

Working Guidelines

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Q232

The relevance of traditional knowledge to intellectual property law

Introduction

- 1) Broadly, traditional knowledge (TK) may be said to comprise the knowledge systems of indigenous or local communities which may encompass intellectual capital, cultural identity, spiritual beliefs and customary legal systems. TK also has a strong practical component as it has often developed over many generations, in response to changing circumstances and hence, may include traditional agricultural, ecological, environmental or medicinal knowledge.
- 2) TK is not necessarily susceptible to a singular or exclusive definition. Strictly speaking, TK encompasses only knowledge and ideas. In a broader sense, it extends to expression of such knowledge and ideas, such expression being referred to as traditional cultural expressions (TCEs) or 'expressions of folklore', which may include music, art, designs, names, signs and symbols, performances, architectural forms, handicrafts, tools, musical instruments and narratives.
- 3) Useful technologies may often be derived from TK. Examples of use of TK by TK holders, which may have a broader application include:
 - a) Thai traditional healers using *plaunoi* plants to treat ulcers;
 - b) sustainable irrigation maintained through traditional water systems such as the aflaj in Oman and Yemen, and the qanat in Iran;
 - c) knowledge of seasonal migration patterns of particular species in the Hudson Bay region maintained by the Cree and Inuit peoples; and
 - d) use of the Ayahuasca vine by indigenous healers in the western Amazon.
 - e) acupuncture and massage used by Chinese people for curing diseases.
- 4) The interaction between TK and modern legal systems, particularly intellectual property law, has been a mixed bag. Controversial examples relate to representatives of TK holders opposing patents drawing on their TK, such as the use of extracts from the neem tree and the use of turmeric as a wound-healing agent. More positive examples include:
 - a) an agreement giving traditional healers in Samoa a share of the benefits of a new AIDS drug drawing on their knowledge of the *mamala* tree; and
 - b) the Kani tribe of South India sharing in the benefits of a new sports drug based on their TK on the medicinal plant, *arogyapaacha*.

- 5) Commercial exploitation of TK, outside the original domain of the TK holders, raises questions of its legal protection against misuse, the role of prior informed consent and the need for equitable benefit-sharing. In this context, the role of intellectual property (IP) systems in relation to TK and how to preserve, protect and equitably make use of TK has been receiving increasing attention in international policy discussions.
- 6) Protection of TK is often closely linked to the protection of biodiversity, in particular under the Convention on Biological Diversity (**CBD**). The CBD entered into force on 29 December 1993 and was the first international agreement to make explicit reference to the protection of TK. Article 8(j) of the CBD states:

Each Contracting Party shall, as far as possible and as appropriate: ...

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices...

- 7) In September 2007, the UN General Assembly adopted the UN Declaration on the Rights of Indigenous Peoples, Article 31(1) of which states:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

- 8) Significant efforts at achieving harmonisation are already underway in relation to genetic resources and associated TK. The WIPO Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore (IGC) has dealt with a range of issues concerning the interplay between IP, TCEs, TK and genetic resources, including disclosure requirements in patent applications that relate to genetic resources and associated TK used in a claimed invention.
- 9) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD (Nagoya Protocol) was adopted in 2010. This international agreement aims to share the benefits arising from the utilisation of genetic resources in a fair and equitable way. It is open for signature from 2 February 2011 to 1 February 2012, and will enter into force 90 days after the 50th instrument of ratification. There are currently 70 signatories to the Nagoya Protocol.

Scope of this Working Question

- 10) Focus on TK. While genetic resources, TK and TCEs (sometimes referred to collectively as GRTKF) may be closely related and, in some communities, may form part of an integrated heritage, the IGC has developed different systems and tools in relation to each of these. This Working Question seeks to focus primarily on TK. Where possible, in answering the Questions below, the Groups are asked to focus on TK other than TK associated with generic resources and to treat TCEs as encompassed within TK.

