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TRADITIONAL KNOWLEDGE AND FOLKLORE**

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TRADITIONAL KNOWLEDGE:
POLICY AND LEGAL OPTIONS

Document prepared by the Secretariat

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SUMMARY

1. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) has explored policy questions related to the protection of traditional knowledge (TK). It has considered the extensive experience of WIPO Member States with the protection of TK through the conventional intellectual property (IP) system and through *sui generis* measures within and beyond the general scope of IP law. At its fifth session, the Committee noted and reserved for further consideration a composite study on the legal protection of TK.¹ The Committee also held an informal Panel on Experiences with Existing *Sui Generis* Measures for the Protection of TK (“the TK Panel”), which provided information relevant to setting directions of future work on the legal protection of TK.² To facilitate this further work, the present document provides a succinct summary of policy and legal options for the protection of TK, distilling previous documentation on laws and measures for TK protection and summarizing previous policy debate. It categorizes the legal and policy options that may be considered when developing protection under national laws, and may thus facilitate future work of the Committee concerning protection of TK, including its international dimension. This material is set out at two levels:

- general objectives, principles and legal doctrines, that are common to many national and regional approaches, which may form the basis of a shared international perspective; and
- detailed provisions for giving effect to general principles and policy objectives in national legal systems, reflecting the inherent diversity of national approaches and the need to share understanding about the costs and benefits of particular mechanisms for TK protection.

2. The Committee has reviewed extensive documentation and analysis of the wide-ranging experience of legal protection of TK among WIPO Member States. Surveys and analysis have covered TK protection through conventional IP rights³ and through existing *sui generis* measures, including *sui generis* elements within conventional IP systems and stand-alone *sui generis* laws. The question has been posed whether adequate and appropriate protection of TK is best provided through either the conventional IP system or through an alternative *sui generis* system. However, the documented practical experience of Member States reflects the emerging consensus in other fora that existing IP rights and *sui generis* measures are not mutually exclusive options, but are complementary mechanisms. For instance, the Conference of Parties (COP) of the Convention on Biological Diversity (CBD) has stated that the most appropriate means of protecting TK is “based on a combination of appropriate approaches, ... including the use of existing intellectual property mechanisms, *sui generis* systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice.”⁴

3. Recognizing that national experience with TK protection ranged over the use of conventional IP rights, *sui generis* adaptations and extensions of existing IP systems, and

¹ Report of the fifth session, WIPO/GRTKF/IC/5/15, para. 110, referring to WIPO/GRTKF/IC/5/8 and WIPO/GRTKF/IC/5/7.

² See WIPO/GRTKF/IC/5/INF/4, para. 7.

³ See WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7.

⁴ CBD COP Decision VI/10A, para. 33.

distinct *sui generis* mechanisms within and beyond the scope of IP systems (such as access control regimes for genetic resources), the Committee requested a “composite report” with “a more structured, concrete analysis of specific options.”⁵ Document WIPO/GRTKF/IC/5/8 provided such an analysis. The present document facilitates further analysis and discussion of the legal and policy options for TK protection through a comprehensive review of various legal tools which can be combined to create customized protection for TK.

A structured approach to protection

4. In providing the “structured, concrete analysis of specific options,” this document sets out the options at two levels:

(a) *The level of core principles and general policy objectives.* A set of common principles and objectives would guide and hold together the elaboration of any detailed menu of options, creating a consistent and comprehensive agreed platform for TK protection. Section II below sets out the principles and objectives which have already been identified by Committee members in their statements, submissions and panel presentations to previous sessions of the Committee. It also takes into account principles established in national and regional laws and international instruments for TK protection, which have been provided to the Committee. Based on the list contained in Section II, the Committee is invited to identify and agree upon such basic principles and objectives of TK protection, in view of the strong commonality of core interests already apparent in interventions and other contributions to the Committee’s work. This, in turn, should clarify the legal doctrines which would most effectively achieve the agreed objectives. Section III lists four legal doctrines which have been utilized and referred to by Member States in developing and implementing their TK protection measures. Thus Sections II and III provide a structured analysis of overall objectives of protection and the relevant legal doctrines which can be deployed to achieve agreed objectives. If the Committee so chooses, this elaboration of core principles and objectives, and assessment of applicable legal doctrines, could serve as the basis of a concrete outcome reflecting international consensus on the importance and the appropriate means of protecting TK, and could therefore guide future work on the international dimension of TK protection.

(b) *The level of elaborated legal provisions.* The document further considers the options for detailed legal provisions that would implement agreed policy objectives, embody core principles, and implement the chosen legal doctrines. This entails identifying such elements as right holders, eligibility for protection, the nature of rights held, and the way rights are administered and enforced. Such choices taken at the national level are already diverse, even within dedicated *sui generis* protection of TK, as may be expected in view of different national needs, policy directions, and legal heritage. For instance, different choices have been taken in terms of the nature of rights, exclusivity, and entitlement to remuneration and non-financial remedies. This document sets out the principal elements of TK protection systems so as to contribute to the work of the Committee in analyzing key choices in elaborating the details of protection of TK. These elements have already been identified in previous working documents of the Committee.⁶ If the Committee so decides, based on Committee members’ comments regarding each element, these elements could be annotated with a commentary of policy considerations, and the relative costs and benefits of detailed

⁵ See WIPO/GRTKF/IC/4/15, para.163(i). This report was provided in WIPO/GRTKF/IC/5/8.

⁶ See WIPO/GRTKF/IC/4/8 and WIPO/GRTKF/IC/5/8.

choices for protection. National policy makers could then select and combine these elements in consultation with national TK stakeholders in order to customize appropriate protection for TK in their own jurisdiction. Committee members are invited to deliberate upon the elements that are set out in Section IV and to provide comments for the annotation of the various elements. This component of the menu of options corresponds to paragraphs 52 to 99 of the present document.

5. A comprehensive approach to TK protection includes using existing IP systems (including an array of IP rights and the law of unfair competition), adapted IP systems with *sui generis* elements, and new, stand-alone *sui generis* systems, as well as non-IP options, such as trade practices and labeling laws, liability rules, use of contracts, customary and indigenous laws and protocols, regulation of access to genetic resources, and remedies based on such torts as unjust enrichment, rights of publicity, and blasphemy. The options discussed in this document are either already in use in national or regional systems or have been discussed in Committee sessions or other WIPO activities.

Traditional knowledge protection in an holistic context

6. The irreducibly holistic quality of TK is often stressed, and from the point of view of indigenous and traditional communities, technical traditional knowledge or TK in the strict sense (*stricto sensu*) may be closely related to traditional cultural expressions (TCEs) or expressions of folklore (EoF). Some national and regional legal instruments aim to protect both EoF/TCEs and TK together. However, in line with the practice of the Committee, this document deals specifically with the protection of TK in the strict sense. Document WIPO/GRTKF/IC/6/3 deals with the protection of TCEs/EoF in a directly complementary fashion.

7. The substantive protection of TK necessarily involves consideration of the applicable principles and standards that are established at the international level – for instance, the Paris Convention for the Protection of Industrial Property⁷ requires suppression of unfair competition and may be directly relevant to the protection of TK, and it also establishes a principle of national treatment that may apply to protection of TK through industrial property rights. These standards are discussed as appropriate in this document. However, complementary document WIPO/GRTKF/IC/6/6 provides a more comprehensive discussion of the international dimension of the protection of TK, together with the international dimension of the protection of TCEs/EoF.

Related documents

8. This document is an overview only, intended to facilitate policy debate, and draws on more detailed and more fully documented material already presented to the Committee.⁸ Hence it should be used in conjunction with the following documents:

⁷ The Paris Convention for the Protection of Industrial Property (1979) (“the Paris Convention”).

⁸ For the Committee’s fifth session, ten Committee members contributed their experiences with *sui generis* measures for TK protection to a comparative analysis (WIPO/GRTKF/IC/5/INF/4), and six Committee members made detailed presentations to a Panel on *Sui generis* Protection of TK (These contributions are in the process of being issued as WIPO/GRTKF/IC/5/INF/6 and WIPO/GRTKF/IC/5/INF/7).

- “Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources Within the Patent System” (WIPO/GRTKF/IC/5/6);
- “Consolidated Survey of Intellectual Property Protection of Traditional Knowledge” (WIPO/GRTKF/IC/5/7);
- “Composite Study on the Protection of Traditional Knowledge” (WIPO/GRTKF/IC/5/8);
- “Overview of Activities and Outcomes of the Intergovernmental Committee” (WIPO/GRTKF/IC/5/12);
- “Information on National Experiences with the Intellectual Property Protection of Traditional Knowledge” (WIPO/GRTKF/IC/5/INF/2);
- “Comparative Summary of Existing National *Sui generis* Measures and Laws for the Protection of Traditional Knowledge” (WIPO/GRTKF/IC/5/INF/4).

I. INTRODUCTION: DEVELOPING TRADITIONAL KNOWLEDGE PROTECTION

8. This document provides the “structured and concrete analysis of specific options,” as requested by the Committee, in the form of a menu of legal and policy measures. It is structured as follows:

- Section I sets out background information and contextualizes the approach of this document within overall TK policy debates;
- Section II provides a list of possible key principles for TK protection, which could guide the application and combination of tools, as well as the development of substantive elements of national *sui generis* regimes;
- Section III sets out the main legal doctrines which have been used for a combined approach to the protection of TK;
- Section IV elaborates eleven main elements of national measures for TK protection, based on a comparative analysis of existing measures and on previous discussions of the Committee;
- Section V provides conclusions and an outlook on future work.

9. To facilitate the analysis and development of measures within this composite approach, the present document compares existing measures and identifies elements that are common to existing systems. A better understanding of existing *sui generis* measures, their common elements, and lessons learned during their implementation may contribute to the development of policy and legal options for TK protection that could guide national policy makers and legislators who elect to introduce *sui generis* protection for TK. The comparative analysis of existing *sui generis* measures which was developed by the Committee at its fifth session (document WIPO/GRTKF/IC/5/INF/4) forms the basis of the common elements of *sui generis* measures examined in this document. These common elements are identified for the consideration of the Committee as the starting point of developing elements of *sui generis* measures that could be recommended to countries and communities.

10. A comprehensive, combined approach to TK protection would also recognize the limits of exclusive property rights as an appropriate tool for TK protection. TK holders have themselves pointed to these limits by explaining that the protection of all types of TK through private property rights, even if held by TK holders, may have potentially negative impacts on TK systems themselves. As a form of private right in intangible subject matter, IP rights may, it has been stated, run counter to the characteristics of certain TK elements and may induce

unforeseen side-effects. For example, stakeholders have expressed concern that the legal protection of TK through exclusive property rights should not:

- restrict the customary transmission of TK within the original community;
- diminish the ethos of sharing and collective custodianship of TK;
- fragment TK systems or impair their holistic character;
- create conflict between communities or TK holders who may hold similar or identical TK;
- disrespect the customary, ceremonial, sacred or religious values of TK;
- lead to perverse incentives for TK holders (e.g., to pass off new products as tradition-based, to distort traditions for commercial advantages, etc);
- create incentives for unsustainable use of genetic resources related to TK;
- lead to disintegration of customary institutions and social structures based on or built around the TK;
- unduly restrict access to and utilization of TK or associated biological resources, so that their conservation is endangered;
- raise transaction costs for transmission and preservation of TK;
- allow free-riding appropriation of TK-based innovations by parties other than grassroots innovators;
- replace communal custodianship with individual ownership of TK; nor
- allow others than the true customary holders of TK to acquire ownership rights over the knowledge.

11. The use of private property rights for TK protection should thus be carefully balanced with other policy measures to reflect the characteristics of the protected TK, the stakeholder interests involved, the customary uses, and custodianship patterns. Most countries which have implemented TK protection have therefore supplemented a limited use of private property rights with a combination of other measures. For example, in their respective national *sui generis* measures, Brazil has combined the grant of exclusive rights with access regulation; the United States of America has combined defensive protection of native insignia with repression of unfair competition in native Indian products; and Costa Rica and Portugal have combined exclusive property rights, access regulation and unfair competition law to create tailored TK protection measures. By learning from such national experiences, the combined or comprehensive approach would thus join different legal doctrines and policy tools which have been identified by Member States and have been proven effective in their jurisdictions in order to achieve an appropriate form of protection. As has been pointed out during the TK Panel, the fine-tuning of combined approaches by Member States also reflects a recognition on their part of the need to balance concerns of illegitimate use and dissemination of TK against an appropriate conception of the public domain.⁹

12. This combined approach would result in the availability of TK protection through a bundle of rights at the national level, which would include the use of existing IP rights, *sui generis* measures, and non-IP tools, such as access regulation and contractual agreements. The combination of tools within this bundle would constitute tailor-made protection for TK.

⁹ See WIPO/GRTKF/IC/6/INF/4.

