Issue 8 – What sanctions or penalties should apply to behavior or acts considered to be unacceptable/illegal?</u>

View 1:

- Article 8 ("sanctions, remedies and exercise of rights") of WIPO/GRTKF/IC/11/4C is a good basis for discussion.
- it is neither early nor premature.
- Appropriate and effective sanctions [civil, criminal or administrative] should be provided for.

View 2:

- It is premature to discuss this at this point

Way Forward:

It is agreed that some form of sanction must be available, but for effectiveness, the appropriate rules to be employed must address the different options—civil, criminal as well as administrative.

Sanction must be appropriate and commensurate to the violation.

<u>Issue 9 – Which issues should be dealt with internationally and which nationally, or what division should be made between international regulation and national regulation?</u>

View 1:

- The committee should come up with an internationally binding instrument.

View 2:

- The Committee at this time should only engage in discussions without prejudging any outcomes.

Way Forward:

This question is at the heart of the future work of the IGC and the discussions of the Committee should be with a view to attaining some concrete outcomes that would effectively protect the rights of TCE holders.

The main purpose is to come up with an international instrument.

Issue 10 – How should foreign rights holders/beneficiaries be treated?

View 1:

- principle of national treatment and reciprocity

View 2:

- This should await discussions on other issues/may not be necessary.
- Consistency with other international obligations of Member States

Way Forward:

There is a general consensus that any outcome should be consistent with international obligations of Member States as to the rights of foreign rights holders. The principle of national treatment and reciprocity should be applied.

GENETIC RESOURCES

In view of the current work being undertaken by WIPO within the mandate of the Intergovernmental Committee of Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the IGC"), the African Group appreciates the substantive contributions of the WIPO Secretariat in the area of Genetic Resources as it relates to Intellectual Property (IP). The future work within the IGC on genetic resources (GR) should be carried out in accordance with the substantial developments within other international foras

The African Group acknowledges the process of elaborating and negotiating the International Regime on Access and Benefit-Sharing (ABS) within the Convention on Biological Diversity (CBD) and takes into account the work of WIPO in terms of genetic resources.

The African Group recalls the requests from the CBD to the WIPO IGC in support of its work currently being undertaken with regards to the International Regime on Access and Benefit-Sharing (ABS), without prejudice to the work of other international foras.

With the aim to harmonise and systematize the work already in progress in other international and national foras taking into account the proposals already submitted by the African Group and other Member States, the African Group is of the view that there are key linkages amongst the various international processes and that there is a need for harmonization to enhance better understanding and mutual support amongst these processes.

Recognise the work already carried out by WIPO on the ten issues contained in document WIPO/GRTKF/IC/11/8(a) for continuing our further work and recommends that this work be coupled and synthesized into one summary document to be made available to Member States.

The African Group proposes the following that WIPO:

- (i) Consider developing a range of options for the IP related aspects of ABS arrangements that could ensure benefit-sharing. In doing so, also develop a structured menu of options to guide custodians of genetic resources to facilitate their decision making process.
- (ii) Consider developing disclosure requirements and alternative proposals for dealing with the relationship between IP and GR as requested by the CBD.
- (iii) Consider developing guidelines and procedures with regards to dealing effectively with the IP aspects of access and benefit-sharing arrangements.
- (iv) Consider supporting demand and needs driven capacity building initiatives in Africa relevant to the relationship within IP and GR as well as the interface amongst World Intellectual Property Organisation (WIPO), Convention on Biological Diversity (CBD), World Trade Organisation (WTO) and Food and Agriculture Organisation (FAO).
- (v) Further emphasizes the linkages that exist amongst WIPO, CBD, FAO and WTO. In this regard, encourages these organizations to interact and participate actively amongst themselves, within their respective mandates, to foster synergistic implementation of related activities.

WIPO/GRTKF/IC/14/9 Annex II

REVISED PROVISIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE (document WIPO/GRTKF/IC/9/5)

POLICY OBJECTIVES AND CORE PRINCIPLES

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I.	P()I	AL Y	OBJE	しまい	ИБЭ

(i)	Recognize value
(ii)	Promote respect
(iii)	Meet the actual needs of traditional knowledge holders
(iv)	Promote conservation and preservation of traditional knowledge
(v)	Empower holders of traditional knowledge and acknowledge the distinctive
	nature of traditional knowledge systems
(vi)	Support traditional knowledge systems
(vii)	Contribute to safeguarding traditional knowledge
(viii)	Repress unfair and inequitable uses
(ix)	Concord with relevant international agreements and processes
(x)	Promote innovation and creativity
(xi)	Ensure prior informed consent and exchanges based on mutually agreed
	terms
(xii)	Promote equitable benefit-sharing
(xiii)	Promote community development and legitimate trading activities
(xiv)	Preclude the grant of improper intellectual property rights to unauthorized
	parties
(xv)	Enhance transparency and mutual confidence
(xvi)	Complement protection of traditional cultural expressions

CORE PRINCIPLES

II. GENERAL GUIDING PRINCIPLES

- (a) Responsiveness to the needs and expectations of traditional knowledge holders
- (b) Recognition of rights
- (c) Effectiveness and accessibility of protection
- (d) Flexibility and comprehensiveness
- (e) Equity and benefit-sharing
- (f) Consistency with existing legal systems governing access to associated genetic resources
- (g) Respect for and cooperation with other international and regional instruments and processes
 - (h) Respect for customary use and transmission of traditional knowledge
 - (i) Recognition of the specific characteristics of traditional knowledge
 - (j) Providing assistance to address the needs of traditional knowledge holders

III. SUBSTANTIVE PRINCIPLES

- 1. Protection Against Misappropriation
- 2. Legal Form of Protection
- 3. General Scope of Subject Matter
- 4. Eligibility for Protection
- 5. Beneficiaries of Protection
- 6. Fair and Equitable Benefit-sharing and Recognition of Knowledge Holders
- 7. Principle of Prior Informed Consent
- 8. Exceptions and Limitations
- 9. Duration of Protection
- 10. Transitional Measures
- 11. Formalities
- 12. Consistency with the General Legal Framework
- 13. Administration and Enforcement of Protection
- 14. International and Regional Protection

I. POLICY OBJECTIVES

The protection of traditional knowledge should aim to:

Recognize value

(i) recognize the holistic nature of traditional knowledge and its intrinsic value, including its social, spiritual, economic, intellectual, scientific, ecological, technological, commercial, educational and cultural value, and acknowledge that traditional knowledge systems are frameworks of ongoing innovation and distinctive intellectual and creative life that are fundamentally important for indigenous and local communities and have equal scientific value as other knowledge systems;

Promote respect

(ii) promote respect for traditional knowledge systems; for the dignity, cultural integrity and intellectual and spiritual values of the traditional knowledge holders who conserve and maintain those systems; for the contribution which traditional knowledge has made in sustaining the livelihoods and identities of traditional knowledge holders; and for the contribution which traditional knowledge holders have made to the conservation of the environment, to food security and sustainable agriculture, and to the progress of science and technology;

Meet the actual needs of holders of traditional knowledge

(iii) be guided by the aspirations and expectations expressed directly by traditional knowledge holders, respect their rights as holders and custodians of traditional knowledge, contribute to their welfare and economic, cultural and social benefit and reward the contribution made by them to their communities and to the progress of science and socially beneficial technology;

Promote conservation and preservation of traditional knowledge

(iv) promote and support the conservation and preservation of traditional knowledge by respecting, preserving, protecting and maintaining traditional knowledge systems and providing incentives to the custodians of those knowledge systems to maintain and safeguard their knowledge systems;

Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems

(v) be undertaken in a manner that empowers traditional knowledge holders to protect their knowledge by fully acknowledging the distinctive nature of traditional knowledge systems and the need to tailor solutions that meet the distinctive nature of such systems, bearing in mind that such solutions should be balanced and equitable, should ensure that conventional intellectual property regimes operate in a manner supportive of the protection of traditional knowledge against misappropriation, and should effectively empower traditional knowledge holders to exercise due rights and authority over their own knowledge;

Support traditional knowledge systems

(vi) respect and facilitate the continuing customary use, development, exchange and transmission of traditional knowledge by and between traditional knowledge holders; and support and augment customary custodianship of knowledge and associated genetic resources, and promote the continued development of traditional knowledge systems;

Contribute to safeguarding traditional knowledge

(vii) contribute to the preservation and safeguarding of traditional knowledge and the appropriate balance of customary and other means for their development, preservation and transmission, and promote the conservation, maintenance, application and wider use of traditional knowledge, in accordance with relevant customary practices, norms, laws and understandings of traditional knowledge holders, for the primary and direct benefit of traditional knowledge holders in particular, and for the benefit of humanity in general;