- 11) Policy issues limited to IP. While the relevance of TK to IP generally focuses on the legal protection of TK, TK protection involves important policy issues beyond the domain of IP. Other aspects of protection focus on the environment, health, trade and development, food and agriculture and indigenous rights, as well as broader human rights considerations. Matters beyond the relevance of TK to IP law are outside the scope of this Working Question.
- 12) Focus on core IP laws. While the law of unfair competition and other non-IP options, such as trade practices and labelling laws, civil liability, the use of contracts, customary and indigenous law and protocols, regulation of access to genetic resources and associated TK and remedies based on torts such as unjust enrichment may all have a part to play in a comprehensive system of protection of TK, this Working Question is intended to focus on core elements of IP law only, ie patents, trade marks (and other distinctive signs), geographical indications, copyright, designs and confidential information/trade secrets.

Previous work of AIPPI

- 13) Special Committee Q166 ('Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore') monitors, studies and advises on the development of IP and GRTKF.
- 14) **Resolution of Special Committee Q166:** Through a Questionnaire distributed in 2006, Special Committee Q166 collected information and opinions concerning national legal requirements for indicating the country of origin or the source for genetic resources and TK in patent applications involving genetic resources. Thirty-seven Groups responded. The AIPPI Gothenburg Congress (2006) passed a Resolution on the basis of the results from the 2006 Questionnaire. The 2006 Resolution of Special Committee Q166 is annexed to these Working Guidelines as Annexure A for ease of reference.
- 15) **2010 Questionnaire:** In February 2010 Special Committees Q94 ('WTO/TRIPs') and Q166 jointly distributed a Questionnaire to update information collected for the 2006 Questionnaire and to collect information on practical experience with the application of any relevant laws and regulations. Thirty-four Groups responded, of which 12 reported a legal requirement in their country that the source and/or country of origin of biological/genetic resources and TK must be indicated in patent applications for inventions based on biological/genetic resources or TK. Of the Groups who responded in the negative, four reported that there was a relevant project, bill or draft law dealing with the topic, which was underway in their respective countries.

Discussion

- 16) The scope of this Working Question is different from the previous work of AIPPI described above, in two respects. First, it focuses specifically on TK and its relevance to IP law. Secondly, within this perspective, this Working Question considers broader issues than those canvassed in the Questionnaires and Resolution of Special Committee Q166 to date.

Definition(s)

- 17) TK is not static. The content of TK, as it relates to any given group, develops and changes over time. A question therefore arises in the context of exploring legal protection for TK as to whether it is desirable, or even possible, to develop a definition of the term 'traditional knowledge'.
- 18) Various sample 'definitions' (or more accurately, 'descriptions') below illustrate the

challenge of trying to arrive at a singular definition, and the dynamic nature of TK.

- (a) '[K]nowledge that is unique to a given cultural society ... [and which] contrasts with the international knowledge system generated by universities, research institutions and private firms.' (Warren, 1991)
- (b) '[A] body of knowledge built by a group of people through generations living in close contact with nature.' (Johnson, 1992)
- (c) '[K]nowledge that people in a given community have developed over time, and continue to develop. ... based on experience, often tested over centuries ...'. (International Institute for Rural Reconstruction, 1996)
- (d) '[C]ontent or substance of knowledge resulting from intellectual activity in a traditional context, [including] the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, all contained in codified knowledge systems passed between generations.' (WIPO/GRTKF/IC/19/IMF/8)

19) It may not be possible to develop a precise definition of TK. However, a singular definition may not be necessary to delimit the scope of the subject matter of TK for which IP protection is sought. Definitions in many national IP systems function satisfactorily on the basis of inclusive definitions. Some of the fundamental concepts of the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works are not exclusively defined. Arguably, the more important definitional and conceptual issues are around eligibility for protection, the scope of protection and how any rights are exercised.

