GAP Analysis on the Protection of Traditional Knowledge

Comments of the United States of America

GENERAL

At the twelfth session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the "IGC" or the "Committee"), the members of the Committee requested the Secretariat to prepare a working document describing existing obligations, provisions and possibilities at the international level for the protection of Traditional Knowledge (TK), identifying "gaps," if any, in the international framework, and related considerations, and describing options to address any identified gaps.

In response to this request, the Secretariat has produced a useful working document that will help to facilitate the work of the Committee. Over the last several sessions, the United States and many other delegations have stressed the importance of focusing the Committee's attention on concrete, achievable outcomes to address specific issues and concerns related to the protection of TK. By cataloguing and describing existing legal and other options for the protection of TK, the Secretariat will help to accelerate the Committee's work. Consistent with the request of the IGC, this document is largely descriptive in nature, appropriately drawing on information in other IGC documents. In the view of the United States, gathering and organizing this relevant information in a single place itself will facilitate deliberations within the IGC.

With the goal of the document clearly confined, the objective of these comments is similarly circumscribed. First, these preliminary comments offer recommendations on how certain information provided by the Secretariat for the use of the Committee might be stated with greater clarity, precision, and/or balance. Second, these comments highlight options that, on preliminary basis, appear to merit the close attention of the Committee. The difficult task of substantively evaluating the identified gaps in the international framework, along with the options to address those gaps and related policy issues, must take place in the course of the Committee's deliberations.

Looking ahead, much work remains to be done. First, in the view of the United States, the Committee will need to closely examine each identified gap, with a view toward reaching an enhanced mutual understanding of these unmet needs. As this analysis correctly points out, a consensus has yet to emerge within the IGC on these important issues. Second, the IGC will need to match the identified gap more closely with the options to address it. The United States continues to believe that this aspect of our deliberations will be enriched significantly by the exchange of national experiences. Third, the Committee will need to explore in greater depth the specific options and related policy considerations briefly discussed in this document. Finally, mindful of the

need to accelerate our work, the Committee will need to prioritize discussion of those options that hold the greatest promise of delivering concrete outcomes or otherwise significantly advancing the work of the Committee.

SPECIFIC

WORKING DEFINITIONS OF TK

Defining Traditional Knowledge

Paragraph 2. In paragraph 2, the document usefully points out there is "no internationally settled or accepted definition" of TK.

Paragraph 4. The document WIPO/GRTKF/IC/8/5, Annex, Revised Draft Provisions for the Protection of Traditional Knowledge, Article 4, provided a similar definition of the term "traditional knowledge" with a difference being in the chapeau. In Article 4, the chapeau states "Protection should be extended at least to that traditional knowledge which is" whereas the draft gap analysis provides that "traditional knowledge may need to be." No difference in meaning is understood from the different terminology, but the definition itself is important as it ties the willingness to provide protection to the existence of knowledge that has been generated, preserved and transmitted in a traditional context, so that it is distinctively associated with a specific community or people and is integral to the cultural identity of that community. As a result, knowledge that has been acquired recently, by specific members of a community, but which is not associated with the community is not understood to fall within the knowledge in need of a new form of protection. In fact, the current system of intellectual property protection may provide a vehicle for protection of innovations occurring within the traditional context.

Meaning of Protection

Paragraph 7, while recognizing that physical protection is one means to protect TK, the introduction defines protection as legal protection. By steering the analysis towards legal protection only, without continue to consider other mechanisms to protect TK, the work of the IGC is biased toward legal outcomes. The IGC should be mindful that physical protection or encouraging widespread use continue to be a means to protect TK, and may be the most cost effective and long lasting means of protection.

Paragraph 9, the fourth indent, "TK may be subject to diverse forms of ownership, custodianship, entitlement and equitable interests". TK may also be part of the common heritage of mankind and not vested exclusively in a specific community or state. (Note that while it may be said that "Traditional knowledge is itself a subset of the common heritage of mankind." WIPO/ECTK/SOF/01/3, Dr. Alexandru-Cristian Ştrenc, this is not understood to mean that all TK is necessarily subject to a claim of ownership.)

Paragraph 9, the fifth indent, "Some approaches to gap analysis may need to address possible differences in treatment between indigenous knowledge and the broader

concept of traditional knowledge, noting, for instance, that rights of indigenous peoples relating to traditional knowledge have recently been identified in an international declaration (discussed below)." The Declaration on the Rights of Indigenous Peoples was adopted by the Third Committee of the UN General Assembly, but did not have the support of all members. Among the countries voting in favor of its adoption, a number noted the aspirational nature of the document, and perhaps due to this aspirational nature, the meaning of many terms such as "rights of indigenous peoples relating to traditional knowledge" is not clear. As a result, the Declaration should not be cited as a reason for treating indigenous knowledge separately from other TK.