Repress unfair and inequitable uses

(viii) repress the misappropriation of traditional knowledge and other unfair commercial and non-commercial activities, recognizing the need to adapt approaches for the repression of misappropriation of traditional knowledge to national and local needs;

Respect for and cooperation with relevant international agreements and processes

(ix) take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that regulate access to and benefit-sharing from genetic resources which are associated with that traditional knowledge;

Promote innovation and creativity

(x) encourage, reward and protect tradition-based creativity and innovation and enhance the internal transmission of traditional knowledge within indigenous and traditional

communities, including, subject to the consent of the traditional knowledge holders, by integrating such knowledge into educational initiatives among the communities, for the benefit of the holders and custodians of traditional knowledge;

Ensure prior informed consent and exchanges based on mutually agreed terms

(xi) ensure prior informed consent and exchanges based on mutually agreed terms, in coordination with existing international and national regimes governing access to genetic resources;

Promote equitable benefit-sharing

(xii) promote the fair and equitable sharing and distribution of monetary and non-monetary benefits arising from the use of traditional knowledge, in consistency with other applicable international regimes, the principle of prior informed consent and including through fair and equitable compensation in special cases where the individual holder is not identifiable or the knowledge has been disclosed;

Promote community development and legitimate trading activities

(xiii) if so desired by the holders of traditional knowledge, promote the use of traditional knowledge for community-based development, recognizing the rights of traditional and local communities over their knowledge; and promote the development of, and the expansion of marketing opportunities for, authentic products of traditional knowledge and associated community industries, where traditional knowledge holders seek such development and opportunities consistent with their right to freely pursue economic development;

Preclude the grant of improper IP rights to unauthorized parties

(xiv) curtail the grant or exercise of improper intellectual property rights over traditional knowledge and associated genetic resources, by requiring, in particular, as a condition for the granting of patent rights, that patent applicants for inventions involving traditional knowledge and associated genetic resources disclose the source and country of origin of those resources, as well as evidence of prior informed consent and benefit-sharing conditions have been complied with in the country of origin;

Enhance transparency and mutual confidence

(xv) enhance certainty, transparency, mutual respect and understanding in relations between traditional knowledge holders on the one hand, and academic, commercial, educational, governmental and other users of traditional knowledge on the other, including by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent;

Complement protection of traditional cultural expressions

(xvi) operate consistently with protection of traditional cultural expressions and expressions of folklore, respecting that for many traditional communities their knowledge and cultural expressions form an indivisible part of their holistic identity.

II. GENERAL GUIDING PRINCIPLES

These principles should be respected to ensure that the specific substantive provisions concerning protection are equitable, balanced, effective and consistent, and appropriately promote the objectives of protection:

- (a) Principle of responsiveness to the needs and expectations of traditional knowledge holders
- (b) Principle of recognition of rights
- (c) Principle of effectiveness and accessibility of protection
- (d) Principle of flexibility and comprehensiveness
- (e) Principle of equity and benefit-sharing
- (f) Principle of consistency with existing legal systems governing access to associated genetic resources
- (g) Principle of respect for and cooperation with other international and regional instruments and processes
- (h) Principle of respect for customary use and transmission of traditional knowledge
- (i) Principle of recognition of the specific characteristics of traditional knowledge
- (j) Principle of providing assistance to address the needs of traditional knowledge holders

III. SUBSTANTIVE PROVISIONS

ARTICLE 1

PROTECTION AGAINST MISAPPROPRIATION

- 1. Traditional knowledge shall be protected against misappropriation.
- 2. Any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge.
- 3. In particular, legal means should be provided to prevent:
- (i) acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach or inducement of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means;
- (ii) acquisition of traditional knowledge or exercising control over it in violation of legal measures that require prior informed consent as a condition of access to the knowledge, and use of traditional knowledge that violates terms that were mutually agreed as a condition of prior informed consent concerning access to that knowledge;
- (iii) false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over

traditional knowledge-related subject matter when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access;

- (iv) if traditional knowledge has been accessed, commercial or industrial use of traditional knowledge without just and appropriate compensation to the recognized holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on its user, and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge; and
- (v) willful offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge and is contrary to ordre public or morality.
- 4. Traditional knowledge holders should also be effectively protected against other acts of unfair competition, including acts specified in Article 10bis of the Paris Convention. This includes false or misleading representations that a product or service is produced or provided with the involvement or endorsement of traditional knowledge holders, or that the commercial exploitation of products or services benefits holders of traditional knowledge. It also includes acts of such a nature as to create confusion with a product or service of traditional knowledge holders; and false allegations in the course of trade which discredit the products or services of traditional knowledge holders.
- 5. The application, interpretation and enforcement of protection against misappropriation of traditional knowledge, including determination of equitable sharing and distribution of benefits, should be guided, as far as possible and appropriate, by respect for the customary practices, norms, laws and understandings of the holder of the knowledge, including the spiritual, sacred or ceremonial characteristics of the traditional origin of the knowledge.

ARTICLE 2

LEGAL FORM OF PROTECTION

- 1. The protection of traditional knowledge against misappropriation may be implemented through a range of legal measures, including: a special law on traditional knowledge; laws on intellectual property, including laws governing unfair competition and unjust enrichment; the law of contracts; the law of civil liability, including torts and liability for compensation; criminal law; laws concerning the interests of indigenous peoples; fisheries laws and environmental laws; regimes governing access and benefit-sharing; or any other law or any combination of those laws. This paragraph is subject to Article 11(1).
- 2. The form of protection need not be through exclusive property rights, although such rights may be made available, as appropriate, for the individual and collective holders of traditional knowledge, including through existing or adapted intellectual property rights systems, in accordance with the needs and the choices of the holders of the knowledge, national laws and policies, and international obligations.

ARTICLE 3

GENERAL SCOPE OF SUBJECT MATTER

- 1. These principles concern protection of traditional knowledge against misappropriation and misuse beyond its traditional context, and should not be interpreted as limiting or seeking externally to define the diverse and holistic conceptions of knowledge within the traditional context. These principles should be interpreted and applied in the light of the dynamic and evolving nature of traditional knowledge and the nature of traditional knowledge systems as frameworks of ongoing innovation.
- 2. For the purpose of these principles only, the term "traditional knowledge" refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or 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.

ARTICLE 4

ELIGIBILITY FOR PROTECTION

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. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws.

ARTICLE 5

BENEFICIARIES OF PROTECTION

Protection of traditional knowledge should benefit the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context, who are associated with it and who identify with it in accordance with Article 4. Protection should accordingly benefit the indigenous and traditional communities themselves that hold traditional knowledge in this manner, as well as recognized individuals within these communities and peoples. Entitlement to the benefits of protection should, as far as possible and appropriate, take account of the customary protocols, understandings, laws and practices of these communities and peoples.

ARTICLE 6

FAIR AND EQUITABLE BENEFIT-SHARING AND RECOGNITION OF KNOWLEDGE HOLDERS

- 1. The benefits of protection of traditional knowledge to which its holders are entitled include the fair and equitable sharing of benefits arising out of the commercial or industrial use of that traditional knowledge.
- 2. Use of traditional knowledge for non-commercial purposes need only give rise to non-monetary benefits, such as access to research outcomes and involvement of the source community in research and educational activities.
- 3. Those using traditional knowledge beyond its traditional context should mention its source, acknowledge its holders, and use it in a manner that respects the cultural values of its holders.
- 4. Legal means should be available to provide remedies for traditional knowledge holders in cases where the fair and equitable sharing of benefits as provided for in paragraphs 1 and 2 has not occurred, or where knowledge holders were not recognized as provided for by paragraph 3.
- 5. Customary laws within local communities may play an important role in sharing benefits that may arise from the use of traditional knowledge.

ARTICLE 7

PRINCIPLE OF PRIOR INFORMED CONSENT

- 1. The principle of prior informed consent should govern any access of traditional knowledge from its traditional holders, subject to these principles and relevant national laws.
- 2. The holder of traditional knowledge shall be entitled to grant prior informed consent for access to traditional knowledge, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation.
- 3. Measures and mechanisms for implementing the principle of prior informed consent should be understandable, appropriate, and not burdensome for all relevant stakeholders, in particular for traditional knowledge holders; should ensure clarity and legal certainty; and should provide for mutually agreed terms for the equitable sharing of benefits arising from any agreed use of that knowledge.