13. The formation of such a bundle as “a more structured, concrete analysis of specific options,” as requested by the Committee at its fourth session, could take the form of an annotated menu of possible policy and legal measures. Such an annotated menu of possible measures would include the use of existing IP rights, and policy options for each element of *sui generis* measures, with an analysis of the potential benefits and drawbacks of each option and a consideration of the possibilities for interaction between national systems for TK protection. From this annotated menu, countries might select those measures which suit their own domestic needs, their TK base, and their stakeholder interests. For the purposes of this document, the term “TK protection measures” or simply “*sui generis* measures” refers to all legislative and policy measures which are specifically implemented to improve the legal protection of TK. These comprise:

(i) measures for the improved application of existing IP rights to protect TK: for example, the creation of the USPTO Database of Official Insignia of Native American Tribes, which records official insignia of Native American tribes in the United States of America in order to improve the review of trademark applications and determinations regarding the registrability of marks;¹⁰

(ii) measures for the adaptation of existing rights to deal specifically with TK subject matter: for example, amendments to national IP legislation, such as the Patent (Amendment) Act of 2002 of India precluding as patentable subject matter inventions which are TK or which are an aggregation of known properties of traditionally known components;¹¹

(iii) measures for the creation of new rights or the combination of existing rights with non-IP elements under *sui generis* regimes: for example, the Provisional Measure N.2186-16 of Brazil combines the grant of exclusive IP rights with other legal elements, namely access regulation.¹²

14. A truly comprehensive menu of policy measures for TK protection would thus encompass a spectrum of TK protection measures and would enable national policy makers to select the most suitable measures for their domestic context. Most importantly, given the ongoing policy development processes and the debate over appropriate forms of TK protection, this assessment of options would create a clearer policy context for considering what is an important question for policymakers and legislators:

- whether, and how, it is appropriate to establish or recognize specific, intangible property rights in TK *as such*, akin to patent rights or copyright, or
- whether other forms of protection would be more appropriate, such as various combinations of a right of prior informed consent within an access regime, an entitlement to receive equitable remuneration or compensation, an entitlement to take action against misuse of TK which constitutes misleading, deceptive or offensive behavior, or an entitlement to challenge third party IP rights which are asserted over TK subject matter.

¹⁰ The database is available at the USPTO's web site, as part of the USPTO's internationally accessible Trademark Electronic Search System (TESS). See: www.uspto.gov/main/trademarks.htm.

¹¹ See Section 4(e), Patents (Amendment) Act of 2002.

¹² See WIPO/GRTKF/IC/5/INF/4, Annexes 1 and 2.

15. In order to save space, the present document is focused in the following ways:

(i) The primary focus is on the protection of TK, particularly through *sui generis* or tailored mechanisms, within *national* legal systems, giving effect, as appropriate, to international standards and principles. The international dimension of protection is addressed in-depth in document WIPO/GRTKF/IC/6/6.

(ii) The policy and legal options set out in this document concern only TK *stricto sensu*, i.e. the content or substance of traditional know-how, skills, practices and learning, rather than the form of expression. While some *sui generis* measures referred to in the document may also address related TCEs/EoF, that subject matter is covered in the parallel document WIPO/GRTKF/IC/6/3, and this document focuses on TK as such.

(iii) The comparative analysis of *sui generis* measures concentrates on specific legislation or the establishment of distinct registration mechanisms, rather than on the ancillary *sui generis* measures within many legal and administrative systems.¹³

(iv) Defensive protection of TK is covered only briefly, since documents WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/8 cover this more extensively. Even so, positive and defensive protection can form two sides of the same coin and are frequently combined in practice. Hence, several existing *sui generis* laws for TK protection covered in this document promote both positive and defensive objectives.

(v) The document addresses the positive protection of TK through improved application of existing IPRs, adaptation of existing IP rights, the creation of new *sui generis* IP rights, and the use of legal tools from related policy areas which are combined with IP elements in *sui generis* measures. Aspects of TK have been widely protected through existing, conventional IP rights, and this has been extensively surveyed in past Committee documents.¹⁴ It surveys legal-policy options used in existing *sui generis* measures, in order to inform consideration of the need and direction for specific policy measures for TK protection, in those cases where policymakers elect to develop new measures. This focus is not intended to suggest that existing IP tools and options do not effectively protect TK, nor that the wealth of experience in the practical use of existing IP mechanisms should not be further built upon, as this is a valuable source of benefits for TK holders. As a brief illustration, this kind of effective protection has included patents obtained by TK holders on innovations in traditional medicine, geographical indications and certification marks for TK-based products, design protection for original designs within a TK heritage, and the use of unfair competition and similar laws to protect the authenticity and true indigenous quality of TK-based products.

II. PRINCIPLES AND OBJECTIVES FOR PROTECTION

16. Existing TK protection laws and policy discussions on the protection of TK have articulated and given effect to a number of general principles and objectives. In the Committee's discussions, IP-related principles and objectives have crystallized over two years

¹³ E.g. specific measures concerning the patentability of traditional knowledge as such, whether they are specific legislative provisions (e.g. precluding "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components," note 11 above) or simply administrative practice and judicial decisions concerning this subject matter.

¹⁴ The main documents of the Committee which have exhaustively surveyed and analyzed this issue include WIPO/GRTKF/IC/3/5, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7.

through questionnaire responses,¹⁵ policy statements,¹⁶ panel presentations,¹⁷ document submissions,¹⁸ notified national laws¹⁹ and documented practical experience. The present Section lists some key principles of TK protection that emerge from this background material. The policy objectives that emerge from the same material are listed in Section IV.1 below in five general categories (paragraphs 52 to 55). These lists provide a distillation of common principles and objectives in existing systems for TK protection.

17. The Committee may wish to formulate key principles and objectives for TK protection which it considers appropriate, utilizing the catalogues of existing principles and objectives contained in Sections II and IV.1 of this document. If the Committee so decides, the principles and objectives which are agreed by Committee members could form the nucleus for developing an annotated menu of policy and legal measures. As document WIPO/GRTKF/IC/6/6 on the international dimension of TK protection points out, “[o]ne common element in each of the norm-building processes ... is the identification of certain core principles that would apply to use of the IP system to protect TK.”

18. *A comprehensive and combined approach to TK protection*, including the combined use of existing IP mechanisms, the repression of unfair competition, the grant of exclusive *sui generis* rights and/or the application of prior informed consent requirements linked to access regimes: appropriate protection of TK should be based on a combination of approaches, including any or all of these legal tools. This would ensure the flexibility needed to adapt TK protection to the needs of TK holders, customary uses, custodianship patterns and the legal environment of each respective country or community. It should be noted that the basic principle of a “combined approach” also applies in the conventional fields of IP law and practice. For example, copyright, industrial design and unfair competition laws (such as those suppressing passing off or slavish imitation) can serve as a combined form of protection for ornamental or visually distinctive aspects of products, with the mix of legal measures varying between jurisdictions. A combined approach, employing diverse legal tools, was used in the majority of national TK protection measures described at the fifth session of the Committee and has also been recommended by numerous countries in their statements at past sessions of the Committee.²⁰ A combined approach was also recommended by technical submissions of regional organizations²¹ and multilateral fora specializing in TK protection.²²

¹⁵ See WIPO/GRTKF/IC/Q.1, WIPO/GRTKF/IC/Q.3, WIPO/GRTKF/IC/Q.4.

¹⁶ See WIPO/GRTKF/IC/1/13, WIPO/GRTKF/IC/2/16, WIPO/GRTKF/IC/3/17, WIPO/GRTKF/IC/4/15 and WIPO/GRTKF/IC/5/15.

¹⁷ See WIPO/GRTKF/IC/5/INF/4.

¹⁸ For example, see WIPO/GRTKF/IC/1/8, WIPO/GRTKF/IC/1/10, WIPO/GRTKF/IC/4/14.

¹⁹ See <<http://www.wipo.int/tk/en/laws/index.html>>.

²⁰ See African Group (WIPO/GRTKF/IC/4/15, para. 95, and WIPO/GRTKF/IC/3/15, Annex, page 5), European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5), Andean Community (WIPO/GRTKF/IC/3/17, para.240), Canada (WIPO/GRTKF/IC/4/15, para. 142), Colombia (WIPO/GRTKF/IC/3/17, para. 222), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Nigeria (WIPO/GRTKF/IC/5/15, para. 37), Panama (WIPO/GRTKF/IC/3/17, para. 226, and WIPO/GRTKF/IC/4/15, para. 157), Russian Federation (WIPO/GRTKF/IC/4/15, para. 144), Thailand (WIPO/GRTKF/IC/3/17, para.216), Venezuela (WIPO/GRTKF/IC/3/17, para. 213), Turkey (WIPO/GRTKF/IC/4/15, para. 109), and the Saami Council (WIPO/GRTKF/IC/5/15, para. 53, and WIPO/GRTKF/IC/4/15, para. 115).

²¹ See Conclusions of the Expert Workshop on Intellectual Property, TK and Genetic Resources of the South Asian Association for Regional Cooperation (SAARC), held in New Delhi, India, from November 17 to 18, 2003.

19. *Repression of unfair competition, including appropriation and misuse of distinctive traditional characteristics:* This could entail the legal suppression of any false, misleading or culturally offensive references to TK in the commercial arena, and any false or misleading indications or linkage with or endorsement by TK holders. To this end, the general unfair competition principles of the Paris Convention²³ could be applied more specifically to enhance their effectiveness in relation to TK and the interests of TK holders. Unfair competition principles are variously applied in the national measures of the Costa Rica, Peru, Portugal and the United States of America, and there are a number of judicial decisions that give effect to these principles to defend TK holders' interests, for example in suppressing false claims of 'indigenous' or 'authentic' products. Based on these national experiences, one future venue for appropriate TK protection could be for the Committee to develop and adapt existing unfair competition principles to TK subject matter. A principle of fair competition has also been recommended by a number of Committee members, regional groups and organizations,²⁴ and has been proposed in other fora as well.²⁵

20. *A principle of recognition of rights of TK holders in their traditional innovations and know-how:* such rights might pertain to conventional IP rights arising from the innovation and intellectual activity contained in TK elements; they may be *sui generis* exclusive rights that may be available for TK; they may be entitlements as an aggrieved party to seek certain remedies for misuse of TK, including moral offence or unacceptable commercial behaviour; they may constitute an entitlement to grant or withhold prior informed consent concerning access to TK, or an entitlement to remuneration or equitable benefit-sharing; or the rights may draw on or give effect to rights of TK holders under customary laws and protocols within their communities. This principle is reflected in general terms in existing international legal instruments, which concern TK,²⁶ and in many of the national TK protection measures described at the fifth session of the Committee. It has also been recommended in working documents and statements of Committee members at past sessions of the Committee.²⁷

[Footnote continued from previous page]

²² See, for example, para. 33 of Decision VI/10A of the COP to the CBD. See also the Report of the Second Meeting of the Working Group on Article 8(j) and Related Provisions and the Report of the AHTEG on GURTS.

²³ See paras. 10*bis* and 10*ter* of the Paris Convention, and the WIPO Model Provisions on Protection Against Unfair Competition (1996).

²⁴ See, for example, the statements of the Andean Community (WIPO/GRTKF/IC/3/17, para.240), Norway (WIPO/GRTKF/IC/3/17, para.227²⁴), Panama (WIPO/GRTKF/IC/3/17, para 226), South Africa (WIPO/GRTKF/IC/5/15, paras. 116 and 129), Zambia (WIPO/GRTKF/IC/3/17, para.232) and the document submission of GRULAC (WO/GA/26/9, Annex I, page 2, and Annex II, page 4).

²⁵ See for example the CBD Secretariat study "Legal and Other Appropriate Forms of Protection for the Knowledge, Innovations and Practices of Indigenous and Local Communities Embodying Traditional Lifestyles Relevant for the Conservation and Sustainable Use of Biological Diversity," UNEP/CBD/WG8J/1/2 (January 2000), para. 37.

²⁶ See Article 17(c) of the United Nations Convention to Combat Desertification (UNCCD).

²⁷ See, for instance, the policy statements of the African Group (WIPO/GRTKF/IC/4/15, para. 95), Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 3, and WIPO/GRTKF/IC/4/15, para. 120), Andean Community (WIPO/GRTKF/IC/3/17, para.240), China (para. 95, WIPO/GRTKF/IC/5/15), Colombia (WIPO/GRTKF/IC/3/17, para. 222), India (WIPO/GRTKF/IC/4/15, para. 140), Panama (WIPO/GRTKF/IC/3/17, para 226), Turkey (para. 109, WIPO/GRTKF/IC/4/15), and Venezuela (WIPO/GRTKF/IC/3/17, paragraph 213).

21. *A principle of prior informed consent (PIC)*: This would entail confirming that TK which is held by a traditional community should not be accessed, recorded, used or commercialized without the prior informed consent of traditional knowledge holders.²⁸ This broad principle is variously effected through common-law decisions concerning confidentiality and fiduciary relationships,²⁹ implied in the provisions of international legal instruments,³⁰ implemented in most of the national TK protection measures presented at the fifth session of the Committee,³¹ proposed in several working documents submitted by regional groups to the Committee,³² recommended in numerous policy statements by Committee members,³³ and provided in a number of questionnaire responses on national TK protection in response to questionnaire WIPO/GRTKF/IC/2/5.³⁴ PIC concerning TK is also a common feature of laws governing access to genetic resources, and its application has been further elaborated in the Bonn Guidelines established under the CBD.

22. *A principle of equity and benefit-sharing*: This would provide that the protection of TK should be undertaken in a manner conducive to social and economic welfare, and to a balance

²⁸ See WIPO/GRTKF/IC/6/INF/4, para.4(a)

²⁹ *Foster v. Mountford and Rigby* (1976) 29 FLR 233

³⁰ The CBD Secretariat notes that the principle of PIC is “embedded in the wording of Article 8(j), whereby, subject to national legislation, the wider application of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity should only occur ‘with the approval and involvement of the holders of such knowledge, innovations and practices.’” See also Section IV. C of the Bonn Guidelines.

³¹ See for example the African Model Law, the laws of Brazil, Costa Rica, India, Peru, The Philippines and Portugal (WIPO/GRTKF/IC/5/INF/4, Annex 1.

³² See the submissions of the African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, Proposals 3.3(c) and 3.4(d)) and GRULAC (WO/GA/26/9, Annex I, page 2, and Annex II, page 4).