The meaning of "gaps"

Paragraph 10, as explained in the introduction (pages 5- 9), the draft gap analysis is based upon a certain working definitions. Working definitions are provided for the terms "traditional knowledge" and "protection," but the term "gap" has not been defined. While there are different possible assumptions that can be made in response to a perceived gap, the response should be appropriate to the circumstances. In land use planning, some spaces are private property, and other spaces are left as open space for all to use and enjoy. The same sort of public planning policy should be devoted to deciding how the landscape of knowledge should be protected, preserved and maintained.

Paragraph 14, last line "technical" should be "technically".

Patent Disclosure

Paragraph 15, it is not clear how patent disclosures are a means to protect traditional knowledge. How would a patent disclosure requirement lead to the knowledge being protected? Even if a patent disclosure requirement could, in some circumstances, lead to protection of the knowledge, how is such a requirement primarily a means to protect traditional knowledge instead of primarily a means to offensively undermine patents? It is suggested that paragraph 15, be made into its own section entitled "defensive protection of TK, adding onto the patent system."

Paragraph 16, lists mechanisms that could operate within the patent system to prevent a patent being improperly granted on traditional knowledge, patent disclosure requirements would require Patent Offices to undertake additional responsibilities, outside of the patent process. To the extent that a patent disclosure requirement is within the existing international patent law standards, paragraph 16, could be modified to add an additional element "Requiring the applicant for the patent to disclose information, including its source, that would be material to patentability of the invention." With this requirement, if an applicant files a patent application closely related to traditional knowledge, the applicant would be required to disclose the traditional knowledge as well as its source so that a patent examiner could determine that the claims of the patent do not infringe upon the traditional knowledge. If traditional knowledge information is not relevant to patentability, then the applicant for patent would have no duty to disclose any

information about traditional knowledge of which he or she may have been aware. In the last bulleted item in paragraph 16, it is not clear whether the portal listed would include a searchable database of traditional knowledge. Various proposals have been made in this regard so as to make a database of disclosed traditional knowledge available to at least IP Offices, and it is not clear whether the portal would be the same.

Paragraph 21, the meaning of "commercial value" should be addressed in more detail.

Unfair Competition

Paragraph 26, in the United States, unfair competition is more than acts the create confusion or false or misleading allegations, unfair competition also extends to unfair business practices such as forming monopolies (see the Sherman Antitrust Act (Sherman Act, July 2, 1890, ch. 647, 26 Stat. 209, 15 U.S.C. § 1–7), pricing and linking of products sold to lessen competition (see the Clayton Antitrust Act of 1914, (October 15, 1914, ch. 323, 38 Stat. 730, codified at 15 U.S.C. § 12–27, 29 U.S.C. § 52–53)), and certain pricing schemes (see the Robinson-Patman Act of 1936 (or Anti-Price Discrimination Act, 15 U.S.C. § 13)). It is suggested that paragraph 26, be expanded to recognize that the provision can be reach to allow for protection against other forms of use of traditional knowledge that may be considered honest, but not fair competition, such as predatory pricing.

Objectives in relation to the protection of TK

Paragraphs 33 and 37 note various sources that have been cited to identify the diverse policy objectives for the protection of TK, including documents produced by the IGC. Of these, in view of the United States, the United Nations Declaration on the Rights of Indigenous Peoples expresses the aspirations of certain indigenous peoples. To clarify the nature of this source, the United States recommends the declaration be introduced as follows: "The United Nations Declaration on the Rights of Indigenous Peoples has been cited as a source that reflects the aspirations of indigenous peoples."

Paragraph 33 – the UNDRIP should be removed from a listing of international instruments in the box. As noted in our comments on paragraph 9 is an aspirational document as noted above in our comments on paragraph 9. It is not "public international law". If section (b), which is currently entitled "within other areas of public international law" is going to include the DRIP in its discussion, it should be retitled. A title such as "Within other international texts" would be acceptable.