ARTICLE 8

EXCEPTIONS AND LIMITATIONS

1. The application and implementation of protection of traditional knowledge should not adversely affect:

- (i) the continued availability of traditional knowledge for the customary practice, exchange, use and transmission of traditional knowledge by traditional knowledge holders:
- (ii) the use of traditional medicine for household purposes; use in government hospitals, especially by traditional knowledge holders attached to such hospitals; or use for other public health purposes.
- 2. In particular national authorities may exclude from the principle of prior informed consent the fair use of traditional knowledge which is already readily available to the general public, provided that users of that traditional knowledge provide equitable compensation for industrial and commercial uses of that traditional knowledge.

ARTICLE 9

DURATION OF PROTECTION

- 1. Protection of traditional knowledge against misappropriation should last as long as the traditional knowledge fulfills the criteria of eligibility for protection according to Article 4.
- 2. If competent authorities make available through national or regional measures additional or more extensive protection for traditional knowledge than is set out in these Principles, those laws or measures shall specify the duration of protection.

ARTICLE 10

TRANSITIONAL MEASURES

Protection of traditional knowledge newly introduced in accordance with these principles should be applied to new acts of acquisition, appropriation and use of traditional knowledge. Acquisition, appropriation or use prior to the entry into force of the protection should be regularized within a reasonable period of that protection coming into force. There should however be equitable treatment of rights acquired by third parties in good faith.

ARTICLE 11

FORMALITIES

- 1. Eligibility for protection of traditional knowledge against acts of misappropriation should not require any formalities.
- 2. In the interests of transparency, certainty and the conservation of traditional knowledge, relevant national authorities may maintain registers or other records of traditional knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of traditional knowledge holders. Such registers may be associated with specific forms of protection, and should not compromise the status of hitherto undisclosed traditional

knowledge or the interests of traditional knowledge holders in relation to undisclosed elements of their knowledge.

ARTICLE 12

CONSISTENCY WITH THE GENERAL LEGAL FRAMEWORK

1. In case of traditional knowledge which relates to components of biological diversity, access to, and use of, that traditional knowledge shall be consistent with national laws regulating access to those components of biological diversity. Permission to access and/or use traditional knowledge does not imply permission to access and/or use associated genetic resources and vice versa.

ARTICLE 13

ADMINISTRATION AND ENFORCEMENT OF PROTECTION

- 1.(a). An appropriate national or regional authority, or authorities, should be competent for:
- (i) distributing information about traditional knowledge protection and conducting public awareness and advertising campaigns to inform traditional knowledge holders and other stakeholders about the availability, scope, use and enforcement of traditional knowledge protection;
- (ii) determining whether an act pertaining to traditional knowledge constitutes an act of misappropriation of, or an other act of unfair competition in relation to, that knowledge;
- (iii) determining whether prior informed consent for access to and use of traditional knowledge has been granted;
 - (iv) determining fair and equitable benefit-sharing;
- (v) determining whether a right in traditional knowledge has been infringed, and for determining remedies and damages;
- (vi) assisting, where possible and appropriate, holders of traditional knowledge to use, exercise and enforce their rights over their traditional knowledge.
- (b) The identity of the competent national or regional authority or authorities should be communicated to an international body and published widely so as to facilitate cooperation and exchange of information in relation to protection of traditional knowledge and the equitable sharing of benefits.
- 2. Measures and procedures developed by national and regional authorities to give effect to protection in accordance with these Principles should be fair and equitable, should be accessible, appropriate and not burdensome for holders of traditional knowledge, and should provide safeguards for legitimate third party interests and the public interest.

ARTICLE 14

INTERNATIONAL AND REGIONAL PROTECTION

The protection, benefits and advantages available to holders of TK under the national measures or laws that give effect to these international standards should be available to all eligible traditional knowledge holders, who nationals or habitual residents of a prescribed country as defined by international obligations or undertakings. Eligible foreign holders of TK should enjoy benefits of protection to at least the same level as traditional knowledge holders who are nationals of the country of protection. Exceptions to this principle should only be allowed for essentially administrative matters such as appointment of a legal representative or address for service, or to maintain reasonable compatibility with domestic programs which concern issues not directly related to the prevention of misappropriation of traditional knowledge.

THE PROTECTION OF TRADITIONAL CULTURAL EXPRESSIONS/EXPRESSIONS OF FOLKLORE: REVISED OBJECTIVES AND PRINCIPLES (document WIPO/GRTKF/IC/9/4)

POLICY OBJECTIVES AND CORE PRINCIPLES

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 - (f) Complementarity with protection of traditional knowledge
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I. OBJECTIVES

The protection of traditional cultural expressions, or expressions of folklore, should aim to:

Recognize value

(i) recognize that indigenous peoples and traditional and other cultural communities consider their cultural heritage to have intrinsic value, including social, cultural, spiritual, economic, scientific, intellectual, commercial and educational values, and acknowledge that traditional cultures and folklore constitute frameworks of innovation and creativity that benefit indigenous peoples and traditional and other cultural communities, as well as all humanity;

Promote respect

(ii) promote respect for traditional cultures and folklore, and for the dignity, cultural integrity, and the philosophical, intellectual and spiritual values of the peoples and communities that preserve and maintain expressions of these cultures and folklore;

Meet the actual needs of communities

(iii) be guided by the aspirations and expectations expressed directly by indigenous peoples and by traditional and other cultural communities, respect their rights under national and international law, and contribute to the welfare and sustainable economic, cultural, environmental and social development of such peoples and communities;

Prevent the misappropriation of traditional cultural expressions/expressions of folklore

(iv) provide indigenous peoples and traditional and other cultural communities with the legal and practical means, including effective enforcement measures, to prevent the misappropriation of their cultural expressions and derivatives therefrom, control ways in which they are used beyond the customary and traditional context and promote the equitable

In these provisions, the terms "traditional cultural expressions" and "expressions of folklore" are used as interchangeable synonyms, and may be referred to simply as "TCEs/EoF". The use of these terms is not intended to suggest any consensus among Committee participants on the validity or appropriateness of these or other terms, and does not affect or limit the use of other terms in national or regional laws.

sharing of benefits arising from their use;

Empower communities

(v) be achieved in a manner that is balanced and equitable but yet effectively empowers indigenous peoples and traditional and other cultural communities to exercise rights and authority over their own traditional cultural expressions/expressions of folklore;

Support customary practices and community cooperation

(vi) respect the continuing customary use, development, exchange and transmission of traditional cultural expressions/expressions of folklore by, within and between communities:

Contribute to safeguarding traditional cultures

(vii) contribute to the preservation and safeguarding of the environment in which traditional cultural expressions/expressions of folklore are generated and maintained, for the direct benefit of indigenous peoples and traditional and other cultural communities, and for the benefit of humanity in general;

Encourage community innovation and creativity

(viii) reward and protect tradition-based creativity and innovation especially by indigenous peoples and traditional and other cultural communities;

Promote intellectual and artistic freedom, research and cultural exchange on equitable terms

(ix) promote intellectual and artistic freedom, research practices and cultural exchange on terms which are equitable to indigenous peoples and traditional and other cultural communities;

Contribute to cultural diversity

(x) contribute to the promotion and protection of the diversity of cultural expressions;

Promote community development and legitimate trading activities

(xi) where so desired by communities and their members, promote the use of traditional cultural expressions/expressions of folklore for community-based development, recognizing them as an asset of the communities that identify with them, such as through the development and expansion of marketing opportunities for tradition-based creations and innovations;

Preclude unauthorized IP rights

(xii) preclude the grant, exercise and enforcement of intellectual property rights acquired by unauthorized parties over traditional cultural expressions/expressions of folklore and derivatives thereof;

Enhance certainty, transparency and mutual confidence

(xiii) enhance certainty, transparency, mutual respect and understanding in relations between indigenous peoples and traditional and cultural communities, on the one hand, and academic, commercial, governmental, educational and other users of TCEs/EoF, on the other.