Existing means of protection

- 20) International coordination and cooperation is necessary because ownership and interests in TK and the risk of misuse of TK are not necessarily confined within national boundaries.
- 21) A number of the international agreements and declarations (examples of which are included above) relevant to the legal protection of TK are essentially aspirational in character. By contrast, the Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPs**) establishes minimum standards of legal protection for various categories of IP, including those relevant to the protection of TK (and also TCEs) as follows.

Category of IP	TRIPs reference	Relevant to TK/TCEs
Copyright and related rights	Part II Section 1	TCEs
Trade marks	Part II Section 2	TK/TCEs
Geographical indications	Part II Section 3	TK/TCEs
Industrial designs	Part II Section 4	TCEs
Patents	Part II Section 5	TK (primarily)
Protection of undisclosed information	Part II Section 9	TK (primarily)
Protection of plant varieties	Article 27.3(b)	Traditional agricultural knowledge

22) National laws and regulations are currently the primary mechanism for providing protection to TK and realising practical benefits for TK holders. Brazil, Costa Rica, India, Peru, Panama, the Philippines, Portugal, Thailand and the United States of America (**US**)

have all adopted sui generis laws that protect at least some aspects of TK.

- 23) In some cases, existing IP laws have been adapted to provide TK protection. A recent example (that is not without controversy) is the South African Intellectual Property Laws Amendment Bill which has passed through parliament and is awaiting assent. The Bill, if made law, will amend various IP laws relating to performance, trade marks, copyright and designs. The Bill implements a regime (already in force in relation to patents) whereby IP based on TK cannot be registered without:
 - (a) mandatory disclosure of the TK element;
 - (b) the TK owners' prior informed consent; and
 - (c) entry into a benefit sharing arrangement with the TK owners.
- 24) The policy considerations in relation to protection from exploitation of TK have led to two forms of IP related protection for TK:
 - (a) positive protection – giving TK holders the right to take action or seek remedies against misuse of TK, including by way of granting some form of exclusive rights over TK; and
 - (b) defensive protection – safeguarding against illegitimate IP rights acquired by others over TK subject matter.

Commentators and stakeholders have stressed that these two approaches are complementary and a comprehensive approach to the protection of TK holders' interests requires both forms of protection.

Positive protection

- 25) Positive protection confers on TK holders certain legal rights over their TK, of which the rights to authorise, refuse and determine conditions for access to the TK concerned are the most fundamental. Options for positive protection include use of existing IP laws and legal systems, extending or adapting IP rights specifically to focus on TK (sui generis aspects of IP laws) and new, sui generis or stand alone systems.
- 26) Existing IP laws have been used to protect TK, including laws relating to patents, trade marks, geographical indications, industrial designs and trade secrets. Examples of existing IP rights being used to protect TK include:
 - (a) **Patents:** in 2001, China granted 3300 patents for innovations within the field of traditional Chinese medicine;
 - (b) **Distinctive signs (trade marks, collective marks, certification marks, geographical indications):** the Seri people of Mexico registered the *Arte Seri* trade mark to protect authentic ironwood products produced by traditional methods from the *Olneya tesota* tree from competition from mass production; and
 - (c) **The law of confidential information and trade secrets:** the Tulalip Tribes, a group of North American indigenous communities, have developed a digital collection of their TK, aspects of which are protected as undisclosed information.
- 27) In another example, members of the indigenous Pitjantjatjara Council in Australia obtained an interlocutory injunction to restrain the publication of a book containing information which had been supplied in confidence to an anthropologist decades earlier. The basis for the injunction was a breach of confidence, the court being persuaded that the revelation of sacred secrets contained in the book would undermine social and religious stability in the community.
- 28) There are some limitations to using existing IP laws in this context. For example, TK that is not widely known or readily accessible to people beyond the TK holders may be

protected as undisclosed information. However, due to the communal nature of TK, the threshold question of whether the TK is generally known or has entered the public domain may be a barrier to protection. Similarly, critics who question the relevance of patent protection for TK point to the fact that patent protection is ordinarily limited to one or more individual inventors whose inventions meet the standards of novelty, utility (or 'industrial application') and non-obviousness (or 'inventive step'). For instance, the 3300 patents granted by the Chinese Patent Office in the field of traditional Chinese medicine mentioned above all have to meet the novelty and inventiveness criterion as stipulated in the Chinese Patent Law. Whether these standards can be met for the granting of patents relating to TK innovation and whether those patents can be ultimately sustained, if challenged, may prove another barrier to protection.