³³ See African Group (WIPO/GRTKF/IC/1/13, para. 154, referring to WIPO/GRTKF/IC/1/10), Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/5/15, paragraph 86, WIPO/GRTKF/IC/4/15, paragraph 103, WIPO/GRTKF/IC/2/14, Annex, para. 15), Canada (WIPO/GRTKF/IC/5/15, para. 92), Colombia (WIPO/GRTKF/IC/3/17, para. 222), Cuba (WIPO/GRTKF/IC/5/15, para. 97), Egypt (WIPO/GRTKF/IC/5/15, para. 96, 127 and WIPO/GRTKF/IC/4/15, para. 153), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5, and WIPO/GRTKF/IC/1/8, Annex III, para. 34), Islamic Republic of Iran (WIPO/GRTKF/IC/5/15, paragraph 119), Kenya (WIPO/GRTKF/IC/5/15, para. 69 and WIPO/GRTKF/IC/4/15, para. 111), Mexico (WIPO/GRTKF/IC/5/15, para. 70, and WIPO/GRTKF/IC/4/15, para. 97), Panama (WIPO/GRTKF/IC/3/17, para 226), Peru (WIPO/GRTKF/IC/4/15, paras. 96, 127, and WIPO/GRTKF/IC/3/17, para. 221), the Philippines (WIPO/GRTKF/IC/5/15, para. 85), Turkey (WIPO/GRTKF/IC/4/15, para. 109), the United States of America (WIPO/GRTKF/IC/4/13, para. 8), Venezuela (WIPO/GRTKF/IC/4/15, para. 94, and WIPO/GRTKF/IC/3/17, para. 132), Zambia (WIPO/GRTKF/IC/3/17, para.213), and the Pauktuutit Inuit Women’s Association, the Canadian Indigenous Biodiversity Network and the Kaska Dena Council (WIPO/GRTKF/IC/5/15, para. 75), Tebtebba Foundation (WIPO/GRTKF/IC/5/15, para. 77), Indian Movement Tupaj Amaru (WIPO/GRTKF/IC/5/15, para. 80), the Pauktuutit Inuit Womens Association on behalf of the Arctic Athabaskan Council, the Assembly of First Nations, the Call of the Earth Circle, the Canadian Indigenous Biodiversity Network, the Indigenous Peoples Biodiversity Network, the Kaska Dena Council, the Pauktuutit Inuit Women’s Association, and the Tulalip Tribes of Washington (WIPO/GRTKF/IC/5/15, para. 172), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

³⁴ See WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7.

of rights and obligations, and that the commercial use of TK should be subject to equitable sharing of benefits, as a particular aspect of a general principle of equity.³⁵ A broad principle of equity is central to general IP law³⁶ and is also implied in non-IP international legal instruments.³⁷ It is also expressed in some form in most of the national TK protection measures presented at the fifth session of the Committee,³⁸ in numerous statements of Committee members,³⁹ in various working documents submitted by regional groups to the Committee,⁴⁰ and in a number of questionnaire responses on TK protection provided in response to WIPO/GRTKF/IC/2/5. The application and basic elements of the principle in practice have been further elaborated by soft law instruments such as the Bonn Guidelines⁴¹.

23. *A principle of regulatory diversity, including sectoral distinctions:* This would acknowledge that a comprehensive use of TK protection measures may need to reflect distinct policy objectives in specific sectors, and may need to be integrated with different sectoral regulatory systems at the national level. For instance, distinct measures have been developed at the national level to regulate traditional medicine, traditional agricultural practices, TK associated with genetic resources and tradition-based industries (such as handicraft production). TK protection may need to be tailored and adapted according to the distinct policy needs of these areas of regulation, as well as the distinct characteristics of TK in these sectors. Such sectoral distinctions have been proposed by Committee members when discussing elements of *sui generis* protection for TK,⁴² and are apparent in existing *sui generis* laws which focus on a particular sector, rather than on TK across all sectors. Different policy environments are apparent also in those international instruments which address TK promotion and protection in specific sectors, such as the protection of biodiversity-related TK within the context of conservation of biological diversity, the farmers' rights provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), and the reference to traditional medicine in the World Health Organization's Alma Ata Declaration on Primary Health Care (1978). Conventional forms of *sui generis* IP protection tend also to take account of particular aspects of the sector they are

³⁵ See document submitted by GRULAC (WO/GA/26/9, Annex I, page 3).

³⁶ See Article 7 of the WTO TRIPS Agreement.

³⁷ See Article 8(j) of the CBD, Article 17(c) of the UNCCD, and Section IV. D of the Bonn Guidelines.

³⁸ See the African Model Law and the laws of Brazil, Costa Rica, India, Peru, the Philippines and Portugal.

³⁹ See, for instance, the African Group (WIPO/GRTKF/IC/4/15, para. 12), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5), Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), France (WIPO/GRTKF/IC/5/15, para. 14), Panama (WIPO/GRTKF/IC/3/17, para. 226), Peru (WIPO/GRTKF/IC/4/15, para. 127, and WIPO/GRTKF/IC/3/17, para. 221), the United States of America (WIPO/GRTKF/IC/4/13, para. 9), Venezuela (WIPO/GRTKF/IC/3/17, para. 213), and Zambia (WIPO/GRTKF/IC/4/15, para. 156).

⁴⁰ See the document submissions of the African Group (WIPO/GRTKF/IC/3/15, Annex, page 3, and WIPO/GRTKF/IC/1/10, Annex, Proposals 3.3(c) and 3.4(d)), the European Community and its Member States (WIPO/GRTKF/IC/1/8, Annex III, para. 34), GRULAC (WO/GA/26/9, Annex I, page 2, and Annex II, page 4, and WIPO/GRTKF/IC/1/5, Annex I, page 2).

⁴¹ See Section IV. D of the Bonn Guidelines.

⁴² See statement of the Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 4 and page 7), the Republic of Korea (para. 93, WIPO/GRTKF/IC/5/15), Nepal for SAARC (WIPO/GRTKF/IC/4/15, para. 14), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Norway (WIPO/GRTKF/IC/4/15, para. 133), and the International Chamber of Commerce (WIPO/GRTKF/IC/4/15, para. 161).

aimed at (for example, plant variety rights and integrated circuit protection). This principle would recognize that TK protection has to be coordinated and consistent with policy objectives and regulatory mechanisms in related areas, and may therefore differentiate between different sectors.

24. *A principle of adapting the form of protection to the nature of TK:* TK, like the customary laws and practices and communities that hold it, is diverse in character. When developing and applying legal doctrines to protect TK, whether through exclusive property rights or other means, the form of TK protection may be shaped or guided by the particular characteristics of the TK in question. TK may be disclosed or undisclosed TK, attributable or unattributable, collectively or individually held, codified or uncodified, and may be defined and bounded by diverse forms of customary laws and protocols. Different forms of appropriate protection might include defensive vs. positive protection; protection through exclusive rights vs. unfair competition protection vs. PIC requirements, etc. Such appropriate protection can be ensured by adapting, extending or combining the different legal doctrines tools listed in Section III. For example, exclusive property rights should be granted only where a clear right holder – a community or individual - is identifiable, whereas prior informed consent requirements could be applied more broadly than exclusive rights. Finally, repression of unfair competition and/or compensatory liability rules could be applied even more broadly than prior informed consent requirements and private property rights because they do not grant any right to block uses of TK (other than acts of unfair competition). A similar concept has been termed ‘jurisprudential diversity:’ “Any attempt to devise uniform guidelines for the recognition and protection of indigenous peoples’ knowledge runs the risk of collapsing this rich jurisprudential diversity into a single ‘model’ that will not fit the values, conceptions or laws of any indigenous society.”⁴³

25. *A principle of effective and appropriate remedies:* TK protection should make available effective and expeditious remedies such as injunctions and penalties, or mechanisms for payment of use fees or other compensation where there is no outright prohibition on third party use. In the wider sense this principle might also need to address some practical issues, such as the possible collective administration of rights and the possible role for government agencies in monitoring and pursuing infringements of rights.⁴⁴ This may also extend to choice of law and appropriate means of dispute settlement. One expert has identified as a ‘principle of locality’ the resolution of ‘any disputes over the acquisition and use of indigenous people’s heritage according to the customary laws of the indigenous peoples concerned.’⁴⁵

26. *A principle of safeguarding customary uses:* customary uses of TK and associated genetic resources should be encouraged, and should not be restrained by the formal legal protection of TK nor by other IP rights.⁴⁶ The principle of safeguarding customary uses is

⁴³ Four Directions Council, ‘Forests, Indigenous Peoples and Biodiversity,’ Submission to the Secretariat for the CBD, 1996.

⁴⁴ See, African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, Proposal 3.4(g)).

⁴⁵ Dr. E.A.Daes, ‘Defending Indigenous Peoples’ Heritage,’ Protecting Knowledge: Traditional Resource Rights in the New Millennium, Union of British Columbian Indian Chiefs, February 2000.

⁴⁶ See, for examples, Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15)), Switzerland (WIPO/GRTKF/IC/1/9, Annex, pages 4), Thailand (WIPO/GRTKF/IC/3/17, para.216), the Assembly of First Nations, the Inuit Circumpolar Conference and the Métis National Council (WIPO/GRTKF/IC/4/15, para. 117).

enshrined in two international instruments⁴⁷ and in all but one national TK protection measures that were presented to the Committee at its fifth session. It is further reflected in softlaw instruments that apply to associated genetic resources.⁴⁸

27. *A principle of consistency with access and benefit-sharing frameworks for associated genetic resources:* Many TK protection measures are directly part of legal frameworks which regulate access to genetic resources and benefit-sharing;⁴⁹ others are based on certain provisions within such frameworks;⁵⁰ finally, some measures are stand-alone legislation which, however, need to be consistent with national access laws, which were in force even before TK protection laws were promulgated and which cover TK related to genetic resources as intangible components of biodiversity.⁵¹ Most of these laws are implementing legislation for international instruments which address both access to genetic resources and TK protection or preservation.⁵² Legal protection of TK associated to genetic resources should therefore be coordinated closely with policy frameworks applicable to the associated genetic resources, including their conservation, sustainable use and benefit-sharing. This principle has been emphasized by Committee members in their policy statements,⁵³ document submissions and Panel presentations. In addition to the policy objectives of such frameworks (i.e., conservation, sustainable use and benefit-sharing in respect of genetic resources), TK protection measures might also take into account policy objectives in related fields such as primary health care in traditional medicine, food security in traditional agriculture, etc;

28. The following principles, governing procedural and consultative processes, may also be considered by the Committee as being relevant to the development of TK protection:

(a) *A principle of full and effective participation of TK holders:* Traditional communities should be directly involved in decision-making about the protection, use and commercial exploitation of their TK, using customary decision-making processes, laws and protocols as far as possible. Committee participants have repeatedly articulated this notion as a principle for future work.⁵⁴ From the point of view of the Committee's work, this issue is addressed in documents WIPO/GRTKF/IC/5/11 and WIPO/GRTKF/IC/6/9.

⁴⁷ See Article 10(c), CBD, and Article 8, ITPGR.

⁴⁸ See the Bonn Guidelines, Articles 43(b) and 44(a).

⁴⁹ See the TK protection measures of the African Union, Brazil and Portugal (WIPO/GRTKF/IC/5/INF/4).

⁵⁰ See the laws of Costa Rica and India, and the draft ASEAN Framework Agreement.

⁵¹ See the TK protection measures of Peru and the Philippines.

⁵² In particular the CBD and ITPGR.

⁵³ See African Group (WIPO/GRTKF/IC/3/15, Annex, page 3), European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5), and the United States of America (WIPO/GRTKF/IC/4/13, Annex, page 3), Zambia (WIPO/GRTKF/IC/3/17, para.232).

⁵⁴ See the statements of ARIPO (WIPO/GRTKF/IC/4/15, para. 114), European Community (WIPO/GRTKF/IC/3/16, page 5), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), Colombia (WIPO/GRTKF/IC/4/15, para. 145), Mexico (WIPO/GRTKF/IC/4/15, para. 97), Venezuela (WIPO/GRTKF/IC/4/15, para. 147), Saami Council (WIPO/GRTKF/IC/5/15, para. 76), GRAIN (WIPO/GRTKF/IC/5/15, para. 78), United Nations University (WIPO/GRTKF/IC/5/15, para. 103), GRULAC (para. 12, WIPO/GRTKF/IC/4/15), Indigenous' Biodiversity Network (WIPO/GRTKF/IC/4/15, para. 160), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

(b) *A principle of coordination with other relevant fora and processes*, in particular the relevant processes of the CBD, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO): these processes include the Ad-Hoc Open-ended Working Groups on Access and Benefit-sharing and on Article 8(j) and Related Provisions of the CBD; the FAO Commission on Genetic Resources for Food and Agriculture and the impending Governing Body of the ITPGR; and the WHO Traditional Medicine Program. Other relevant fora and processes might include TK-related activities of the United Nations Convention to Combat Desertification (UNCCD) and of the WTO. Numerous Committee participants have emphasized this need for coordination in their policy statements at previous sessions.⁵⁵

Options: principles and objectives

29. One option for focussing national efforts for protection of TK and promoting cooperation and consensus at the international level would be the identification and authoritative articulation of key principles and policy objectives for TK protection. This would provide a common platform for national, regional and international measures and activities. It would also help to ensure the consistency and compatibility of more elaborated legal and policy options for TK protection.

30. While key principles could provide guidance and unity of overall objectives, more diverse legal doctrines, legal mechanisms and policy tools would have to be employed to provide the necessary flexibility in the implementation of detailed measures that function to serve those objectives. Once principles and objectives of protection have been defined, those legal doctrines which are most appropriate to the domestic context and which effectively implement the agreed objectives could be applied. The next Section outlines several legal doctrines which have been used for TK protection and which, in combination, may provide the necessary flexibility to implement agreed principles and objectives in diverse legal and socio-economic contexts.