II. GENERAL GUIDING PRINCIPLES

- (a) Principle of responsiveness to aspirations and expectations of relevant communities
- (b) Principle of balance
- (c) Principle of respect for and consistency with international and regional agreements and instruments
- (d) Principle of flexibility and comprehensiveness
- (e) Principle of recognition of the specific nature and characteristics of cultural expression
- (f) Principle of complementarity with protection of traditional knowledge
- (g) Principle of respect for rights of and obligations towards indigenous peoples and other traditional communities
- (h) Principle of respect for customary use and transmission of TCEs/EoF
- (i) Principle of effectiveness and accessibility of measures for protection

III. SUBSTANTIVE PROVISIONS

ARTICLE 1:

SUBJECT MATTER OF PROTECTION

- (a) "Traditional cultural expressions" or "expressions of folklore" are any forms, whether tangible and intangible, in which traditional culture and knowledge are expressed, appear or are manifested, and comprise the following forms of expressions or combinations thereof:
- (i) verbal expressions, such as: stories, epics, legends, poetry, riddles and other narratives; words, signs, names, and symbols;
 - (ii) musical expressions, such as songs and instrumental music;
- (iii) expressions by action, such as dances, plays, ceremonies, rituals and other performances, whether or not reduced to a material form; and,
- (iv) tangible expressions, such as productions of art, in particular, drawings, designs, paintings (including body-painting), carvings, sculptures, pottery, terracotta, mosaic,

woodwork, metalware, jewelry, baskets, needlework, textiles, glassware, carpets, costumes; handicrafts; musical instruments; and architectural forms; which are:

- (aa) the products of creative intellectual activity, including individual and communal creativity;
- (bb) characteristic of a community's cultural and social identity and cultural heritage; and
- (cc) maintained, used or developed by such community, or by individuals having the right or responsibility to do so in accordance with the customary law and practices of that community.
- (b) The specific choice of terms to denote the protected subject matter should be determined at the national and regional levels.

ARTICLE 2:

BENEFICIARIES

Measures for the protection of traditional cultural expressions/expressions of folklore should be for the benefit of the indigenous peoples and traditional and other cultural communities:²

- (i) in whom the custody, care and safeguarding of the TCEs/EoF are entrusted in accordance with their customary law and practices; and
- (ii) who maintain, use or develop the traditional cultural expressions/expressions of folklore as being characteristic of their cultural and social identity and cultural heritage.

ARTICLE 3:

ACTS OF MISAPPROPRIATION (SCOPE OF PROTECTION)

Traditional cultural expressions/expressions of folklore of particular value or significance

(a) In respect of traditional cultural expressions/expressions of folklore of particular cultural or spiritual value or significance to a community, and which have been registered or notified as referred to in Article 7, there shall be adequate and effective legal and practical measures to ensure that the relevant community can prevent the following acts taking place without its free, prior and informed consent:

The broad and inclusive term "indigenous peoples and traditional and other cultural communities", or simply "communities" in short, is used at this stage in these draft provisions. The use of these terms is not intended to suggest any consensus among Committee participants on the validity or appropriateness of these or other terms, and does not affect or limit the use of other terms in national or regional laws.

- (i) in respect of such traditional cultural expressions/expressions of folklore other than words, signs, names and symbols:
 - the reproduction, publication, adaptation, broadcasting, public performance, communication to the public, distribution, rental, making available to the public and fixation (including by still photography) of the traditional cultural expressions/expressions of folklore or derivatives thereof;
 - any use of the traditional cultural expressions/expressions of folklore or adaptation thereof which does not acknowledge in an appropriate way the community as the source of the traditional cultural expressions/expressions of folklore;
 - any distortion, mutilation or other modification of, or other derogatory action in relation to, the traditional cultural expressions/expressions of folklore; and
 - the acquisition or exercise of IP rights over the traditional cultural expressions/expressions of folklore or adaptations thereof;
- (ii) in respect of words, signs, names and symbols which are such traditional cultural expressions/expressions of folklore, any use of the traditional cultural expressions/expressions of folklore or derivatives thereof, or the acquisition or exercise of IP rights over the traditional cultural expressions/expressions of folklore or derivatives thereof, which disparages, offends or falsely suggests a connection with the community concerned, or brings the community into contempt or disrepute;

Other traditional cultural expressions/expressions of folklore

- (b) In respect of the use and exploitation of other traditional cultural expressions/expressions of folklore not registered or notified as referred to in Article 7, there shall be adequate and effective legal and practical measures to ensure that:
- (i) the relevant community is identified as the source of any work or other production adapted from the traditional cultural expression/expression of folklore;
- (ii) any distortion, mutilation or other modification of, or other derogatory action in relation to, a traditional cultural expression/expression of folklore can be prevented and/or is subject to civil or criminal sanctions;
- (iii) any false, confusing or misleading indications or allegations which, in relation to goods or services that refer to, draw upon or evoke the traditional cultural expression/expression of folklore of a community, suggest any endorsement by or linkage with that community, can be prevented and/or is subject to civil or criminal sanctions; and
- (iv) where the use or exploitation is for gainful intent, there should be equitable remuneration or benefit-sharing on terms determined by the Agency referred to in Article 4 in consultation with the relevant community; and

Secret traditional cultural expressions/expressions of folklore

(c) There shall be adequate and effective legal and practical measures to ensure that communities have the means to prevent the unauthorized disclosure, subsequent use of and acquisition and exercise of IP rights over secret traditional cultural expressions/expressions of folklore.

ARTICLE 4:

MANAGEMENT OF RIGHTS

- (a) Prior authorizations to use traditional cultural expressions/expressions of folklore, when required in these provisions, should be obtained either directly from the community concerned where the community so wishes, or from an agency acting at the request, and on behalf, of the community (from now on referred to as "the Agency"). Where authorizations are granted by the Agency:
- (i) such authorizations should be granted only in appropriate consultation with the relevant community, in accordance with their traditional decision-making and governance processes;
- (ii) any monetary or non-monetary benefits collected by the Agency for the use of the traditional cultural expressions/expressions of folklore should be provided directly by it to the community concerned.
- (b) The Agency should generally be tasked with awareness-raising, education, advice and guidance functions. The Agency should also:
- (i) where so requested by a community, monitor uses of traditional cultural expressions/expressions of folklore for purposes of ensuring fair and appropriate use as provided for in Article 3 (b); and,
- (ii) establish the equitable remuneration referred to in Article 3 (b) in consultation with the relevant community.

ARTICLE 5:

EXCEPTIONS AND LIMITATIONS

- (a) Measures for the protection of TCEs/EoF should:
- (i) not restrict or hinder the normal use, transmission, exchange and development of TCEs/EoF within the traditional and customary context by members of the relevant community as determined by customary laws and practices;
- (ii) extend only to utilizations of TCEs/EoF taking place outside the traditional or customary context, whether or not for commercial gain; and,

- (iii) not apply to utilizations of TCEs/EoF in the following cases:
 - by way of illustration for teaching and learning;
 - non-commercial research or private study;
 - criticism or review;
 - reporting news or current events;
 - use in the course of legal proceedings;
 - the making of recordings and other reproductions of TCEs/EoF for purposes of their inclusion in an archive or inventory for non-commercial cultural heritage safeguarding purposes; and
 - incidental uses,

provided in each case that such uses are compatible with fair practice, the relevant community is acknowledged as the source of the TCEs/EoF where practicable and possible, and such uses would not be offensive to the relevant community.

(b) Measures for the protection of TCEs/EoF could allow, in accordance with custom and traditional practice, unrestricted use of the TCEs/EoF, or certain of them so specified, by all members of a community, including all nationals of a country.

ARTICLE 6:

TERM OF PROTECTION

Protection of traditional cultural expressions/expressions of folklore should endure for as long as the traditional cultural expressions/expressions of folklore continue to meet the criteria for protection under Article 1 of these provisions, and,

- (i) in so far as TCEs/EoF referred to in Article 3(a) are concerned, their protection under that sub-article shall endure for so long as they remain registered or notified as referred to in Article 7; and
- (ii) in so far as secret TCEs/EoF are concerned, their protection as such shall endure for so long as they remain secret.

ARTICLE 7:

FORMALITIES

- (a) As a general principle, the protection of traditional cultural expressions/expressions of folklore should not be subject to any formality. Traditional cultural expressions/expressions of folklore as referred to in Article 1 are protected from the moment of their creation.
- (b) Measures for the protection of specific traditional cultural expressions/expressions of folklore of particular cultural or spiritual value or significance and for which a level of protection is sought as provided for in Article 3(a) should require that such traditional cultural

expressions/expressions of folklore be notified to or registered with a competent office or organization by the relevant community or by the Agency referred to in Article 4 acting at the request of and on behalf of the community.