- 29) Other shortcomings cited include the duration of most IP rights. Ownership and interests in TK typically span generations, a much longer timeframe than some IP rights. There are also concerns that the cost of using IP systems may be an obstacle for many TK holders.
- 30) As noted above, some communities and countries protect TK through wholly sui generis rights so as to accommodate the particular characteristics of TK and related policy goals. Examples include:
 - a) Peru's Law No 27, 811 of 2002 which collects the knowledge of indigenous people associated with biological resources, granting those people the right to consent to the use of TK and foreseeing payment of equitable compensation for the use of certain types of TK;
 - b) Costa Rica's Biodiversity Law No 778 which provides for the equitable distribution to TK holders of benefits arising from the use of TK on the basis of sui generis community IP rights, the title holder(s) of which is (or are) to be determined by a participatory process with indigenous and small farmer communities; and
 - c) Thailand's Act on the Protection and Promotion of Traditional Thai Medicinal Intelligence, BE 2542 which protects 'traditional Thai medicinal intelligence', and permits registration of rights which give sole ownership in relation to research, development and production.

Defensive protection

- 31) TK is protected defensively by steps that prevent third parties from obtaining or exercising illegitimate IP rights over TK. This type of regime seeks to create a legal framework to prevent third parties from wrongfully claiming rights to elements of TK. The main focus of defensive protection measures has been to seek to ensure that existing TK is not patented or otherwise allowed to be inappropriately exploited by third parties. This is achieved, for instance, by ensuring that relevant TK is taken into account as prior art when examining a patent application for novelty and inventive step. This has two aspects. The first aspect is legal, namely how to ensure that the criteria defining relevant prior art applies to TK, for example orally disclosed information. The second aspect is practical, namely how to ensure TK is available and readily accessible to search authorities and patent examiners.
- 32) Some countries have made the requirement for disclosure of origin a formal condition of patentability, including Brazil, China, Columbia, Costa Rica, Egypt, India, Peru and Switzerland. However, disclosure requirements do not always extend to the TK associated with genetic resources, for example Belgium, Denmark and Sweden. Similarly, China specifically amended its patent law in 2008 to include disclosure of origin as a requirement of patentability for inventions relating to genetic resources only. In contrast, Swiss patent law obliges the patent applicant to provide information regarding the source of a genetic resource and TK in the patent application. Similar disclosure requirements in South and Central American countries also tend to cover both genetic

resources and TK. India requires disclosure of the source and geographic origin of biological material used in an invention, and provides that it is a criminal act to apply for IP rights in any country for an invention based on a biological resource originating in India without prior approval of India's National Biodiversity Authority.

- 33) Some commentators have noted that, to date, national disclosure requirements have had limited impact. This may be because, in most cases, they have not been in force for any substantial period of time. Another reason may be that these requirements usually refer to national patent applications only and do not affect patents filed, for example, through the EPO or under the PCT.
- 34) Other examples of existing IP rights being used to prevent third parties from obtaining or exercising illegitimate rights over TK include:
 - a) a Database of Official Insignia of Native American Tribes, which prevents third parties from registering these insignia as trade marks in the US; and
 - b) New Zealand's trade mark law, which excludes from registration trade marks which would cause offence, this applying particularly to Maori symbols.