⁵⁵ See the African Group (WIPO/GRTKF/IC/4/13, Annex, page 8, and WIPO/GRTKF/IC/1/10, Annex, page 6, proposal 3.3(g)), Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 4), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5), GRULAC (WIPO/GRTKF/IC/4/15, para. 12), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 5), India (WIPO/GRTKF/IC/5/15, para. 100), Niger (WIPO/GRTKF/IC/3/17, para.237), Switzerland (WIPO/GRTKF/IC/3/17, para. 224), Venezuela (WIPO/GRTKF/IC/4/15, para. 122), Zambia (WIPO/GRTKF/IC/5/15, para. 19), FAO (WIPO/GRTKF/IC/5/15, para. 101), Saami Council (WIPO/GRTKF/IC/5/15, para. 76), International Plant Genetic Resources Institute (WIPO/GRTKF/IC/5/15, para. 104), INADEV (WIPO/GRTKF/IC/4/15, para. 116).

III. LEGAL DOCTRINES AND POLICY TOOLS FOR PROTECTION

31. The diversity of already existing TK protection systems, the diversity of TK formations and the diversity of the needs, legal heritage and social structures of TK holders will require a degree of flexibility in how agreed principles and objectives would be implemented at the national level. Existing *sui generis* measures manifest similar broad goals and principles, even though the specific choices taken to carry them out in elaborated legislation are already diverse and variable. When developing a menu of legal and policy options, such flexibility can be achieved by drawing selectively on general legal doctrines in order to tailor the form of protection to the specific needs, TK subject matter, and legal systems of a given jurisdiction. A similar situation prevails in other branches of IP law. Existing IP instruments allow for flexibility in how protection is made available at the national level. This applies especially to some forms of *sui generis* protection established in international instruments, which may be undertaken through special-purpose IP laws, existing IP laws, and other areas of law beyond IP. For example, the *sui generis* protection of layout-designs of integrated circuits established in the Washington Treaty on Intellectual Property in Respect of Integrated Circuits (1978) provides (at Article 4) that:

“Each Contracting Party shall be free to implement its obligations under this Treaty through a special law on layout-designs (topographies) or its law on copyright, patents, utility models, industrial designs, unfair competition *or any other law or a combination of any of those laws.*” (emphasis added)

Similarly, the Phonograms Convention (Article 3) provides that its means of implementation ‘shall be a matter of domestic law ... and shall include’ protection by means of one or more of ‘the grant of copyright or other specific right,’ ‘the law relating to unfair competition,’ or ‘penal sanctions.’

32. Flexibility at the level of national law may also be necessary in determining the identity of right holders and confirming their legal personality or standing (*locus standi*), the beneficiaries from TK protection, the nature of benefits provided, and the means of administering the sharing of benefits, even though this may conform with broad principles.

33. In keeping with established precedents in the IP field while recognizing the diversity of existing TK protection measures in different national systems, this Section sets out four basic doctrines which have been used as policy tools for TK protection in national law. These doctrines are not mutually exclusive but are complementary. The Committee is therefore not required to choose among them, but rather may combine them flexibly, in order to suit its needs, priorities and objectives. The doctrines have been used in various combinations by national lawmakers to provide adequate and customized forms of legal protection. So selective combination of these legal tenets could build a sufficiently versatile doctrinal basis for TK protection. This would help to develop the range of legal and policy options that could accommodate diverse national legal systems and tailor flexible bundles of measures which could provide customized protection for different types of TK. The creation of a scaled bundle of protection measures may be required because different types of TK may require different forms of protection. By drawing upon variable sources of legal doctrine, an annotated menu of policy options could facilitate a “combined approach” to TK protection as outlined in the previous Sections. The main doctrines that have been used in their existing protection systems are:

(a) *the grant of exclusive property rights for TK*: the creation of property rights, giving the right to prevent others from certain use of the protected TK. Such rights may be communally or collectively held. Typically, including in existing *sui generis* systems, this entails the protection of certain aspects of TK which are susceptible to misappropriation, rather than a direct equivalence with all aspects of TK in its customary setting. This approach may include:

- (i) use of existing IP rights;
- (ii) modified, adapted or extended forms of conventional IP rights;
- (iii) *sui generis* measures granting newly defined exclusive property rights;

(b) *the application of the principle of prior informed consent*: this approach provides TK holders with the entitlement for prior informed consent (PIC) for the use, reproduction or commercial exploitation of their TK, and provides for benefit-sharing arrangements to be established as a condition of access. Measures applying the PIC principle to TK are often part of a regime regulating access to genetic or biological resources;

(c) *a compensatory liability approach*: systems providing for some form of equitable remuneration or compensation to TK holders for the use of their TK, without creating an exclusive IP right over the TK. This is found in some national copyright and related rights systems, such as compulsory licensing arrangements for certain public uses of musical works. A compensatory liability approach for the protection of TK is found in the *sui generis* law of Peru, ‘in cases where the collective knowledge has passed into the public domain within the previous 20 years,’ in which case a payment is made into a common fund based on “a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge.”⁵⁶

(d) *an unfair competition approach*: the suppression of unfair competition and misleading or deceptive trade practices through the application of a cluster of principles such as truth-in-advertising, the protection of confidentiality, unjust enrichment, and passing off.

(e) *the recognition of customary law*: for Indigenous and local communities, the recognition and protection of TK is often rooted in customary laws and protocols, that govern how knowledge is generated, maintained and transmitted within the community, and the call has been made for TK protection to be based on enhanced respect for these customary laws. Several *sui generis* measures, as well as conventional IP law, have recognized elements of such customary law within a broader framework of protection.

34. There is considerable overlap between these different approaches, and the boundaries between them are not precise. Nonetheless, they are useful characterizations of the main general possibilities that have been used. Most existing *sui generis* systems combine at least two of these legal concepts. For example, some *sui generis* protection laws for TK regulate access and benefit-sharing for a broad range of TK and also provide for the grant of exclusive rights over a more confined span of TK.⁵⁷ A compulsory liability regime or PIC regime (setting a rate of compensation for use of protected TK) could be combined with a right to

⁵⁶ See WIPO/GRTKF/IC/5/INF/2, Annex II, page 14.

⁵⁷ See African Model Legislation of 2000; Provisional Measure No. 2186-16 of 2001 of Brazil; Law No. 7788 of 1998 on Biodiversity of Costa Rica; Biological Diversity Act of 2002 of India; Law No. 27,811 of 2002 of Peru; Indigenous Peoples’ Rights Act of 1997 of the Philippines; and Decree Law No.118 of 2002 of Portugal.

exclude culturally offensive or degrading uses altogether. Customary law could be used in conjunction with any of the other doctrines to determine questions of ownership, sharing of benefits within the community, nature and degree of damages and other remedies, and means of dispute settlement.

35. The following paragraphs will elaborate each of these tools and contextualize them within a combined approach to TK protection with their advantages and disadvantages. If the basic principle of a combined and comprehensive approach were adopted by the Committee, this elaboration may allow the identification of the basic policy tools, which the Committee may wish to use in developing protection measures which could be recommended.

1 Grant of exclusive rights over TK

36. A core characteristic of numerous intellectual property systems is the grant and exercise of exclusive property rights in the protected subject matter, and this is one option for TK that is sufficiently distinct and has a clear owner or custodian, even if this entails recognizing rights and entitlements that are communally or collectively held. Exclusive property rights in protectable elements of TK can be undertaken through (i) conventional forms of IP rights; (ii) amended forms of existing IP rights; or (iii) new *sui generis* rights which are tailored to suit the characteristics of TK subject matter and the interests of TK holders. This is the distinctive mechanism most associated with IP policy and legislation, and is common to most forms of IP protection, although other associated mechanisms (moral rights, rights to equitable remuneration or other compensation, standing as an aggrieved party to take action against unfair competition and similar wrongs) are also part of the broader architecture of the IP system.

Use of Conventional IP Rights

37. Although the limitations of existing IP laws have been widely underlined in the TK debate, conventional IP mechanisms have been effectively used to protect TK and related genetic resources. There are many examples of the successful use of existing IP rights to protect TK against misuse, misappropriation and commercial free-riding, including through the laws of patents, trademarks, geographical indications, industrial designs, and trade secrets.⁵⁸ Certain modifications to IP law may improve its functionality in TK protection. For example, concerns have been expressed that TK holders have difficulty in availing themselves of the benefits of the IP system, because of the costs associated with the acquisition, maintenance and enforcement of IPRs. A number of improvements have been considered by the Committee to improve the access for TK holders to existing IP systems. These include legal evolution (including identifying the legal personality of traditional communities, altering evidentiary rules, altering the base of prior art used in assessing TK-related patents, revisiting the application of the concept of 'person skilled in the art' in assessing inventive step,⁵⁹ and recognizing customary law), capacity building and appropriate dispute settlement mechanisms.

⁵⁸ See WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7 for a survey of existing uses of these IPR tools for TK protection in WIPO Member States.

⁵⁹ See Asian Group submission, WIPO/GRTKF/IC/4/14.

38. Existing IP rights have been used to protect TK or TK-related subject matter in the following ways:⁶⁰

- Geographical indications or collective/certification marks: these forms of IP have been used to protect products made with traditional technologies, including products that are particularly associated with a particular region or community (for example, Vietnam is establishing geographical indications to protect traditional Vietnamese pickled food products, which are associated with a particular region);
- Unfair competition and trade practices laws: such laws have been used to take action against false claims of indigenous authenticity or other claims that a product is produced by or associated with a particular traditional community;
- Patent rights: the patent system has been used by practitioners of traditional medicine to protect their innovations (for example, in 2002 China granted 4479 patents for Traditional Chinese Medicine(TCM) in China), and systems have been developed to ensure that illegitimate patent rights are not granted over non-novel TK subject matter;
- Trade mark rights: distinctive signs, symbols and terms associated with TK have been protected as trade marks, and have been safeguarded against third parties' claims of trade mark rights (for example, the logo for the Kyana Aboriginal Cultural Festival has been registered by the indigenous artist who created it⁶¹);
- Copyright and related rights: while extending only to the form of expression of TK, and not its ideas or content, copyright and related rights have been useful in protecting TK when it is recorded in a fixed form, or protecting against the illicit recording of TK, for instance when it may be passed on by the performance of a traditional chant, song or story (document WIPO/GRTKF/IC/6/3 deals with legal and policy options for the protection of traditional cultural expressions);
- The law of confidentiality and trade secrets: non-disclosed TK, including secret and sacred TK, has been protected as confidential or undisclosed information, and remedies have been awarded for breach of confidence in contravention of customary laws.

39. In its past work, the Committee has developed possible means for improving access of TK holders to existing IP rights systems. Ways of enhancing existing IP systems to take account of TK holder interests may include:⁶²

- Clarifying the legal identity and status as IP right holders of TK holders as individuals or as communities;

⁶⁰ See ARIPO (WIPO/GRTKF/IC/4/15, para. 114), European Community (WIPO/GRTKF/IC/3/16, page 3, and WIPO/GRTKF/IC/1/8, Annex IV, page 6), Argentina (WIPO/GRTKF/IC/4/15, para. 158), the Republic of Korea (WIPO/GRTKF/IC/4/15, para. 155) and the United States of America (WIPO/GRTKF/IC/4/15, para.128).

⁶¹ See Case Study 2, page 13 ('Use of Trade Marks to protect Traditional Cultural Expressions') in *Minding Culture: Case-Studies on Intellectual Property and Traditional Cultural Expressions*. See WIPO/GRTKF/STUDY/2.

⁶² See Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 4, and WIPO/GRTKF/IC/4/15, para. 14), ARIPO (WIPO/GRTKF/IC/4/15, para. 114), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 3), France (WIPO/GRTKF/IC/5/15, para. 14), Japan (WIPO/GRTKF/IC/4/15, para. 129) and Switzerland (WIPO/GRTKF/IC/4/15, para. 135).

- Applying established principles such as protection of *ordre public* and morality in a manner that deals with concerns about offence to Indigenous and local communities;
- Clarifying the status of pre-existing TK as prior art and as unpatentable subject matter to ensure that third parties cannot obtain valid patents over such TK;
- Recognition of community interests and customary law considerations in determining sanctions, such as additional damages for cultural offence, in the enforcement of IP rights;
- Recognition of community interests and customary law considerations in giving standing to traditional communities on the basis of an equitable interest in a protected work;
- Tailoring alternative dispute resolution mechanisms to create appropriate and accessible avenues for TK holders to seek remedies.

For further details on these options see documents WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/8.⁶³

Use of sui generis exclusive rights

40. In the judgement of some communities and countries, however, the above-mentioned adaptations of existing IP rights systems may not be fully sufficient to cater to the holistic and unique character of TK subject matter.⁶⁴ The call for *sui generis* measures generally arises from such perceived shortcomings of conventional IP rights. Surveys of national experiences with the IP protection of TK⁶⁵ have mentioned the following issues, which may be relevant to the development of *sui generis* measures:

(i) difficulty meeting requirements such as novelty or originality, and inventive step or non-obviousness (this may be due at least in part to the fact that TK often dates back prior to the time periods associated with conventional IP systems, or are developed in a more diffuse, cumulative and collective manner, making invention or authorship difficult to establish at a fixed time);

(ii) requirements in many IP laws for protected subject matter to be fixed in material form (given that TK is often preserved and transmitted by oral narrative and other non-material forms);

(iii) the frequently informal nature of TK and the customary laws and protocols that define ownership (or other relationships such as custody and guardianship) which form the basis of claims of affinity and community responsibility;

⁶³ See WIPO/GRTKF/IC/5/8.