- (i) To the extent that such registration or notification may involve the recording or other fixation of the traditional cultural expressions/expressions of folklore concerned, any intellectual property rights in such recording or fixation should vest in or be assigned to the relevant community.
- (ii) Information on and representations of the traditional cultural expressions/expressions of folklore which have been so registered or notified should be made publicly accessible at least to the extent necessary to provide transparency and certainty to third parties as to which traditional cultural expressions/expressions of folklore are so protected and for whose benefit.
- (iii) Such registration or notification is declaratory and does not constitute rights. Without prejudice thereto, entry in the register presumes that the facts recorded therein are true, unless proven otherwise. Any entry as such does not affect the rights of third parties.
- (iv) The office or organization receiving such registrations or notifications should resolve any uncertainties or disputes as to which communities, including those in more than one country, should be entitled to registration or notification or should be the beneficiaries of protection as referred to in Article 2, using customary laws and processes, alternative dispute resolution (ADR) and existing cultural resources, such as cultural heritage inventories, as far as possible.

ARTICLE 8:

SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS

- (a) Accessible, appropriate and adequate enforcement and dispute-resolution mechanisms, border-measures, sanctions and remedies, including criminal and civil remedies, should be available in cases of breach of the protection for traditional cultural expressions/expressions of folklore.
- (b) The Agency referred to in Article 4 should be tasked with, among other things, advising and assisting communities with regard to the enforcement of rights and with instituting civil, criminal and administrative proceedings on their behalf when appropriate and requested by them.

ARTICLE 9:

TRANSITIONAL MEASURES

(a) These provisions apply to all traditional cultural expressions/expressions of folklore which, at the moment of the provisions coming into force, fulfill the criteria set out in Article 1.

(b) Continuing acts in respect of traditional cultural expressions/expressions of folklore that had commenced prior to the coming into force of these provisions and which would not be permitted or which would be otherwise regulated by the provisions, should be brought into conformity with the provisions within a reasonable period of time after they enter into force, subject to respect for rights previously acquired by third parties.

ARTICLE 10:

RELATIONSHIP WITH INTELLECTUAL PROPERTY PROTECTION AND OTHER FORMS OF PROTECTION, PRESERVATION AND PROMOTION

Protection for traditional cultural expressions/expressions of folklore in accordance with these provisions does not replace and is complementary to protection applicable to traditional cultural expressions/expressions of folklore and derivatives thereof under other intellectual property laws, laws and programs for the safeguarding, preservation and promotion of cultural heritage, and other legal and non-legal measures available for the protection and preservation of traditional cultural expressions/expressions of folklore.

ARTICLE 11:

INTERNATIONAL AND REGIONAL PROTECTION

The rights and benefits arising from the protection of traditional cultural expressions/expressions of folklore under national measures or laws that give effect to these international provisions should be available to all eligible beneficiaries who are nationals or habitual residents of a prescribed country as defined by international obligations or undertakings. Eligible foreign beneficiaries should enjoy the same rights and benefits as enjoyed by beneficiaries who are nationals of the country of protection, as well as the rights and benefits specifically granted by these international provisions.

GENETIC RESOURCES (document WIPO/GRTKF/IC/11/8(a))

CONTEXT

1. At its tenth session, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') requested the preparation of (i) a document listing options for continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts; and (ii) a factual update of international developments relevant to the genetic resources agenda item. This document, WIPO/GRTKF/IC/11/8 (a), provides the required list of options, and the companion document, WIPO/GRTKF/IC/11/8 (b) provides the required factual update of international developments.

LIST OF OPTIONS

2. Following is a brief list of options for continuing or further work identified in this process, covering the areas of "the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts," as required by the Committee's decision. Further details are provided in the discussion set out in Annex I, which is an update of the summary earlier provided to the Committee in document WIPO/GRTKF/IC/8/9.

Options for continuing or further work

- 3. The options listed below are derived exclusively from proposals put to the Committee by Member States and other Committee participants, including national and regional submissions, proposals by other participants, and the Committee's working documents. Each option would be subject to the overarching requirement in the current mandate of the Committee that its work should not prejudice the work of other forums, both within and beyond WIPO. In some instances, however, this work corresponds to direct invitations or encouragements of other forums, in particular the Conference of Parties of the Convention on Biological Diversity (see document WIPO/GRTKF/IC/11/8(b)).
- (i) Development of a mandatory disclosure requirement such as has been tabled in the Committee:
- (ii) Further examination of issues relating to disclosure requirements, such as the questions addressed or identified in earlier studies and invitations;
- (iii) Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/Q.5.;
- (iv) Guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources;

- (v) Other work on provisions for national or regional patent laws to facilitate consistency and synergy between access and benefit-sharing measures for genetic resources and national and international patent law and practice;
- (vi) Extension of already approved defensive protection mechanisms for traditional knowledge to address genetic resources more specifically, including the review and greater recognition of further sources of already disclosed information about genetic resources;
- (vii) Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources;
- (viii) Considering options for the expanded use, scope and accessibility of the Online Database of IP clauses in mutually agreed terms for access and equitable benefit sharing;
- (ix) Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9; and
- (x) Development of case studies, describing licensing practices in the field of genetic resources which extend the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.
- 4. As a response to the Committee's decision at the tenth session, this document is intended to set out, objectively and succinctly, the range of options for the Committee's work on genetic resources that have been discussed in the past ten sessions of the Committee. These options have not been listed according to the three categories established in the Committee's decision, as there is some overlap between the categories and no prejudgement was made as to the appropriate categorization. Further background and more extensive references are available in Annex I (a description of the past work and issues discussed) and Annex II (a summary of the Committee's materials on genetic resources issues).
 - 5. The Intergovernmental Committee is invited to review and draw on this document as appropriate in its discussions under agenda item 10 on genetic resources.

[Annexes follow]

ANNEX I: SUBSTANTIVE ISSUES CONSIDERED BY THE COMMITTEE

- 6. This Annex provides an overview of the Committee's work on genetic resources issues. It covers the three clusters of substantive questions which have been identified in the course of this work, namely technical matters concerning (a) defensive protection of genetic resources; (b) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources. In conclusion, the document catalogues certain technical measures or activities, which have been identified by Committee participants at past sessions to partially address these issues. Committee members may wish to consider these possible options in order to provide guidance on the Committee's further work regarding IP and genetic resources, without prejudice to the work of other fora.
- 7. The document recalls that the mandate of the Committee indicates that its work is "without prejudice to work in other fora". With particular relevance to genetic resources issues, the Committee itself has identified the principle that its work shall "be fully complementary with, and supportive of, the work of the CBD and FAO in particular." Recalling these principles, the present document provides background to Committee members in case they wish to discuss possible directions for continuing work on genetic resources issues.

II. SUBSTANTIVE ISSUES ARISING FROM RECENT DEVELOPMENTS

- 8. Following the decision of the Committee at its tenth session, this section provides information relevant to "continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts."
- 9. During the above-mentioned discussions and analyses in the Committee and other fora within and beyond WIPO, a number of substantive issues have emerged as ongoing concerns and themes that have been expressed by Committee participants. Some technical aspects of these substantive issues are briefly summarized here in three clusters: (i) defensive protection of genetic resources; (ii) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (iii) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

<u>Substantive IP issues concerning the interface between the patent system and genetic resources, particularly defensive protection of genetic resources.</u>

10. A range of Committee participants have called for the improved defensive protection of genetic resources against the grant of illicit intellectual property titles (disclosure requirements were highlighted as a particular form of defensive measure, discussed below). Some submissions illustrated specific cases of potential misappropriation of genetic material.

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See Document WO/GA/30/8, paragraph 93.

In particular, case studies⁴ submitted by the Delegation of Peru described "actions against pending patent applications or patents obtained or developed from the use of a biological resource or traditional knowledge without the prior informed consent of the country of origin of the resource or of the indigenous people owning rights in the knowledge, and without providing for any type of compensation to that country or indigenous people" and set out the following purposes: (a) ascertaining how a mega-diverse country makes a serious attempt to address this phenomenon through its institutions; (b) understanding to some extent the methodology and standards used in the search for such patents, thereby helping other countries or regions which might wish to initiate similar efforts; (c) gaining knowledge of the large number of inventions referring to resources of Peruvian origin that might reflect cases of biopiracy (either because such resources have been obtained illegally, or because they involve the unauthorized use, without compensation, of traditional knowledge); and (d) demonstrating that a systematic and methodical search and analysis of "problem" patents can be undertaken.