Paragraph 35, the description of the Bonn Guidelines is confusing. Rather than have such a long sentence, it would be preferable to delete "which are described…recommending" and to insert in place "recommends". In addition, it would be helpful if paragraph 18 adds a discussion of paragraph 31, of the Bonn Guidelines, namely that established legal rights need to be respected. The Bonn Guidelines did not promote the creation of new legal rights, instead it emphasized that existing legal rights

needed to be respected. Lastly, it would be helpful in the discussion of the Bonn Guidelines to add the objective of the Guidelines to "contribute toward the development of access and benefit regimes that recognize the protection of traditional knowledge" (Paragraph 11(j)) as well as that countries should consider "cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements" (as well as some of the other provisions of paragraph 16 that are equally relevant to TK.

Paragraph 37. The section should be relabeled per our comment to paragraph 33 or the entire reference and discussion of the UNDRIP should be deleted, because the UNDRIP is an international text, not international law. The first sentence is rather confusing, it should be redrafted. One possibility would be to replace both the first and second sentence with the following: "The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) provides that"

Paragraph 39(i), in the second indent "tradition knowledge" should be "traditional knowledge". In paragraph 39(ii), there appears to be text missing spanning pages 20 and 21.

Gaps in Policy Objectives

Paragraph 43, this paragraph is said to list "gaps in the policy objectives expressed at the international level." What is a gap in a policy objective? Paragraph 43 is understood to list various policy objectives expressed at the international level in the legal protection of traditional knowledge. The policy objectives or rationales of protection all appear to be directed towards reasons why protection of traditional knowledge may be appropriate, but nothing in the list of policy objectives appears to take a step back and consider the policy objectives of having a protection system, and what conflicting policy objectives may exist. For example, a policy objective of the patent system is to promote innovation. A conflicting policy objective could be considered as the need to promote research and use of new innovations by others. Similarly, within the list of policy objectives should be the societal interest in sharing technology and knowledge- the concept of promoting access to knowledge.

Moreover, missing from the discussion of policy objectives is a discussion of why traditional knowledge should be protected, but other knowledge should not be. This is an important discussion, because without an understanding of why certain knowledge is to be accorded a new type of protection, we will not necessarily address the true problem to be solved. For example, a policy objective of providing for protection of traditional knowledge is frequently stated as to enable traditional ways of living to be sustained. Many claim that traditional ways of living are not sustainable, and that income from traditional knowledge is necessary to enable traditional ways of life to continue. If creation of a revenue stream is an objective, it should be listed in paragraph 43. If creation of such a revenue stream is the main objective for protection of traditional knowledge, then perhaps another mechanism could be created that would provide assistance to communities in need of assistance, without also providing affluent communities another opportunity to insist upon additional compensation.

In addition, the listed policy objectives do not reflect the interest of the international community in reducing the costs associated with enforcement of contracts,

so that when access to traditional knowledge has been granted, and mutually agreed terms have been reached, those contracts can be enforced at a minimum cost. Yet another policy objective in the legal protection of TK is to create conditions to facilitate access to knowledge, including traditional knowledge. Public policy dictates that the transaction costs associated with obtaining traditional knowledge are reasonable, and do not themselves create a barrier to access to knowledge. A gap in the policy objectives expressed in the international level is understood to include explaining how to balance the interest of a community to control their traditional knowledge, with the interest of the remaining public in obtaining that knowledge. Are there any circumstances under which the traditional knowledge holder could be forced to divulge the knowledge (akin to a compulsory license of a patent, or fair use of a copyright?)

Lastly, for the policy objectives listed in paragraph 43 on page 22, if the international community recognizes a right, and a specific community does not exercise that right, does the international community have a custodial responsibility to exercise the right on the part of the local community?

Paragraph 45, - "recognizes the rights" needs to be changed to "provides" or "states" for the . In addition, “far” should be deleted in front of “broader.”

Beneficiaries

Paragraph 47, (ii) “beneficiaries or right holders not recognized” This section treats beneficiaries and right holders as the same entity. As explained above, those identified as beneficiaries may be a distinct or overlapping group with the group that consists of the right holders, and for purposes of identification of gaps the two should be analyzed separately. In addition, presumably the right holder would be the entity that could appropriately grant prior informed consent. Does such an entity need to be defined on the international level, or is it appropriate to have national laws govern? If national laws govern, how would conflicting claims as to the appropriate right holder or owner be addressed?

Paragraph 47, comment, line 2, “item A” should be III(a).

In paragraph 47, on page 24, “innovation that is cumulative and collective over generations within the one community,” the following sentence appears to be missing some text “But on the whole protection of TK relates to the protection of TK relates to protection of cumulative knowledge that is collectively held, unless it is considered undisclosed or confidential information.”