⁶⁴ Regional organizations which have expressed such views include of African Group (WIPO/GRTKF/IC/4/15, para. 95, and WIPO/GRTKF/IC/3/15, Annex, page 3), ARIPO (WIPO/GRTKF/IC/4/15, para. 114), the European Community and its Member States (WIPO/GRTKF/IC/3/16, Annex, page 5, and WIPO/GRTKF/IC/5/15, para. 18), and the GRULAC (WIPO/GRTKF/IC/4/15, para. 12). For statements to this effect by individual countries, see China (WIPO/GRTKF/IC/4/15, para. 134), France (WIPO/GRTKF/IC/5/15, para. 14), India (WIPO/GRTKF/IC/5/15, para. 100), New Zealand (WIPO/GRTKF/IC/3/17, para.230), Norway (WIPO/GRTKF/IC/4/15, para. 133), Turkey (WIPO/GRTKF/IC/4/15, para. 109), Venezuela (WIPO/GRTKF/IC/5/15, para. 98), Zambia (WIPO/GRTKF/IC/5/15, para. 19 and WIPO/GRTKF/IC/4/15, para. 100). See also United Nations University (WIPO/GRTKF/IC/5/15, para. 103).

⁶⁵ See WIPO/GRTKF/IC/5/7

(iv) the concern that protection systems should correspond to a positive duty to preserve and maintain TK, and not merely provide the means to prevent or exclude others from making unauthorized use (the characteristic function of IP rights);

(v) the perceived tension between individualistic notions of IP rights (the single author or inventor), as against the tendency for TK to be originated, held and managed in a collective environment (often making it difficult to identify the specific author, inventor or analogous creator that IP law is viewed as requiring); and

(vi) limitations on the term of protection in IP systems (calls for better recognition of TK often highlight the inappropriate nature of relatively brief terms of protection in conventional IP systems, as need for protection are seen as enduring beyond individual life spans for TK subject matter).

41. In practice, some of these shortcomings have in fact been overcome within the conventional IP system (for example, providing for communally held rights in TK). Even so, for policymakers in a number of countries these factors have led to the judgement that *sui generis* measures should be considered.⁶⁶ Section IV below discusses the key elements of *sui generis* measures, which would have to be considered in the development of any national system or any agreed model for protection. In cases where the grant of exclusive property rights – be they conventional IP rights or *sui generis* exclusive rights – may not be appropriate, the three other policy tools for TK protection may be considered, namely the prior informed consent principle, liability rules and unfair competition law. If the choice were taken to establish a stand-alone exclusive right in TK *per se*, this right would need to be communally held and exercised, associated with certain well-defined subject matter, and create the entitlement to take legal action to exclude third parties from certain prescribed uses of the protected TK

2 TK and prior informed consent

42. Regulation of TK is often linked with the regulation of access to tangible biological material and benefit-sharing. Under such regimes, access or other acts in relation to TK may be dependent on the prior informed consent (PIC) of the TK holders, and contracts, licenses or agreements may determine how benefits arising from the use of the TK are shared. The application of the PIC principle to TK enables a regulatory option to control the use of TK by third parties and ensure a flow of benefits to the knowledge holders, in a way that may be consistent with the collective nature of TK. Numerous Committee members have therefore integrated PIC into their TK protection measures or their policy statements.⁶⁷ PIC may be

⁶⁶ See African Group (WIPO/GRTKF/IC/3/15, Annex, page 3), the European Community and its Member States (WIPO/GRTKF/IC/5/15, para. 18), Canada (WIPO/GRTKF/IC/4/15, para. 142), Egypt (WIPO/GRTKF/IC/4/15, para. 153), Ghana (WIPO/GRTKF/IC/4/15, para. 149), Guyana (WIPO/GRTKF/IC/4/15, para. 143), Haiti (WIPO/GRTKF/IC/4/15, para. 154), Morocco (WIPO/GRTKF/IC/4/15, para. 152), Myanmar (, WIPO/GRTKF/IC/5/15, para 16), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Panama (WIPO/GRTKF/IC/4/15, para. 157), Venezuela (WIPO/GRTKF/IC/4/15, para. 147), Inuit Circumpolar Conference (WIPO/GRTKF/IC/4/15, para. 159), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

⁶⁷ See, African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, proposal 3.3(b)), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), Colombia (WIPO/GRTKF/IC/3/17, para. 223), Peru (WIPO/GRTKF/IC/3/17, para. 221) South Africa (WIPO/GRTKF/IC/3/17, para. 225), Venezuela (WIPO/GRTKF/IC/3/17, paragraph 213).

granted by a competent State authority;⁶⁸ it may be dependent on consent of the indigenous/local community or the TK owner.⁶⁹ Conditions for the grant of PIC may differ according to the proposed use of the TK.⁷⁰ Continuing access for customary uses of TK may be expressly exempted from the requirement for prior informed consent.⁷¹

3 Compensatory Liability Regimes

43. Suggestions have also been made for TK-specific innovation laws, built on modified liability principles. Such laws would entitle TK holders to compensatory contributions from TK users who borrowed traditional know-how for industrial applications of their own during a specified period of time. Some *sui generis* regimes utilize similar rules to reward TK holders for the conservation and development costs invested by the communities in certain elements of TK, without endowing exclusive property rights to control such uses.⁷² They would combine the equitable reallocation of benefits without constraining open access to know-how, and avoid the division or atomization of the community's shared TK base into ever-smaller parcels that are withdrawn from the TK holding community's own intellectual commons through the vehicle of private property rights. In some cases, there is concern that a web of exclusive rights over pre-existing TK, overlaying communal customary laws, could stand in tension with collective transmission and custodianship. The compensatory liability approach has also been used in cases where TK has already been published and publicly available for some time, so as to balance equitable benefit-sharing with prior use of TK undertaken in good faith.⁷³

4 Repression of unfair competition

44. While the repression of unfair competition has been recognized since 1900 as an object of industrial property protection under the Paris Convention⁷⁴, it does not grant exclusive rights over intangible property to the right holder. The law of unfair competition, construed in the broadest sense, covers a wide range of remedies, including repression of misleading and deceptive trade practices, unjust enrichment, passing off, and taking of unfair commercial advantage. Unfair competition law is potentially broad in scope, and it has been used in international instruments as a potential basis for protection of integrated circuit layout designs, geographical indications, undisclosed information and test data, and phonograms; in practice, it is also associated with the protection of trade marks, especially unregistered marks. As in other industrial property systems, it has therefore been discussed and used as a

⁶⁸ See Art.4 (1)(xi) and 4(1)(x), African Model Law; Art.11 (IV)(b), Brazilian Provisional Measure; Art.62, Costa Rican Biodiversity Law; Art.3(1), Indian Biodiversity Act; Art.7(1), Portuguese Decree Law 118.

⁶⁹ See, African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders (2000); Brazilian Provisional Measure Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge; Costa Rican Biodiversity Law No. 7788; Peruvian Law No. 27,811 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources; and Portuguese Decree Law No. 118 of 2002.

⁷⁰ Laws of Peru and Portugal (as above-mentioned in foot note No. 71).

⁷¹ Art.2(2)(ii), African Model Law, and Art.7, Indian Biodiversity Act.

⁷² See Peruvian Law No. 27811 of August 10, 2002.

⁷³ See, GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 2), Panama (WIPO/GRTKF/IC/4/15, para. 157) and Peru (WIPO/GRTKF/IC/6/INF/6 and Peru WIPO/GRTKF/IC/3/17, para. 221).

⁷⁴ See Art.1(2) and Art.10*bis*, Paris Convention.

tool for *sui generis* systems of TK protection,⁷⁵ which supplements the grant of exclusive rights and the application of PIC for TK subject matter. This is the case, for example, in several *sui generis* measures, which apply a truth-in-advertising approach to the marketing of indigenous craft products⁷⁶. The courts have also applied general unfair competition laws.

Customary laws and protocols

45. With each of these possible policy tools special attention must be given to the recognition of customary laws and protocols, which functions as a cross-cutting interface with local legal systems in all the above-mentioned tools.⁷⁷ A number of existing *sui generis* systems utilize references to customary laws and protocols as an alternative or as a supplement to the creation of modern IP rights over TK. For example, the African Model Law and the *sui generis* laws of Peru and the Philippines incorporate by reference certain elements of customary laws into the *sui generis* protection of TK. The relation between modern *sui generis* laws and customary laws ranges from the principle of independence of the rights granted by the modern and traditional systems (Peru) to the principle that the State protects rights specified in the modern *sui generis* legislation “as they are enshrined and protected under the ... customary law found in ... the concerned local and indigenous communities, whether such law is written or not” (African Model Legislation). The substantive use of customary laws ranges from obtaining Prior Informed Consent for access to TK “in accordance with customary laws” (Philippines), over the settlement of disputes arising among indigenous peoples in the implementation of TK protection (Peru), to the identification, interpretation and ascertaining of “community, knowledge or technology ... under their customary ... law” (African Model Law).

46. Even though the policy discussions surrounding customary laws and TK protection have been extensive, actual references to customary laws in existing *sui generis* laws have, to date, been fairly limited. Most existing *sui generis* laws do not contain direct references to customary laws, although recognition of customary law may be important in their practical implementation.

Issues and options: legal basis for protection

47. The following legal doctrines may be drawn on in developing a flexible and adaptable implementation of the agreed core principles and policy objectives:

⁷⁵ See GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 2), South Africa (WIPO/GRTKF/IC/5/15, paragraphs 116 and 129), and the United States of America (WIPO/GRTKF/IC/3/17, para. 213).

⁷⁶ See, for example, the Indian Arts and Crafts Act of 1990 of the United States of America.

⁷⁷ See document submission of the African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, proposal 3.3(b)). See the statements of the African Group (WIPO/GRTKF/IC/4/15, para. 95 and WIPO/GRTKF/IC/3/5, Annex, page 5), European Community (WIPO/GRTKF/IC/1/8, Annex IV, page 6), Iran (WIPO/GRTKF/IC/4/15, para. 150), Switzerland (WIPO/GRTKF/IC/1/9, Annex, pages 4 and 9), Peru (WIPO/GRTKF/IC/3/17, para. 221), South Africa (WIPO/GRTKF/IC/3/17, para 225), Venezuela (WIPO/GRTKF/IC/3/17, paragraph 213), Saami Council (WIPO/GRTKF/IC/5/15, para. 76), Indigenous Peoples’ Biodiversity Network (WIPO/GRTKF/IC/4/15, para. 160)

- provision of exclusive property rights, including conventional IP rights, adaptations of existing rights, and *sui generis* exclusive rights for TK;
- the repression of unfair competition;
- compensatory liability regimes;
- access and benefit-sharing mechanisms for TK, along the lines of genetic resource regimes; and
- recognition of customary laws and protocols.

Should the Committee elect to identify a common set of policy objectives and core principles, it would be possible to create a comprehensive study about how these legal doctrines have been used in practice to advance particular objectives and to give effect to particular principles, as the basis for a common, more elaborated approach to TK protection.

Aspects of traditional knowledge to be protected

48. In considering the choice of legal bases for protection, and in applying the objectives of protection, it may be necessary to consider the different aspects of TK and associated subject matter that may be protected, especially if a comprehensive approach is to be taken. Generally, the use of IP-related laws and doctrines may focus on three general aspects of traditional knowledge and culture:

(i) the content, substance or idea of traditional knowledge (such as traditional know-how about the medicinal use of a plant, traditional ecological management practices, traditional agricultural practices, etc.) – corresponding to the subject matter of patents, plant variety protection, utility models and know-how or trade secrets (this kind of protection concerns TK *strictu sensu*, and is treated in the present document);

(ii) the form, expression or representation of traditional cultures (such as a traditional song, performance, oral narrative or graphic design) – corresponding to the subject matter of copyright and performer's rights and rights in industrial and textile designs (this kind of protection concerns expressions of folklore or traditional cultural expressions (TCEs), and is treated in document WIPO/GRTKF/IC/6/3, among other documents); and

(iii) the reputation and distinctive character of signs, symbols, indications, patterns and styles associated with traditional cultures, including the suppression of misleading, deceptive and offensive use of this subject matter – corresponding to the subject matter of trademarks and geographical indications, the specific protection for national symbols under paragraph 6^{ter} of the Paris Convention, and unfair competition law in general.

49. A comprehensive framework for TK protection could include objectives and principles of protection, the legal doctrine on which the protection will be based, and clarification of the specific aspects of TK that are to be protected. On this basis, it is possible to tailor the elements of legal protection measures to give more precise effect to those objectives and principles. The next Section briefly sets out the chief elements of *sui generis* measures for TK protection that can be used in achieving this comprehensive but tailored protection for TK.

IV. DETAILED ELEMENTS OF PROTECTION IN NATIONAL LAWS

50. Some countries and communities have judged that the unique and holistic character of TK will require protection other than that available through conventional forms of IPR protection and non-IPR forms of protection (such as access regulation and contract law).⁷⁸ In these cases, countries have opted to establish *sui generis* approaches, which protect TK either in the intellectual property sense or in a related way, such as by governing access to resource-related TK. Some of these systems recognize elements of TK as intangible property, through the creation of specific rights in these elements. In other cases, private IP rights as such are not created, but protection operates by regulating access to TK and sharing of the benefits from its use. Most systems draw on multiple legal doctrines including those which are associated with IP and those that derive from related policy areas, such as biodiversity conservation and regulation, agriculture or traditional medicine and primary health care.