Submissions by Committee members also put forward options for addressing cases of wrongly granted patents, such as a proposal submitted by the Delegation of Japan.⁵ This complements extensive work undertaken in the first six sessions of the Committee to establish an array of defensive mechanisms to promote, and complements the development of patent examination guidelines for TK-related patents. Other UN agencies, such as the FAO, have requested WIPO to cooperate in analyzing and addressing similar concerns in specific sectors. International organizations working in the genetic resource field, such as the International Plant Genetic Resources Institute (IPGRI), have worked closely with WIPO to explore how to reduce the practical likelihood of illegitimate patents by linking their genetic resource information systems to a WIPO Portal which has been created in order to improve defensive protection of disclosed genetic material. The technical measures that have been identified as possible means to address these concerns include improving the availability and searchability of publicly available information about disclosed genetic resources to patent examiners; improved search tools for prior art searches, in particular thesauri for genetic resource nomenclature in order to allow examiners to translate between scientific and vernacular names of genetic resources that might be referred to in patent applications on the one hand and prior art documentation on the other. In furtherance of the work already done for the existing WIPO Portal for defensive protection of genetic resources, specific proposals were submitted during the ninth session of the Committee. For example, document WIPO/GRTKF/IC/9/13 suggests that "an effective solution ... is to establish a database related to genetic resources and traditional knowledge, which is accessible by examiners in any country, in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge."⁷.

 $^{^4}$ See documents submitted by Peru (WIPO/GRTKF/IC/5/13, WIPO/GRTKF/IC/8/12, WIPO/GRTKF/IC/9/10)

⁶ See FAO document CGRFA-9/02/REP.

WIPO/GRTKF/IC/9/13, para 34

<u>Substantive IP issues concerning disclosure requirements and alternative proposals for dealing</u> with the relationship between intellectual property and genetic resources

- 12. Discussions also covered questions surrounding specific disclosure requirements in patent applications for information relating to genetic resources which have been utilized in the claimed invention and alternative proposals for dealing with the relationship between intellectual property and genetic resources. This has been highlighted mostly in relation to improved defensive protection of genetic resources and in relation to emerging linkages of IP systems with national and international access and benefit-sharing regimes for genetic resources. As described above, other multilateral fora, such as the CBD, have invited WIPO to examine certain aspects of this cluster of issues, and that examination is currently in progress. Specific WIPO-administered treaties, such as the Patent Cooperation Treaty (PCT), have considered this issue within their own reform processes, and the matter has been raised in the SCP discussions on a draft Substantive Patent Law Treaty. Other multilateral organizations have taken up the issue with regard to specific agreements administered by them, such as the WTO with regard to the TRIPS Agreement; a specific proposal has been tabled to amend the TRIPS Agreement so as to introduce a mandatory disclosure requirement.
- These discussions have focussed on the potential integration of new or expanded disclosure requirements into existing patent systems as well as multiple alternative measures and proposals for dealing with the relationship between intellectual property and genetic resources. The debate also raises conceptual and practical questions about the linkages and synergies of intellectual property mechanisms with access and benefit-sharing regimes. References to disclosure requirements have been included in the terms of reference for negotiations which are currently under way in the CBD on an international regime for access and benefit-sharing. A formal proposal⁸ has already been tabled in the Committee for a mandatory disclosure requirement. Some Committee participants argue for a mandatory requirement but have called for it to proceed in other forums, either within or beyond WIPO, cautioning that the Committee's work should not prejudice outcomes elsewhere. Another view is that it would be wrong to assume that a new disclosure requirement within the patent system will accomplish the objectives of ensuring access and equitable benefit-sharing, and they have cautioned that the Committee should be wary of upsetting the delicately balanced patent system. ¹⁰ Another perspective is that disclosure requirements can under certain circumstances relate to larger regulatory questions about access and benefit-sharing frameworks, in addition to the question of their compatibility with, and integration into, specific existing IP agreements. Several further points of view have been expressed by commentators, who have pointed out that these conceptual questions regarding the interrelation and synergies between patent disclosure requirements and access and benefit-sharing regimes are not exhaustively addressed in the discussions on the compatibility of disclosure requirements with existing patent systems or their integration into the mechanics of existing systems.
- 14. The technical study on disclosure issues developed earlier by the Committee and transmitted to the CBD COP identified 'some key issues' in the following manner:

Document WIPO/GRTKF/IC/8/11, described further below.

Since the present document was drafted, a second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10.

WIPO/GRTKF/IC/8/13 ('Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore', submission by the United States of America)

A key issue is the relationship between the genetic resource and traditional knowledge on the one hand, and the claimed invention on the other. This includes clarification of 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. Clarity in this area is required so that patent or judicial authorities and the patent applicant or owner know when the obligation takes effect, and when on the other hand the relationship between background genetic resources or traditional knowledge is sufficiently remote or non-essential not to trigger the obligation. This is particularly so if the obligation is mandatory, bears a burden of proof or due diligence responsibility, or may lead to invalidation of patent rights. In the discussion of possible disclosure requirements, a diverse range of ways of expressing a linkage between genetic resources and traditional knowledge is canvassed. General patent law principles provide certain 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. The degree of clarity and predictability of impact of any disclosure requirement, and thus its practical impact, is likely to depend on whether the requirement can be analysed or expressed in terms of patent law.

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. Some of the legal and policy questions that arise are:

- 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 GR/TK;
- the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with nonpatent laws and regulations, or whether it incorporates compliance
- 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;
- 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;

- 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:
- 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.¹¹
- The 'examination of issues' developed in response to the second invitation by the CBD COP (prepared not within the Committee, but by a separate ad hoc intergovernmental process within WIPO culminating in the Ad Hoc Intergovernmental Meeting (WIPO/IP/GR/05/1) held in June 2005) noted that:

Analyzing disclosure requirements may also require some consideration of 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 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?
- is the patent law the appropriate vehicle for ABS?¹²
- what impact would a new disclosure requirement have on innovation?
- will the pursuit of ABS through the patent system cause greater harm than benefit?
- how would a new disclosure requirement transfer benefits?
- have any of the disclosure requirements that have been implemented promoted ABS in an effective manner?

Annex to document WIPO/GRTKF/IC/5/11, paras 205 and 206. This and the following six questions were included in the comments of the United States of America on

WIPO/IP/GR/05/1.

¹¹

- how have new disclosure requirements affected rates of innovation in those countries?
- are additional disclosure requirements necessary in view of already existing patentability requirements?¹³
- are national patent offices the appropriate bodies to enforce licences or contract-based interests of providers of genetic resources or associated TK?¹⁴
- 16. At the eighth session of the Committee, in June 2005, the European Community and its Member States submitted a proposal entitled 'Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications.' This proposal included the following summary:
- (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.

These proposals attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications."¹⁵

<u>Substantive</u> issues concerning intellectual property aspects of access and benefit-sharing contracts

17. A primary means of giving effect to the equitable sharing of benefits arising from the use of genetic resources is through mutually agreed terms, which are to be developed between provider and user of the resource for the granting of access to the resource, according to the CBD. The CBD thus foresees that "[a]ccess, where granted, shall be on mutually agreed

This and the following question were included in comments of an observer, IFPMA, subsequent to the June 3, 2005 Ad Hoc Meeting.

Annex to document WO/GA/32/8, paragraph 74.

Document WIPO/GRTKF/IC/8/11

terms,"¹⁶ which are mostly agreed through contracts or permit systems. IP potentially plays a role in mutually agreed terms for the sharing of monetary benefits, according to the CBD Bonn Guidelines (Appendix II), ¹⁷ as well as in the sharing of non-monetary benefits. ¹⁸ The CBD-COP, in its Decision VI/24, "*encourages* the World Intellectual Property Organization 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."¹⁹ The initial task which the Committee adopted on IP and genetic resources concerned IP clauses in access and benefit-sharing agreements. As described above, a Database of existing access and benefit-sharing agreements was created under the Committee's oversight as a capacity building tool, a questionnaire on such agreements was prepared and circulated, and initial drafts of guide practices for access and benefit-sharing agreements were prepared. The Database has been updated with several new agreements, and has been increasingly used as a practical capacity building (non-normative) tool.

The latest draft on guide practices – 'Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing' – was circulated for consideration at the Committee's seventh session. This document noted that the terms of access to genetic resources may include a requirement not to take out IP at all on derivative research, or an obligation to consult with the resource provider in the event of potential IP activity, and may structure ownership and management of any agreed resultant IP in a range of different ways, including co-ownership between access provider and resource user and different mechanisms for ensuring access to technology and other equitable benefits. These draft guidelines were developed according to the principles set out and discussed by the Committee since its second session:

Principle 1: The IP-related rights and obligations set out in [the Guide Contractual Practices] should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.

Principle 2: The IP-related rights and obligations set out in [the Guide Contractual Practices] should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.

Principle 3: The IP-related rights and obligations set out in [the Guide Contractual Practices] should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP clauses for access and benefit-sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement.

Principle 4: The IP-related rights and obligations set out in [the Guide Contractual Practices] should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.

¹⁶ Art. 15.4 CBD.