In paragraph 47, on page 24, the paragraph beginning “such knowledge may be considered” “relevant for” should be deleted after “related to”. Some text is also missing at the end of the same paragraph.

Page 25, describing the UNDRIP, first complete paragraph, second to last line, “of rights” should be deleted.

Patents

Page 25, (iii) forms of misuse and other illegitimate actions that cannot be prevented under existing law. As to the first subheading, "an express norm against illegitimate patenting of traditional knowledge"- The first comment, "Gap" and corresponding example should be deleted. The international norm is that a patent can only be granted if the invention is novel, applying a global standard. Clearly, if the invention is not novel, granting a patent on the invention would be a mistake on the part of a Patent Office. There is no gap in the international norms in this instance. National laws may provide such a gap, particularly if only a local standard of novelty is applied, but internationally there is no gap for failing to set an international norm against the patenting of inventions that are not novel.

Page 26, "a specific disclosure requirement relating to TK". In the fist line of the Comment "defensive protection" should be deleted. As explained above in paragraph 15, disclosure requirements appear more likely to undermine the patent system than to provide any protection of TK. Using terms such as "defensive protection mechanisms" implies that such a mechanism is merely defensive, not offensive, and offers some sort of protection. Without objective evidence showing that such terminology is accurate, neutral terminology such as "specific mechanisms" should be used. In the third line of the comment "enhanced disclosure" should be changed to "additional". To suggest that a disclosure of the source or origin of traditional knowledge necessarily enhances the disclosure of a patent application is misleading. Such background information is as likely to be irrelevant or unnecessary additional information. As a result, instead of characterizing a disclosure of source or origin of traditional knowledge as "enhanced disclosure requirements" the phrase "additional requirements" should be used.

Also, this comment does not acknowledge that many countries have opposed adding such a comment. The failure of this Comment, and others, to reflect the range of opinions on this issue is disconcerting.

Page 26, "Protection against unjust enrichment or misappropriation of TK". This comment presupposes that use by one party by information learned from another is unjust enrichment. When a patent expires, is it unjust enrichment for others to use the knowledge disclosed in the expired patent? What is the difference between information disclosed in a patent, and information that has benefited a community for generations? To suggest that it would be unjust or misappropriation for knowledge to be used in one situation, but not in another requires further explanation, and should not be summarily determined to be a gap.

Right of Acknowledgement and Integrity

Page 27, "A right of acknowledgement and integrity" – while many of the proposed gaps call into question when traditional knowledge is actually used, the right to prior informed consent and the right acknowledgement do so most clearly. Knowledge is the building block of mankind, and often small pieces of knowledge are used. In the example on page 24, a community is said to have developed a range of useful applications for a medicinal plant, including an understanding of how this plant is to be

cultivated, harvested and used. If the system of cultivation is not unique to that community, but is common to many communities, would a company that cultivates different plants that begins to use the same cultivation step after learning from a number of communities, and learning that they all use the same cultivation step, need to obtain prior informed consent and acknowledge the other known use to all or just one of the communities? What would be the significance of the company later learning that the fertilizer that they have been using has a compound within it that is the same as what the communities applied during cultivation? How would a right of integrity be balanced with other public policy considerations? For example, suppose a community has a means for treating malaria, but within the community it is believed that the treatment method must be administered only by certain specifically trained people. When would the method be able to be used without such people, in an emergency? What if the community is particularly sensitive, for example, clothing of a specific color is considered objectionable if worn by men, when would the community have a right to insist that the color be worn only by women? The section "a right to acknowledgement and integrity" will need to additional details to help to sort through what such a right would mean to other communities.

Right of Remuneration

Pages 27-28, (iv) absence of entitlement to obtain remuneration or other benefits, this section does not address the complexity of the issues related to sharing of benefits, and instead appears to focus on a collective right to receive benefits. There may be many different holders of traditional knowledge, and an individual right to compensation/receipt of benefits may also be a gap. On the other hand, the right to have a global fund for the payment or delivery of benefits may be a gap. Others have claimed that the gap is the right of a state to entitlement to equitable remuneration or other equitable benefit sharing from the commercial use of TK or other derivation of benefits from TK.

Page 29, the international debate on the protection of traditional knowledge appears to be driven by concepts of social responsibility, and this should be listed as a consideration relevant to whether a gap should be addressed. It is noted that the "substantive considerations" includes some discussion of social considerations. Substantive considerations tend to be quantifiable (the concept that without protection, a certain amount of knowledge will be lost), whereas social considerations are more basic, and include concepts of morality (e.g., the right to attribution).