51. How may the Committee articulate basic features or principles of national systems for TK protection which may be recommended internationally? To assist in the policy process, this section outlines the main elements and policy options for *sui generis* protection of TK. It draws on existing *sui generis* mechanisms and the lessons learned by other countries and regions, and identifies elements common to existing systems. One practical question is whether consistencies or similarities emerge in the different *sui generis* approaches that are being developed. Identifying areas of consistency and communalities at the national and regional levels would have implications for international developments, including the international articulation of basic features or principles of national systems for TK protection. This would allow a coordinated, bottom-up approach to the development of an international approach⁷⁹ by distilling the essence of national standards and experiences, thus grounding the international discussion in a practical understanding of what has been found effective, useful and appropriate for traditional communities at the national level.

1 Policy Objectives

52. How a *sui generis* system is shaped and defined will depend to a large extent on the policy objectives it is intended to serve. Identifying the main policy objectives of recommended national *sui generis* measures would therefore be a good starting point for developing recommended elements for national *sui generis* measures.⁸⁰ Certain Committee members have already proposed specific policy objectives for projected TK protection

⁷⁸ See, African Group (WIPO/GRTKF/IC/3/15, Annex, page 3), the European Community and its Member States (WIPO/GRTKF/IC/1/8, Annex IV, page 6), Canada (WIPO/GRTKF/IC/4/15, para. 142), Egypt (WIPO/GRTKF/IC/4/15, para. 153), Ghana (WIPO/GRTKF/IC/4/15, para. 149), Guyana (WIPO/GRTKF/IC/4/15, para. 143), Haiti (WIPO/GRTKF/IC/4/15, para. 154), Morocco (WIPO/GRTKF/IC/4/15, para. 152), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Panama (WIPO/GRTKF/IC/4/15, para. 157), Venezuela (WIPO/GRTKF/IC/4/15, para. 147), Inuit Circumpolar Conference (WIPO/GRTKF/IC/4/15, para. 159), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

⁷⁹ See WIPO/GRTKF/IC/6/5.

⁸⁰ Committee members have already expressed their views on appropriate policy objectives. See, for example, Brazil (WIPO/GRTKF/IC/3/17, para. 220), Japan (WIPO/GRTKF/IC/4/15, para. 137), Russian Federation (WIPO/GRTKF/IC/4/15, para. 144), Switzerland (WIPO/GRTKF/IC/4/15, para. 135).

systems.⁸¹ Most existing *sui generis* systems draw upon IPR elements and combine them with non-IPR elements. This is also reflected in their stated policy objectives. The ten *sui generis* laws analyzed, have stated policy objectives which fall in the following five categories:

- (a) Objectives related directly to TK and TK holders:
 - to create an appropriate system for access to TK;⁸²
 - to ensure fair and equitable benefit-sharing for TK;⁸³
 - to promote respect, preservation, wider application and development of TK;⁸⁴
 - to provide mechanisms for the enforcement of rights of TK holders;⁸⁵
 - to improve the quality of TK-based products and remove low quality traditional medicine from the market;⁸⁶
- (b) Objectives related to biodiversity and genetic resource policy:
 - to promote the conservation and sustainable use of biological resources and associated TK;⁸⁷
 - to promote the legal safeguarding and transfer of genetic resources associated with TK;⁸⁸
- (c) Objectives related to indigenous peoples rights:
 - to promote development of indigenous peoples and local communities;⁸⁹
 - to recognize, respect and promote the rights of indigenous peoples and local communities;⁹⁰
- (d) Objectives related to sustainable development and capacity building:
 - to enhance scientific capacity at the national and local levels;⁹¹
 - to promote the transfer of technologies which make use of TK and associated genetic resources;⁹²

⁸¹ At the first session of the Committee, the GRULAC has proposed a list of six policy objectives for *sui generis* measures of TK protection (WIPO/GRTKF/IC/1/5, Annex I, page 3). These objectives are integrated into the items listed below.

⁸² See the laws of the African Union, Brazil, Costa Rica, Peru.

⁸³ See the laws of the African Union, Brazil, Costa Rica, Indian Biological Diversity Act of 2002, Peru. See also Objective (2) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁸⁴ See the laws of Peru and Portugal. See also Objective (1) of the six objectives of TK protection proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁸⁵ See the African Model Law.

⁸⁶ See multiple *sui generis* administrative regulations of China.

⁸⁷ See the African Model Law and the Biological Diversity Act of India. See also Objective (6) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁸⁸ See the law of Portugal.

⁸⁹ See the law of Peru. See also Objective (5) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁹⁰ See the laws of the African Union, Peru and the Philippines Indigenous Peoples Rights Act (1997).

⁹¹ See the African Model Law and the law of Peru.

⁹² See the provisional measure of Brazil.

- (e) Objectives related to innovation promotion:
- to promote and recognize innovation based on TK;⁹³
 - to promote the development of Native arts and crafts.⁹⁴

53. These objectives are not mutually exclusive but rather complementary to each other. The Committee may wish to formulate policy objectives with respect to TK, utilizing the categories and examples identified above.

54. A broad-brush approach, setting a wide range of policy objectives, is likely to be more inclusive and responsive to a wider range of TK-related interests; yet it could be more difficult to implement in practice and to adapt to the diverse interests of TK holders. An approach that focuses on specific policy objectives – such as promotion of traditional medicine, and protection of TK associated with genetic resources – would focus the mechanism on better defined areas of TK and would make it easier to define the rights granted and to administer and enforce them.

55. Section III above sets out the various legal doctrines that could form the basis of specific protection of TK and the aspects of TK that may be particularly susceptible to protection. Setting the policy objectives for protection may help clarify what legal doctrine or doctrines would be the basis of protection for TK – for example, whether ‘protection’ should be through exclusive rights in TK as such, through the suppression of unfair competition, through an entitlement to compensation or remuneration (or equitable benefit-sharing), or through an entitlement based on PIC. A blend of legal doctrines may apply. For example, a law could regulate access to TK associated with genetic resources and provide for prior informed consent, while also providing for suppression of unfair competition (on the model of the protection of undisclosed information and geographical indications, which is linked in the WTO TRIPS Agreement to Paris Convention standards on unfair competition).

2 Scope of Protected Subject Matter

56. Determining the subject matter that should be eligible for TK protection may entail two steps:

- settling on use of terms; and
- specifying the criteria which apply to eligible subject matter.

Use of terms

57. Two uses of the term ‘traditional knowledge’ have become customary in the Committee: first, a general sense (TK *lato sensu*), which embraces the content of knowledge itself as well as traditional cultural expressions (TCEs)/expressions of folklore, and distinctive signs and symbols associated with TK;⁹⁵ and, second, a more precise sense (TK *stricto sensu*),

⁹³ See the laws of China and Costa Rica. See also Objective (3) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁹⁴ See the *sui generis* measures of the United States of America, in particular the Indian Arts and Crafts Act of 1990.

⁹⁵ One definition of TK *lato sensu* is ‘the ideas and expressions thereof developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the

which refers to “the content or substance of traditional know-how, skills, practices and learning;” this can be recognized as distinct subject matter, even though this “content or substance may be considered integral with traditional ways of expressing the knowledge and the traditional context in which the knowledge is developed, preserved and transmitted.”⁹⁶ This second, more precise, sense is used in the present document.⁹⁷ (as already noted, protection of TCEs/expressions of folklore is covered in the parallel document WIPO/GRTKF/IC/6/3).

58. While the meaning of the term could be further specified by an inclusive list, which illustrates the concept without setting firm boundaries, or by an exhaustive definition, it is not a prerequisite for effective protection for there to be a formal and detailed definition.⁹⁸ However, the meaning of the term may be specified by reference to policy goals – e.g. TK can be limited to the context of protection of biodiversity and regulation of access to genetic resources. One general way of characterizing TK is knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or Indigenous culture or community which preserves and transmits it between generations;
- linked to a local or Indigenous community through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge or a sense that to permit misappropriation or demeaning usage would be harmful or offensive; this relationship may be expressed formally or informally by customary law or practices;
- ‘knowledge’ in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and
- identified by the source community as being TK.⁹⁹

Determining the aspect or focus of protection

59. There is a wide range of options in how countries have delimited the scope of TK which they protect through their *sui generis* measures. By way of comparison, patent law does not protect technological knowledge as such, but prescribes a distinct scope of protectable subject matter, namely the patentable invention. Most *sui generis* measures delimit the scope of subject matter through some combination of sectoral distinctions, association with tangible subject matter and linkage with traditional communities. Based on examples of existing *sui generis* systems, the following three options, or combinations thereof, can be used.

[Footnote continued from previous page]

needs imposed by their physical and cultural environments and that serve as means for their cultural identification.’

⁹⁶ See WIPO/GRTKF/IC/5/12, para. 44.

⁹⁷ Protection of TCEs/expressions of folklore is covered in the parallel document WIPO/GRTKF/IC/6/3.

⁹⁸ See, Andean Community (WIPO/GRTKF/IC/3/17, para.240), Argentina (WIPO/GRTKF/IC/4/15, para. 158), Bolivia (WIPO/GRTKF/IC/4/15, para. 151), Brazil (WIPO/GRTKF/IC/4/15, para. 148), India (WIPO/GRTKF/IC/4/15, para. 140), Iran (WIPO/GRTKF/IC/4/15, para. 150), Norway (WIPO/GRTKF/IC/4/15, para. 133), South Africa (WIPO/GRTKF/IC/3/17, para. 225), Uganda (WIPO/GRTKF/IC/4/15, para. 146), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

⁹⁹ See WIPO/GRTKF/IC/5/8, para. 69 and WIPO/GRTKF/IC/5/12, para. 45.

Protecting TK by Sectors

60. Some TK protection laws concentrate on specific sectors, rather than broadly covering all subject matter that could be described as traditional knowledge.¹⁰⁰ For example, the Thai Act on Protection and Promotion of Traditional Thai Medicinal Intelligence covers only traditional medicine¹⁰¹ and Portugal's Decree-Law No.118 of 2001 covers only traditional agricultural knowledge associated with landraces.¹⁰² Some laws cover TK in all sectors, but include distinct sets of rights for different sectors. For example, the African Model Legislation provides for farmers' rights in the agricultural sector, in addition to community intellectual rights for all sectors.

Association of the TK with tangible subject matter

61. Some laws make the protection of a TK element dependent upon its association with a tangible subject matter, mostly specified components of biodiversity. For example, the laws of India, Peru and the African Model Law make protection of TK contingent upon its association with "biological resources." Other laws concern TK related to genetic heritage (Brazil)¹⁰³ or any properties of biological diversity (Costa Rica).¹⁰⁴

Association of TK with specific knowledge holders

62. Most TK protection laws specify that TK, in order to be protectable, must be held, created or maintained by certain knowledge holders, such as indigenous peoples,¹⁰⁵ members of 'Indian tribes' or Indian crafts organizations,¹⁰⁶ or farming communities.¹⁰⁷

63. Most *sui generis* laws use a combination of these criteria (normally, at a minimum, the first and second criteria) in order to delimit the scope of their subject matter (e.g. African Model Law, Brazil, India, Peru and Portugal).

Differentiated scope

64. Finally, some *sui generis* laws differentiate the scope of TK into different types of TK and make available a different scope of rights for each type of TK (e.g. the laws of Costa Rica, Peru, and Thailand). For example, the Costa Rican Biodiversity Law firstly defines the scope of TK to which the Law regulates access (this covers all "intangible components" within the term biodiversity, which includes any knowledge associated with genetic or biochemical components, whether it is traditional or not, individual or collective), and secondly it sets out the scope of TK for which the Law provides exclusive rights (both

¹⁰⁰ See the statements of Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 4 and page 7), the European Community and its Member States (WIPO/GRTKF/IC/3/17, para. 137), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Norway (WIPO/GRTKF/IC/4/15, para. 133) and the International Chamber of Commerce (WIPO/GRTKF/IC/4/15, para. 161).

¹⁰¹ Thailand's Act on Protection and Promotion of Traditional Thai Medicinal Intelligence B.E 2542.

¹⁰² Portugal's Decree-Law No.118 of 2001.

¹⁰³ Brazil's Provisional Measure N.2186-16 of August 23, 2001.

¹⁰⁴ Costa Rica's Biodiversity Law.

¹⁰⁵ Peru's Law N. 27,811 of 2002.

¹⁰⁶ The Indian Arts and Crafts Act (1990) in the United States of America.

¹⁰⁷ African Model Legislation (2000).

industrial property rights and *sui generis* community intellectual rights – this narrower scope of TK is limited to “knowledge of indigenous peoples related to the use of components of biodiversity”). This approach has been emphasized by a number of Member States.¹⁰⁸

Issues and options: defining traditional knowledge

65. In establishing a general framework for protection of TK, the Committee may wish to assess and define:

- which type of TK subject matter requires legal protection;
- which criteria should determine the subject matter that should be eligible for specific protection, including criteria based on:
 - different sectors and differential scope of protection,
 - knowledge holders, and
 - association with certain tangible subject matter.

3 Formal requirements for acquisition of rights

66. Protection of eligible TK may apply automatically, with no formalities required (just as copyright is available as soon as an original work is created); or there may be a requirement to take certain formal steps, such as registering or declaring the TK that is to be protected. This can also involve making an application that is examined by a separate body, similar to an application for patent or trademark rights. A requirement for registration need not be mandatory: it can be used to supplement, provide evidence for and facilitate the exercise of rights or entitlements that in principle can be enjoyed without formalities.