See Items 1(j) in the catalogue of Monetary Benefits listed in Appendix II of the Bonn Guidelines.

See item 2(q) of Appendix II, Bonn Guidelines.

See Decision VI/24C, Convention on Biological Diversity, para. 9.

WIPO/GRTKF/IC/7/9

18. Additional principles put forward by Committee members included:

- the Guide Contractual Practices should be non-binding,²¹ flexible²² and simple;²³
- the Committee's work on the Guide Contractual Practices should be without any prejudice to, and closely coordinated with, the work of the CBD and FAO;²⁴
- the IP rights and obligations set out in the Guide Contractual Practices should reflect the requirements of Prior Informed Consent which may apply to genetic resources;²⁵
- the Guide Contractual Practices should recognize the sovereign rights of Member States over their genetic resources;
- the Guide Contractual Practices should provide for terms on access to and transfer of technology as established in the CBD;²⁶ and
- the Guide Contractual Practices should foresee the possibility of a special tribunal established to adjudicate issues surrounding contracts for access to genetic resource and benefit-sharing.²⁷

III. POSSIBLE OPTIONS FOR CONTINUING OR FURTHER WORK OF THE COMMITTEE

19. In the course of its work on genetic resources in its past sessions, the Committee has considered various options for possible activities that could partially address the substantive issues which have been described above in Section II. The concern has been expressed, and the current mandate of the Committee underscores, that its work should not prejudice work of other fora, both within WIPO and elsewhere. This appears to be pertinent to the issue of genetic resources, given the array of activity only partially surveyed in the present document. Committee participants may wish to identify substantive issues which have been identified as requiring action at the international level, and to indicate how this work could be done by the Committee in such a way as to support and not prejudice the work of other fora, including key partners such as the CBD, CGIAR, FAO and UNEP.

See European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), United States of America (WIPO/GRTKF/IC/2/16, para. 74).

Algeria (WIPO/GRTKF/IC/2/3, para. 78), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56), Venezuela (WIPO/GRTKF/IC/2/3, para. 57).

See INADEV (WIPO/GRTKF/IC/2/16, para. 88).

See Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Colombia (WIPO/GRTKF/IC/2/16, para. 58), European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), Indonesia (WIPO/GRTKF/IC/2/16, para. 63), Japan (WIPO/GRTKF/IC/2/16, para. 76), New Zealand (WIPO/GRTKF/IC/2/16, para. 73), Peru (WIPO/GRTKF/IC/2/16, para. 69), Switzerland (WIPO/GRTKF/IC/2/16, para. 83), United States of America (WIPO/GRTKF/IC/2/16, para. 74), BIO (WIPO/GRTKF/IC/2/16, para. 92), ICC (WIPO/GRTKF/IC/2/16, para. 95), Chair (WIPO/GRTKF/IC/2/16, para. 54 and 96).

See Canada (WIPO/GRTKF/IC/2/3, para.77), USA (WIPO/GRTKF/IC/2/3, para.74).

See Ecuador (WIPO/GRTKF/IC/2/16, para.55), European Community and its Member States (WIPO/GRTKF/IC/2/16, para.75), Morocco (WIPO/GRTKF/IC/2/16, para.79), Peru (WIPO/GRTKF/IC/2/16, para.69), Singapore (WIPO/GRTKF/IC/2/16, para.66), Switzerland (WIPO/GRTKF/IC/2/16, para.83), Turkey (WIPO/GRTKF/IC/2/16, para.67).

See (WIPO/GRTKF/IC/1/13, para. 106), Ecuador (WIPO/GRTKF/IC/2/3, para. 55), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56).

20. As possible facilitative input to any such consideration of the issues, this Section briefly recapitulates options put before the Committee, noting the Committee session at which the option was identified. Each option is then followed by a footnote containing references to Committee documents which contain more details or additional information about that option. This is not intended to prompt or pre-empt consideration of any particular approach, but to provide a distillation of past more voluminous documentation in more readily accessible form, in case this will be of use to Committee participants.

Questions for guidance on the interface between the patent system and genetic resources, particularly defensive protection

- 21. To improve the defensive protection of genetic resources, much can be learned from the Committee's extensive work on defensive protection of traditional knowledge (TK). It has been suggested that activities successfully completed for TK could be translated, applied and executed in relation to disclosed genetic resources. The following options may be relevant:
- A.1 (second session): The Committee could compile an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the PCT;²⁸
- A.2 (*third session*): The Online Portal of Registries and Databases which was established by the Committee at its third session, could be extended to include existing databases and information systems for access to information on disclosed genetic resources (additional financial resources would be required to implement this option).²⁹ A concrete proposal for such a system was presented at the ninth session and proposed that "a new system has to be a one-stop system where genetic resources ... can be searched once and comprehensively and not a system in which each database created by each country has to be searched separately. The one-stop database system thus proposed could be an all-in-one consolidated system or be composed of multiple systems easily searchable with one click. Sufficient discussion has to be conducted to determine how to create the most efficient database in the foreseeable future."³⁰
- A.3 (second session): The Committee could discuss a possible development of recommendations or guidelines that existing search and examination procedures for patent applications take into account disclosed genetic resources as well as a recommendation that patent granting authorities also make national applications which involve genetic resources subject to 'international-type' searches as described in the PCT Rules.³¹

This has already been successfully accomplished for periodicals concerning disclosed TK, as foreseen in WIPO/GRTKF/IC/2/6, paras 41 to 45.

See WIPO/GRTKF/IC/3/6, para 15.

See WIPO/GRTKF/IC/9/13, para 40

This has already been for patent applications involving disclosed TK. See WIPO/GRTKF/IC/2/6, para 52.

Questions for guidance on disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources

- The implications and possible integration of proposals for additional genetic resource disclosure requirements into specific international IP agreements are being addressed in specialized for which are competent for amendment or reform of those IP agreements (for example, implications for the TRIPS Agreement are being addressed in the TRIPS Council, and implications for the PCT were discussed in the Working Group for Reform of the PCT). The broader relation between disclosure requirements and access and benefit-sharing frameworks raises a number of conceptual questions which are not being fully analyzed on their own terms in those specialized fora. These broader conceptual linkages exceed the technicalities of integration into specific IP agreements. In part, they emerge in the process of responding to the second CBD invitation on disclosure issues, which WIPO Member States agreed should be prepared in a distinct process separate from the Committee (culminating in the Ad Hoc Intergovernmental Meeting on this matter, held on June 3, 2005 and leading to the examination of issues which WIPO forwarded to the CBD COP). This leaves open the question of whether the Committee would consider options such as the following, which have been identified at previous sessions, while noting the strong concerns expressed that there should be no prejudice to the work of other fora:
- B.1 (*first session, sixth session*): The Committee could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international intellectual property law and practice on the other;³²
- B.2 (*fifth session*): The Committee could consider the development of guidelines or recommendations on achieving objectives related to proposals for patent disclosure or alternative mechanisms and access and benefit-sharing arrangements;³³
- B.3 (*ninth session*): The Committee could consider the creation of a dedicated international information system on disclosed genetic resources as prior art in order to prevent the erroneous grant of patents on genetic resources was submitted at the ninth session as an alternative proposal for dealing with the relationship between intellectual property and genetic resources;³⁴

Questions for guidance on IP aspects of access and benefit-sharing contracts

23. Mutually agreed terms for benefit-sharing have been widely discussed as an element of of access frameworks for genetic resources pursuant to the CBD. In this context, they are crucial for regulating access and ensuring benefit-sharing. Choices made by access providers concerning IP may play a role in contributing to equitable benefit-sharing arising from such access, including both commercial and non-commercial benefits. More recently, however,

The Committee considered such proposals at its first session (WIPO/GRTKF/IC/1/3, Annex 4) and as a request from the CBD-COP at its sixth session (see WIPO/GRTKF/IC/6/11, para. 4, quotation of COP Decision VII/19, para. 8(a) of the CBD).

The Committee considered such proposals at the first and fifth session. See WIPO/GRTKF/IC/5/10, para 12(ii).