International Texts

Paragraph 51, (second bullet), "The adoption of the United Nations Declaration on the Rights of Indigenous Peoples, which articulates a wide range of rights with direct bearing both on traditional knowledge as such, and IP related to TK" recommend deletion here as this document was not intended to develop intellectual property policy in this field; it was a side issue with no experts on TK from any country being present in the room.

All Viewpoints

Paragraph 53, this paragraph is said to reflect social, cultural, political and economic considerations, but does not appear to list the considerations from all viewpoints. For example, this paragraph assumes that the use of TK is increasing "in a host of industrial and commercial applications" and "in a range of regulatory contexts" but there is no evidence provided that such use has not been cyclical, with such uses increasing and decreasing over time. The word "increasing" is not necessary in this context and should be deleted. Also, if the use of traditional knowledge has increased recently, then the use of knowledge in general of other societies has increased. Accordingly, a social, cultural and economic consideration that may be viewed as potentially relevant should also be the global environment in which we live, where information can be shared easily through the internet and goods are transported around the world on a regular basis.

Global Community

Similarly, although the global community may be making use of TK in addressing environmental concerns such as forest fires, traditional knowledge holders are also making use of knowledge from the global community. What is the social responsibility of TK holders to the global community or to other similarly situated communities for the use of their knowledge? What are the cultural, political or economic considerations if organizations outside of the TK holder's community play a significant role in the preservation of TK?

Paragraph 54, line 2, "increasingly" should be deleted. Whether TK is increasingly referenced or used depends upon the time period or the circumstances, and the use of this subjective term in this context is not necessary. Similarly, there is no evidence to support that TK is increasingly referenced in the "Increasing overlap between traditional knowledge as such an formal disciplines of biotechnology". This bullet should be deleted or reworded.

Paragraph 55, the fact that many national or regional processes are developing stronger protection of TK does not necessarily suggest that there may be impediments or obstacles if there no international dimension providing a "common platform". An international dimension could itself create difficulties or obstacles to countries or regions providing more specific protection. Although the reduction in legal uncertainty would appear to be beneficial, the law could clearly create new costs due to new ownership claims. For example, a first country could claim ownership of a certain textile pattern that has been also used for a long period in a second country. The new law could create significant costs to address the claim of TK protection. As a result, in the last bullet, "common international approach towards TK protection issues" should be changed to a "creation of a new form of intellectual property protection".

Paragraph 55, the suitability of contracts to address the use of traditional knowledge should be considered relevant to the need for addressing perceived gaps.

Paragraph 61, the reference to the Universal Declaration on Human Rights should be deleted, as it was not intended to develop intellectual property policy. Similarly, in the

second paragraph in the box in paragraph 61, the reference to the "Universal Declaration of Human Rights" should be deleted.

Paragraph 62, box, the reference to examples in intellectual property refer to documents, such as the Sub-Commission's text, that were not drafted or adopted by States nor adopted by experts in intellectual property law, and, therefore, does not seem to support the overall objective of paragraph 62.

Annex

Many of the points raised above apply equally to the table in the annex and each point has not been repeated. The table does not appear to address the gaps created by providing for protection of TK, to allow for certain "fair uses" of TK, or to address conflicting moral values.

Page 3, "Defensive Patent Protection" the identified "gap" does not properly fall within a defensive patent provision. Traditional knowledge does not itself tend to be patentable, because the TK is not novel, have an inventive step, or invented by the applicant for patent. Also, disclosure requirements do not protect the traditional knowledge and appear to have a greater potential for undermining patents than to enhance benefit sharing opportunities.

Page 9, "illegitimate patenting" – why use "illegitimate" here? If the aspect is protection of an invention that builds upon Traditional Knowledge, why not use a more neutral phrase? Disclosure requirements that have been adopted in many countries often fail to have a specific link to the traditional knowledge being an important component of the invention rather than an incidental or tangential relationship. By having the same disclosure requirement for all traditional knowledge, whether the "spark" for the invention or one of the myriad of alternates that are encompassed within a broad patent claim, disclosure requirements themselves have gaps because of their failure to address the complexity of the requirement.

Page 12 - reference to the UNDRIP as a source of public international law should be removed, and the reference could be added to a new section of international texts.

Page 13, one objective appears to be to enable the traditional lifestyle to be sustained, by creating an opportunity for the collection of financial benefits from others' use of traditional knowledge.

On page 14, the reference to disclosure requirements is not understood – is this a disclosure beyond patents, a disclosure in other uses of TK, such as Internet postings?

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