67. Three laws expressly state that the acquisition of *sui generis* rights is without formalities (African Model Law, Costa Rica and Peru); four laws establish registries of TK but do not expressly link them to the acquisition of rights (the African Model Law, Brazil, Costa Rica, India); finally, four laws expressly require registration as a condition for the operation of a *sui generis* measure (China, Portugal, Thailand and the United States of America). Other laws do not specify the procedural basis for the acquisition of rights.¹⁰⁹

68. There is trend towards the use of registration mechanisms among existing *sui generis* systems. Of ten *sui generis* laws recently surveyed, nine foresee the establishment of some form of registration mechanisms for protected TK subject matter or for *sui generis* titles granted. The *sui generis* law of Peru establishes three registers, namely a Public National

¹⁰⁸ See, Asian Group (WIPO/GRTKF/IC/4/14, Annex, pages 4 and 7), New Zealand (WIPO/GRTKF/IC/4/15, paragraph 138), Norway (WIPO/GRTKF/IC/4/15, paragraph 133), Thailand (WIPO/GRTKF/IC/3/17, para.216), International Chamber of Commerce (WIPO/GRTKF/IC/4/15, paragraph 161).

¹⁰⁹ For a technical proposal on formal requirements for acquisition of rights see African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, Proposal 3.3(a)). Other technical comments on formal requirements of acquisition were made by Bolivia (WIPO/GRTKF/IC/4/15, para. 151), Brazil (WIPO/GRTKF/IC/3/17, para. 220), Dominican Republic (WIPO/GRTKF/IC/3/17, para.215), Panama (WIPO/GRTKF/IC/4/15, para. 157), Venezuela (WIPO/GRTKF/IC/3/17, para. 213).

Register, a Confidential National Register and the Local Registers of Collective Knowledge of Indigenous Peoples. Several of these registration mechanisms are already functional, but others are in the process of currently being established and put into effect.

69. Internationally agreed technical data standards for the registration of TK and genetic resources in databases and registries already exist. The Committee has adopted a Data Specification for such registration mechanisms (document WIPO/GRTKF/IC/4/14). If the Committee considers that the acquisition of rights may be contingent upon registration procedures, it may wish to consider these international standards.

70. There are trade-offs between predictability and clarity on the one hand, and flexibility and simplicity on the other hand. A registration-based system provides greater predictability, and puts the public clearly on notice about what is protected; it also makes it easier in practice to enforce the rights. But it can mean that the TK holders need to take specific legal steps, potentially within a defined time-frame, or risk losing the benefits of protection; this may impose burdens on communities who lack the resources or capacity to undertake the necessary legal procedures. A system without formalities has the benefit of automatic protection, and requires no additional resources or capacity for the right to be available – but it can, by the same token, be more difficult to enforce the right.

4 Substantive Criteria for Protection

71. Apart from meeting a definition and complying with any formalities, TK may need to meet certain substantive conditions or criteria to be eligible for protection. Not all material that is defined as ‘traditional knowledge’ will necessarily be considered eligible for legal protection – just as not every innovation that meets the definition of ‘invention’ will necessarily be patentable, since it must comply with other patentability criteria.¹¹⁰

72. A few existing *sui generis* measures specify the criteria for protection (Panama, Peru, Thailand, United States of America). Two elements in Panama’s *sui generis* law illustrate how protected subject matter could be better focused through the articulation of substantive criteria for protection. First, only elements of TK that remain “traditional,” in the sense that they remain intrinsically linked to the community that has originated them, would be protected under the *sui generis* system. In contrast, elements of TK which have lost that link, through a process of industrialization, for example, would not be protected. Second, it may be possible to limit protection to TK that is susceptible of commercial application, since third parties are unlikely to engage in unauthorized or distorting use of TK that has no commercial or industrial utility. This highlights the need to clarify the distinction between the underlying holistic subject matter, and those aspects of TK that would be protected by specific legal means. This entails a balance between practicality and inclusiveness.

73. A number of *sui generis* laws do not specify the conditions of protection that apply to TK, such as the African Model Legislation and the laws of Costa Rica, Thailand and the Philippines. The African Model Law and the Costa Rican Law provide that the requirements of protection shall be determined by a consultative process led by the National Competent

¹¹⁰ For technical comments on substantive protection criteria see Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/3/17, para 220), the Dominican Republic (WIPO/GRTKF/IC/3/17, para.215), Venezuela (WIPO/GRTKF/IC/3/17, para.213).

Authorities. Requirements in existing laws for the grant of *sui generis* titles include: its collective nature, a relation to biological diversity, creation and development by indigenous peoples, residency of the creator of the TK in the concerned jurisdiction, creation of the TK element after a certain date, registration of the TK, and description so that it can be utilized by third parties. Under the law of Portugal additional and higher protection is granted to undisclosed TK and TK which has commercial novelty.

74. Protection that has retrospective effect can create difficulties because third parties may have already used the protected material in good faith, believing it to be in the public domain; the rights and interests of such third parties may need to be respected. On the other hand, the traditional context of TK means that proponents of protection seek some degree of retrospectivity. Limiting protection to commercial novelty is one way of addressing this dilemma.

75. Eligibility criteria that involve some input from the traditional community may be important in establishing the legitimacy of the system – TK may be that knowledge with which the TK holder community actively to as a component of its cultural identity (rather than relying totally on an external decision maker). This would entail a balance between legitimacy and practicality – a system that involved extensive consultation and interaction to determine the nature of each individual item of TK may be highly desirable in principle, but may be too burdensome to implement (particularly in multiple jurisdictions). Some form of objective criteria for determining the ‘traditional’ status of TK may become necessary.

Issues and options: eligibility for protection

76. Determining the requirements that TK should meet in order to be eligible for protection may entail paying regard to:

- the need for continuing traditional character of the knowledge, or a living link with a traditional community;
- the current public domain status of TK, including the question of commercial novelty, and the policy implications of retrospective protection;
- the benefits and costs of a system based on documentation, fixation or recordal of TK, and the benefits and costs of a system which automatically confers rights; and
- the possibility of a consultative process involving the community directly so as to establish TK rights based on the input of TK holders themselves.

5 Nature of rights in traditional knowledge

77. Rights or entitlements associated with TK may differ depending on the specific legal doctrine that is relied upon (see the discussion in Section III above).¹¹¹ The quintessential IP right is an exclusive right over the protected subject matter, which confers on the right holder

¹¹¹ For technical comments on the nature of rights were provided by the European Community and its Member States (WIPO/GRTKF/IC/1/8, Annex IV, page 6); Norway (WIPO/GRTKF/IC/4/15, para. 133), India (WIPO/GRTKF/IC/4/15, para. 140) and Venezuela (WIPO/GRTKF/IC/4/15, para. 147).

the entitlement to prevent its use in certain ways (exactly what it allows the right holder to prevent is covered under ‘scope of the right’ below). Alternative rights or legal entitlements that may be associated with IP systems, but differ from this kind of right include an entitlement to be compensated when TK is used by a third party, a right to be consulted before access to TK, and an entitlement to take action when aggrieved by misuse of TK (such as unfair commercial practices, breach of confidence, or culturally offensive misuse of TK).

78. The nature of rights and entitlements conferred will depend on the legal doctrine or doctrines that form the basis of protection. The nature of rights and entitlements could include the following options:

- exclusive rights in the TK as such;
- procedural rights such as the right to be consulted;
- entitlement to compensation;
- rights to prevent certain damaging uses of TK.

79. The exact rights and entitlements that are defined will depend very much on the aim of protection, and the overall policy objectives. Rights over TK are likely to focus on the unauthorized use of the knowledge as such, including commercial dealing with products embodying TK. One approach would be to limit exclusive rights to those uses of TK that involve deriving economic benefit from TK, leaving open uses of TK for research and educational purposes. This would be consistent with the concept of ‘commercial novelty’ as a criterion for protection. This would also simplify and focus the exercise and enforcement of rights on those areas of potentially greatest damage or misappropriation of value. However, rights may also be claimed over material where damage caused is not economic but nonetheless substantive. This may include culturally offensive and degrading uses, use in bad faith, and false and misleading behavior. Safeguards against some such illegitimate uses could also be provided by the application of unfair competition principles.

6 Scope of Rights and Exceptions

80. The scope of the rights will determine the degree of control which the right holder will be able to exercise over the protected TK.¹¹² It defines what activities the right holder is entitled to prevent, and what exceptions may limit the exercise of such rights. Potential rights over TK may include the entitlement to prevent:

- unauthorized access to, recording of or disclosure of the protected TK;
- unauthorized commercial use of the protected TK;
- third party IP claims over protect TK subject matter;
- culturally offensive, degrading or inappropriate use of TK material;
- a form of moral right, such as rights to integrity and attribution of source of TK; or
- misleading or deceptive practices relating to the use of TK, and other forms of unfair competition associated with TK such as unjust enrichment, taking inequitable commercial advantage or slavish imitation.

Such rights or entitlements need not require stand-alone *sui generis* property rights, and have typically been implemented in a range of national laws by various combinations of the foundational legal doctrines set out in paragraph 44 (a) to (d) above. TK holders need not be

¹¹² For technical comments on the appropriate scope of rights and exceptions see Norway (WIPO/GRTKF/IC/4/15, para. 133) and Thailand (WIPO/GRTKF/IC/3/17, para.135).

identified as distinct right holders in order to have the entitlement to exercise rights, which may be open to any aggrieved or interested party, including community representatives and government authorities.

81. The rights available to TK holders may also vary according to the nature of the knowledge held. The laws of Costa Rica and India provide that the scope of rights shall be determined in due course by the National Competent Authority, in the case of Costa Rica through a consultative process. Three laws grant two different sets of rights with differing scope: the African Model Law grants ‘community intellectual rights’ and farmers’ rights which have different scopes, and the laws of Peru and Portugal grant a wider scope of rights if TK has remained undisclosed, has not entered into the public domain, or has commercial novelty. Ideally, the scope of protection should also recognize communities’ customs and traditions involving the permission for individuals to use elements of TK, within or outside the community concerned, as well as issues concerning ownership, entitlement to benefits, damages and dispute settlement.¹¹³

82. Like all other IP rights (as well as all other private property rights), rights in TK may be limited or qualified so as to avoid unreasonable prejudice to the interests of society as a whole, and other legitimate interests. Rights over TK subject matter may, therefore, be subject to exceptions, such as the use by third parties for academic or purely private purposes, or compulsory licenses on grounds of public interest. Exceptions or limitations may also deal with the interests of third parties who develop follow-on innovations based on TK, similar to arrangements for dependent patents. In general, potential exceptions and limitations to the granted rights include:

- the exemption of traditional exchange systems of TK among communities;
- research, personal and other non-commercial use;
- measures necessary for the preservation and development of TK, and the promotion of traditional innovation;
- production of traditional medicines for household use or use in public health facilities;
- continuing prior use in good faith by third parties;
- no limitations or prejudice to other IP rights; and
- an exemption of customary use from the scope of rights granted.

Options and issues: scope of rights

83. The options for setting the scope of rights to be provided by TK protection measures include:

- defining the scope of rights by specifying what third party activities in relation to the protected TK which the right holder or aggrieved party is entitled to restrain;
- clarifying how different tiers of rights may need to be recognized for different categories of TK that fulfill different criteria;

¹¹³ Those customs and traditions could be described and recorded together with the elements of TK, so that legal security could be created not only as regards the appropriated elements of TK themselves, but also in connection with their sharing within the communities. For instance, see Panama’s *sui generis* law.

- providing for some aspects of the scope of rights to be determined through a consultative process with TK holders in the course of the implementation of possible measures, including references to customary law requirements; and
- defining appropriate exceptions and limitations to the scope of rights, such as the exemption of customary use of TK, conservation activities, and research activities.

7 Right Holder, Owners, Custodians or Beneficiaries

84. Different concepts of ownership and of right holders may apply in relation to TK. TK is generally understood as a collective product of a TK holding community, even though individual innovators or TK holders may have distinct personal rights or entitlements within the community structure. The general rule would therefore be for TK rights to be vested in communities, rather than in individuals, but to recognize individual rights (including conventional IP rights) for innovators or creators of original works.¹¹⁴ The collective right holder should have legal personality for the purpose of legal procedures, including enforcing their rights. This issue has international dimensions, if the TK holder is to be granted rights in foreign jurisdictions. The Paris Convention (Article 7*bis*) already provides for the protection of ‘collective marks belonging to associations the existence of which is not contrary to the law of the country of origin, even if such associations do not possess an industrial or commercial establishment.’

85. But IP need not be separately owned by distinct right holders. Collective marks and certification marks may be protected on behalf of a group of beneficiaries. Some forms of IP protection, such as geographical indications, need not have distinct ‘owners’ and may be administered by the state, on behalf of groups of eligible producers. Where the ‘right’ over TK is essentially an entitlement to seek certain legal remedies and injunctions, there may not be a need to identify a specific right holder, and it may be possible to define aggrieved or interested parties who may have standing to take action. International standards reflect this approach in referring to obligations to ensure that ‘persons shall have the possibility of preventing’ certain actions,¹¹⁵ to ‘provide the legal means for interested parties to prevent’ certain actions,¹¹⁶ and ‘to provide measures to permit federations and associations ... to take action in the courts or before the administrative authorities.’¹¹⁷

86. Similarly, national TK laws do not necessarily identify beneficiaries of TK protection as holders of distinct intangible property rights as such, although some have elected to establish distinct rights, either through registration or automatic entitlement. Four laws identify the right holders through the terms “local communities,” “indigenous peoples,” or a combination thereof. The Chinese Regulation on the Protection of Varieties of Traditional Chinese

¹¹⁴ For technical comments on the identification of right holders see the statements of the African Group (WIPO/GRTKF/IC/3/5, Annex, page 5, para. 1(c)), Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/3/17, para 210), the Russian Federation (WIPO/GRTKF/IC/4/15, para. 144), South Africa (WIPO/GRTKF/IC/3/17, para 225), Thailand (WIPO/GRTKF/IC/3/17, para.135) and Venezuela (WIPO/GRTKF/IC/3/17, para.216), Zambia (WIPO/GRTKF/IC/3/17, para.232).