WIPO/GRTKF/IC/9/13, para

contractual practices for new IP management models in the field of genetic resources have also been discussed in relation to an extension of the concepts of distributive innovation to the utilization of genetic resources. Again, it should be noted that strong concerns exist that any work by the Committee should not prejudice work in other fora. Some options for further development of this work, which have been identified in the past, include:

- C.1 (second session): The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders;³⁵
- C.2 (*fifth, sixth and seventh sessions*): Based on the additional information available and included in the Database, the Committee might wish to consider to further develop the guide contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9;³⁶ and
- C.3 (*sixth session*): compile information, possibly in the form of case studies, that describes licensing practices in the field of genetic resources which extends the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.³⁷
- 24. It is to be emphasized that all the possible options identified above would be categorically without prejudice to the work undertaken in other fora. While the Committee may consider initiating some of these activities, it should at all times take into account the work of these other fora and should conduct this in a manner of mutual supportiveness.
- 25. Annex II of document WIPO/GRTKF/IC/8/9 identified the following past options for possible activities that have been mentioned at past sessions to address substantive issues identified by the Committee in the field of IP and genetic resources

A. Options for possible activities on defensive protection

- A.1 (second session): The Committee could compile an inventory of existing periodicals, databases and other information resources which, which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the PCT;
- A.2 (*third session*): The Online Portal of Registries and Databases which was established by the Committee at its third session, could be extended to include existing databases and information systems for access to information on disclosed genetic resources (additional resources would be required to implement this option);
- A.3 (second session): The Committee could discuss a possible development of recommendations or guidelines that existing search and examination procedures for patent applications take into account disclosed genetic resources as well as a recommendation that patent granting authorities also make national applications which

See WIPO/GRTKF/IC/6/14

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³⁵ See WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16.

See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9.

involve genetic resources subject to 'international-type' searches as described in the PCT Rules.

- B. Options for possible activities on disclosure requirements
- B.1 (*first session, sixth session*): The Committee could consider the development of appropriate (model) provisions for national or regional patent laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international patent law and practice on the other;
- B.2 (*fifth session*): The Committee could consider the development of guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resource;
- C. Options for possible activities on IP and mutually agreed terms for fair and equitable benefit-sharing
- C.1 (second session): The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders;
- C.2 (*fifth, sixth and seventh session*): Based on the additional information available and included in the Database, the Committee could consider to further develop the guide contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9;
- C.3 (*sixth session*): compile information, possibly in the form of case studies, that describes licensing practices in the field of genetic resources which extends the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.

IV. CONCLUSION

26. This Annex describes three clusters of substantive questions which have been identified in the course of the Committee's work, namely technical matters concerning (a) the interface between the patent system and genetic resources, particularly defensive protection; (b) IP issues concerning disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources. Finally, the document recalls certain technical measures or activities which have been identified in past sessions, which would partially address these substantive issues, noting the need to ensure no prejudice to the work of other fora. This material is provided to the Committee in view of its possible contribution to discussion of genetic resource issues.

IGC RESOURCES RELEVANT TO WORK ON IP AND GENETIC RESOURCES

Overview of issues and activities

WIPO/GRTKF/IC/1/3 Initial outline of potential issues and activities, including those

concerning genetic resources

WIPO/GRTKF/IC/8/9 Overview of the committee's work on genetic resources

Intellectual property clauses in mutually agreed terms for access and equitable benefit-sharing

WIPO/GRTKF/IC/2/3 Operational principles for IP clauses of mutually agreed terms

concerning access to genetic resources and benefit-sharing

discussed and supported in WIPO/GRTKF/IC/2/16

(paragraphs 52 to 110)

WIPO/GRTKF/IC/2/13 Information document on contractual agreements concerning

access to genetic resources and benefit-sharing (submitted by the

Delegation of the United States of America)

WIPO/GRTKF/IC/3/4 WIPO/GRTKF/IC/5/9

WIPO/GRTKF/IC/6/5

WIPO/GRTKF/IC/7/9 Progressive development of draft guidelines on IP aspects of

mutually agreed terms for access and equitable benefit-sharing

Database of clauses relating intellectual property, access to genetic resources and benefit-sharing

WIPO/GRTKF/IC/2/12 Proposal for establishment of the database (submitted by the

Delegation of Australia)

WIPO/GRTKF/IC/3/3 Call for comments on the draft structure of the database

WIPO/GRTKF/IC/3/4 Proposed structure of the database

WIPO/GRTKF/IC/Q.2 Questionnaire and stakeholder responses on current practices and

clauses

WIPO/GRTKF/IC/5/9 Analysis of stakeholder responses to the questionnaire on current

practices and clauses

WIPO/GRTKF/IC/6/5 Draft IP guidelines, based on responses to the questionnaire and

subsequent analysis, concerning IP aspects of mutually agreed

terms for access and benefit-sharing

WIPO/GRTKF/IC/7/9 Draft IP guidelines, based on responses to the questionnaire and

subsequent analysis - reissued version of document

WIPO/GRTKF/IC/6/5, as requested by the Committee

WIPO/GRTKF/IC/4/10 Report on establishment of the database

URL of database: http://www.wipo.int/tk/en/databases/contracts/index.html

Disclosure requirements relating to genetic resources and TK

WIPO/GRTKF/IC/1/6 Information provided by Member States in response to a

questionnaire on protection of biotechnological inventions,

including questions on disclosure requirements

WIPO/GRTKF/IC/1/8 Directive 98/44/EC on the Legal Protection of Biotechnological

Inventions and an Explanatory Note on Recital 27 of the Directive, which concerns the indication of the geographical origin of biotechnological inventions. Also contains a paper on the relationship between IP rights and biodiversity (submitted by

the European Community and its Member States)

WIPO/GRTKF/IC/2/11 Report of the CBD Ad Hoc Open-Ended Working Group on

Access and Benefit-Sharing (submitted by the CBD Secretariat)

WIPO/GRTKF/IC/2/15 Survey of patents using biological material and mentioning of the

country of origin of the material (submitted by the Delegation of

Spain)

WIPO/GRTKF/IC/Q.3 Questionnaire and stakeholder responses on disclosure

requirements

WIPO/GRTKF/IC/4/11 First report on technical study

WIPO/GRTKF/IC/5/10 Draft technical study

UNEP/CBD/COP/7/INF/17 Technical study on disclosure requirements related to Genetic

resources and traditional knowledge. Submission by WIPO

WIPO/GRTKF/IC/6/9 Report on the transmission of the Technical Study to the CBD

WIPO Publication 786 Final text of the technical study

WIPO/GRTKF/IC/6/13 Decisions of the CBD-COP concerning access to genetic

resources and benefit-sharing, including an invitation to WIPO to

examine certain issues related to disclosure requirements

(Submitted by the CBD Secretariat)

WIPO/GRTKF/IC/7/INF/5 Further Observations by Switzerland on its Proposals Regarding

the Declaration of the Source of Genetic Resources and

Traditional Knowledge in Patent Applications (Submitted by the

Government of Switzerland)

WIPO/GRTKF/IC/7/10 Update on recent developments regarding disclosure requirements

WIPO/GRTKF/IC/8/11 Disclosure of Origin or Source of Genetic Resources and

Associated Traditional Knowledge in Patent Applications (submitted by the European Community and its Member States)

Technical standards on databases and registries

WIPO/GRTKF/IC/4/14Proposal of the Asian Group (adopted by the Committee)

Studies and texts on IP and equitable benefit-sharing

Publication 769 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

WIPO/GRTKF/IC/1/9 Draft Guidelines on Access and Benefit Sharing Regarding the

Utilization of Genetic Resources (submitted by the Government

of Switzerland)

WIPO/GRTKF/IC/1/11 Decision 391 - Common Regime on Access to Genetic Resources,

and Decision 486 - Common Intellectual Property Regime (submitted by the Member States of the Andean Community)

WIPO/GRTKF/IC/2/INF/2 International Treaty on Plant Genetic Resources for Food and

Agriculture (submitted by the FAO)

Other defensive protection measures

WIPO/GRTKF/IC/5/6 Practical Mechanisms for the Defensive Protection of Traditional

Knowledge and Genetic Resources within the Patent System (includes discussion of the Enola case referred by the FAO)

WIPO/GRTKF/IC/6/8 Further update on defensive protection measures relating to

intellectual property, genetic resources and traditional knowledge

WIPO/GRTKF/IC/8/12 Patent System and the Fight against Biopiracy - The Peruvian

Experience

WIPO/GRTKF/IC/9/12 Analysis of Potential Cases of Biopiracy (submitted by the

Delegation of Peru)

Further IGC resources

WIPO/GRTKF/IC/2/14 Declaration of Shamans on Intellectual Property and Protection of

Traditional Knowledge and Genetic Resources (submitted by the

Delegation of Brazil)

WIPO/GRTKF/IC/4/13 Access to Genetic Resources Regime of the United States

National Parks (Submitted by the Delegation of the United States

of America

WIPO/GRTKF/IC/5/13 Patents Referring to Lepidium Meyenii (maca): Responses of

Peru

[End of Annexes and of document]