¹¹⁵ TRIPS Agreement, Article 39.

¹¹⁶ TRIPS Agreement, Article 22.

¹¹⁷ Paris Convention, Article 10*ter*.

Medicine refers only to “manufacturing enterprises,” reflecting the policy context of this regulation in relation to the manufacturing sector. The Indian law does not identify right holders, but defines that “benefit claimers” shall include “creators and holders of knowledge and information relating to biological resources.” Other laws contain open definitions such as “those who have registered their IPRs on traditional Thai medical intelligence” and “any entity, whether public or private, Portuguese [or not], individual or corporate.” Finally, the Costa Rican law provides that the titleholder of *sui generis* community intellectual rights shall be determined by a participatory process. An alternative to the attribution of rights to communities is the designation of the State as the custodian of the interests and rights of TK holders, to be exercised on their behalf and in their interests;¹¹⁸ some forms of unfair competition and geographical indication law entail direct enforcement by the State in the community’s interests.

87. Although TK protection is generally perceived as a matter of collective rights, it may nonetheless be vested in individuals within a traditional knowledge system. Customary law can therefore help establish the attribution of rights and benefits within the community. An example of how customary law can be integrated into a *sui generis* system of TK protection is found in the Panamanian Law.¹¹⁹

88. In sum, identifying the right holder or beneficiary for TK rights may require three elements:

- the right holder or the entity seeking legal remedies should be recognized under the law as having legal personality – this may entail recognizing a collective, a traditional community as having distinct legal existence; or the TK holding community may designate a distinct legal person (such as an association, a legal representative, a trustee, a corporation, or a government agency) as right holder in trust;
- the right holder may have to meet specific criteria (such as being an indigenous or local community); and
- a sufficient connection must be established between the right holder and the protected TK; this linkage would normally be defined by or at least consistent with customary law or community practices.

Issues and options: right holders and beneficiaries

89. The options for identifying ownership, custodianship and beneficiary status in relation to TK protection include:

- identifying particular groups, communities or beneficiaries as being entitled to the benefits of protection;
- requiring a certain defined linkage between TK and the beneficiaries of protection of the TK;
- providing that right holders and beneficiaries would be identified through a consultative process in the course of the implementation of the law; and

¹¹⁸ An approximate precedent in international law for this approach can be found in Article 15(4)(a) of the Berne Convention.

¹¹⁹ See Article 15, Law No. 20 of Panama.

- defining a form of collective or community ownership and custodianship, based on existing legal models in domestic law and the experience with community-held IP such as collective marks and geographical indications, and drawing on applicable customary law.

8 Expiration and Loss of Rights

90. The duration of the right is normally a key issue in establishing the appropriate policy balance in IP protection.¹²⁰ The discussion concerning TK stresses the need for a longer, inter-generational time-frame to be taken into account – and this is one of the arguments put forward for its protection through *sui generis* means, rather than conventional IP laws. Therefore, some *sui generis* laws do not contain express provisions on the expiration and loss of rights. For example, the African Model Law states that community intellectual rights “shall at all times remain inalienable” (Art.23(1)). The Chinese, Portuguese and Thai Acts establish specific terms of protection, varying between terms ranging from 7 to 30 years; 50 years from the time of application for the right; and 50 years after the death of the right holder. Furthermore, under the Chinese and Portuguese laws the term may be renewed. If the protection of TK is to be established upon an initial act of commercial exploitation (for example, a fixed term counted from the first commercial act involving the protected element of TK, which could be renewable for a certain number of successive periods), then it might make sense to establish a predefined expiration, provided it would apply exclusively to those isolated elements of TK which have a commercial or industrial application, rather than the holistic background of TK. Other laws provide for the lapse of rights in TK once the original community has ceased to identify with it.

Issues and options: term of protection

91. The term or other conditions of expiration of rights and entitlements in TK may be determined with reference to the following possibilities, which may co-exist within the one comprehensive framework for protection:

- the possibility of inalienable and perennial rights, for instance in relation to an entitlement to take action against derogatory or damaging activities, and to prevent illegitimate third-party IP rights;
- the possibility of a limited term for some forms of protection, for instance in relation to protection of those aspects or elements of TK that are considered important to cultural exchange and development, or have been commercially or industrially applied by the TK holders;
- the possibility of rights or entitlements lapsing when the original community has ceased to identify with the TK, or the TK has ceased to be protected in its country of origin;
- the possibility of a two-tier system to balance various legitimate interests by allowing for expiration of rights over material that has been commercially exploited.

¹²⁰ For technical comments on expiration and loss of rights see Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), Fiji (WIPO/GRTKF/IC/3/17, para.236), Thailand (WIPO/GRTKF/IC/3/17, para.216), Zambia (WIPO/GRTKF/IC/3/17, para.232).

9 Sanctions and Enforcement

92. TK protection would require effective and expeditious remedies such as injunctions and penalties, or mechanisms for payment of use fees or other compensation where there is no outright prohibition on third party use. There may be practical difficulties for holders of TK to enforce their rights, which raises the possibility of administration of rights through a distinct mechanism, possibly a collective or reciprocal system of administration, or a specific role for government agencies in monitoring and pursuing infringements of rights.¹²¹ Most *sui generis* laws provide that acts that contravene the laws shall be punished with sanctions such as warnings, fines, confiscation of products derived from TK, cancellation/revocation of access to TK, etc. Two laws in particular foresee that customary laws shall be used and referred to for sanctions and enforcement of TK protection (African Model Law and Philippines). The difficulty of using the formal legal system, potentially in multiple jurisdictions and using a patchwork of different legal remedies, may create a practical need for an adapted form of alternative dispute resolution, such as mediation or arbitration which can be adapted to take account of TK holders' resource constraints, cultural and customary law concerns and interests in having appropriate remedies

Issues and options: remedies and management of rights

93. The availability of effective remedies may entail considering:
- what kind of legal and alternative dispute resolution procedures would be most appropriate to the needs and resource constraints of TK holders;
 - what kind of systems may be used for the collective management of rights and for the distribution of equitable benefits derived from access to and use of TK;
 - the role of government authorities in monitoring or enforcing the protection of TK.

10 Defensive Protection

94. Some existing *sui generis* laws reflect defensive protection objectives, but this is generally only secondary to the positive protection of TK subject matter. Some laws contain defensive measures in the form of information compiled in registers of disclosed TK (African Model Law, Costa Rica, Peru, and the United States of America). These measures are set out and analyzed in detail in documents WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/8.

11 Linkage with access and benefit-sharing regimes

95. Some TK is closely associated with biological and genetic resources, particularly when these resources are linked with traditional ways of life and practices. A number of existing laws use the regulation of access to biological resources as the basis for *sui generis* protection of TK. Under some laws, access to TK is granted by the competent State authority.¹²² Even

¹²¹ See Venezuela (WIPO/GRTKF/IC/3/17, para. 213).

¹²² See Art.4 (1)(xi) and 4(1)(x), African Model Law; Art.11 (IV)(b), Brazilian Provisional Measure; Art.62, Costa Rican Biodiversity Law; Art.3 (1), Indian Biodiversity Act; Art.7 (1), Portuguese Decree Law 118.

if access is ultimately granted by the State, in some laws the indigenous/local community or the TK owner may refuse access to the TK.¹²³ In two cases the access conditions differ, depending on the purpose of utilization for which access is requested¹²⁴ and in two laws many customary uses of TK are expressly exempted from access regulation.¹²⁵ Specific conditions of access to TK may apply to specified national institutions.¹²⁶

96. Some access regimes therefore control the use of TK and ensure benefit-sharing without creating exclusive rights in TK. This option may apply to some types of biodiversity-related TK, when a private property right is considered inappropriate, where the TK holder cannot be identified, or where property rights could not be exercised and enforced. In these cases, access regulation provides an alternative tool to control the use of TK by third parties and to ensure equitable benefit sharing for TK, which is not contingent upon or limited to the innovative elements of TK systems. Furthermore, access regulation should be coordinated with the regulation of access to genetic resources by the State, whether or not those resources are related to the TK.

97. Biodiversity access regulation which covers TK might follow the tenets of prior informed consent that have been developed internationally (in particular, the Bonn Guidelines), with a view to:

- providing for legal certainty and clarity;
- minimizing transaction costs for access procedures;
- ensuring that restrictions on access are transparent, legally based, and do not lead to the non-transmission of TK and the stifling of traditions;
- securing consent of the relevant competent national authority(ies) in the provider country, as well as the consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law.

98. Finally, the *sui generis* measure, and its implementing rules and regulations, could establish certain basic elements of an access system:

- Specifying the competent authority(ies) granting access;
- Timing and deadlines;
- Specification of use;
- Procedures for obtaining prior informed consent (PIC);
- Mechanism for stakeholder consultations on access.

Issues and options: linkage with access regimes

99. A comprehensive approach to TK protection measures may need to be coordinated with legal frameworks regulating access to genetic resources. This is particularly the case if protection of TK is linked to the application of the principle of prior informed consent (PIC) to access and use of certain TK elements associated with genetic resources. Practical implementation of the PIC principle to TK subject matter may entail:

¹²³ See, African Model Legislation; Brazilian Provisional Measure; Costa Rican Biodiversity Law; Peruvian Law; and Portuguese Decree Law.

¹²⁴ Laws of Peru and Portugal.

¹²⁵ Art.2 (2)(ii), African Model Law and Art.7, Indian Biodiversity Act.

¹²⁶ Brazilian Provisional Measure and Indian Biodiversity Act.

- Coordination between the work of the Committee with the work of the CBD on access and benefit-sharing issues;
- Consideration of the respective roles and responsibilities of the State, indigenous and local communities, and possible owners or custodians of elements of TK in granting PIC on certain acts regarding TK, such as disclosure, reproduction and use of certain TK elements;
- Coordination with the access regime applicable to genetic resources;
- Clarification of basic principles of access regulation, such as prior informed consent, legal certainty, minimized transaction costs, and transparent access restrictions;
- Review of the choices required in establishing the basic elements of an access system, including procedures for prior informed consent, specified competent national authorities, mechanisms for stakeholder consultations, timing and deadlines, and specification of use; and
- An exemption of customary uses of TK from access restrictions and from the application of the PIC principle.

100. This concludes an initial identification of the main elements and options for TK protection measures. These elements are listed in the preceding paragraphs on the basis of past discussions and documents of the Committee and are identified merely as a starting point for the Committee's technical discussions on TK protection. They do not represent an authoritative assessment of the issues or preempt any larger policy decisions regarding the need for, requirements of, and components of, possible *sui generis* measures for TK protection.

101. In order to advance the work of the Committee, it could be possible to develop further, distilled and precise analysis and comparison of national experiences and policy concerns that have guided choices taken on the issues identified throughout this Section. In turn, this would provide guidance on how the Committee could work towards the further elaboration of such options and elements in the form of an agreed common platform for TK protection.

V. CONCLUSIONS

102. This document builds on the practical experience that existing IP rights and *sui generis* measures need not be mutually exclusive options for TK protection, but should be combined as appropriate to create a comprehensive, adaptable and appropriate framework for protection of TK. This may mean that the preferred approach to a common platform for protection would be a combined approach using multiple legal tools to customize TK protection to the specificities of each national situation and the diversity of TK and TK holders' needs, priorities and resource constraints. The Committee could consider the development of an agreed platform for comprehensive TK protection, based on the identification of common policy objectives and core principles, and supplemented by an array of the detailed legal mechanisms, annotated and clarified, that could be used as flexible and adaptable means to achieve shared objectives within national law and in consultation with TK holders and the intended beneficiaries of protection. With a view to facilitating the development of such an annotated menu, this document lays out options for TK protection which combine different legal doctrines and policy tools into a customized bundle of measures for TK protection. These options include the use of existing IP mechanisms, adapted IP mechanisms, *sui generis* measures, unfair competition principles and tools from related policy areas, such as liability

rules and prior informed consent principles. The bundle would be tied together through a set of key principles and objectives for TK protection.

103. This document has also explored some of the policy objectives and general principles that have been drawn on in applying IP protection to TK subject matter in a wide range of Member States. These objectives and principles are closely related to the core principles of the IP more generally. It is intended to facilitate the identification by the Committee of objectives and core principles that should guide WIPO's future work, policy dialogue, capacity-building and technical cooperation on the protection of TK. This statement of core principles could be supplemented by an outline of the policy options and legal mechanisms for the protection of TK subject matter, based on the full range of approaches already considered by the Committee, together with a brief commentary of the policy and practical implications of each option. This commentary could also clarify the overlap and interface between conventional IP and *sui generis* approaches to protection, and the relationship between IP and non-IP forms of protection. This outline and analysis would provide a succinct basis for future substantive work, including national policymaking, regional cooperation and WIPO's legal-technical assistance. It would also provide a clear framework for continuing international dialogue on policy options, the international coordination of protection of TK, and the articulation of an agreed international platform for TK protection, should the Committee decide to produce such a concrete outcome in the current phase of its work.

104. The Intergovernmental Committee is invited to:

(i) consider the contents of this document;

(ii) consider the possibilities for focusing and accelerating its substantive work on protection of traditional knowledge, including by developing first drafts of:

- an overview of policy objectives and core principles for TK protection;

- an outline of the policy options and legal elements for the protection of TK subject matter, together with a brief analysis of the policy and practical implications of each option and element.

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