Questions

I. Analysis of current law and case law

The Groups are invited to answer the following questions under their national laws:

- 1) Is TK defined in your national law?
- 2) If yes to question 1, what is the source of the definition?
- 3) If yes to question 1, how is TK defined?
- 4) If TK is not defined in your national law, is there any 'working definition' described in any draft law or regulation, policy document or other discussion material?
- 5) Does your national law provide for any protection (whether positive or defensive) for TK?
- 6) If yes to question 5, is the protection found in:
 - a) existing IP laws or regulations;
 - b) adaptation of IP laws or regulations through sui generis measures for TK protection;
 - or
 - c) wholly sui generis laws or regulations relating to TK protection?
- 7) If yes, to any part of question 6, please provide details of the law(s) or regulation(s), including where such detail exists:
 - a) criteria for eligibility for protection;
 - b) beneficiaries of protection;
 - c) scope of protection;
 - d) sanctions, remedies and exercise of rights;
 - e) administration of rights;
 - f) exceptions to and limitations on rights;
 - g) term of protection;

- h) formalities to which protection is subject;
- i) transitional measures;
- j) consistency with other laws;
- k) national treatment and foreign interests; and
- l) trans-boundary cooperation.

Note: the items in this non-exhaustive list are taken from the IGC draft articles relating to the protection of TK dated 20 May 2011: WIPO/GRTKF/IC/19/5. Groups may benefit from referring to this document in answering question 7, but should also add any additional criteria, which exists in their national law.

8) Are the protections described in response to questions 6 and 7:

- a) referable to TK alone; or
- b) related to or linked to the concepts of protection of:
 - (i) genetic resources; or
 - (ii) TCEs?

9) If yes to question 8(b), please provide details of any linkages.

10) Please identify any shortcomings in any protection of TK in your country by reference to the matters in questions 6 to 9 above.

11) Please identify any significant case law in connection with protection of TK in your country.

II. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised rules in relation to the role of TK in relation to IP law.

11) Is a harmonised definition of TK desirable?

12) If yes to question 12, please propose a definition of TK, or the concepts that should be included in any proposed harmonised definition of TK.

13) Is it desirable to have only one form of protection for TK, either positive or defensive, or both forms? Please state reasons.

15) Should TK be protected by:

- a) existing IP laws or regulations;
- b) adaptation of IP laws or regulations through sui generis measures for TK protection; or
- c) wholly sui generis laws or regulations relating to TK protection? In your answer, please identify which and state reasons.

16) If yes to any part of question 15, is a harmonised approach to protection desirable? In your answer, please state reasons.

17) If yes to question 16, how should that approach be implemented

- a) at an international level; and
- b) at a national or regional level?

18) Having regard to WIPO/GRTKF/IC/19/5, please provide any proposals you have as to a harmonised approach concerning:

- a) criteria for eligibility for protection;
- b) beneficiaries of protection;
- c) scope of protection;
- d) sanctions, remedies and exercise of rights;
- e) administration of rights;
- f) exceptions to and limitations on rights;
- g) term of protection;
- h) formalities to which protection is subject;
- i) transitional measures;
- j) consistency with other laws;
- k) national treatment and foreign interests; and
- l) trans-boundary cooperation.
- m) any specific measures for facilitating protection of TK, eg, systems for recording TK, specific mechanisms for benefit-sharing, or collective or reciprocal systems of administration on behalf of indigenous people or local communities.

National Groups are invited to comment on any additional issue concerning the relevance of TK to IP law.

NOTE:

It will be helpful and appreciated if the following points could be taken into consideration when editing the Group Report:

- kindly follow the order of the questions and use the questions and numbers for each answer
- if possible type your answers in a different colour
- please send in a word document
- in case images need to be included high resolution (not less than 300 dpi) is required for good quality printing

ANNEXURE A

Resolution

Question Q166

Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

AIPPI

Observing the struggle of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to come to final conclusions on the topics;

Noting that

- the Convention on Biological Diversity accepts the sovereignty of states over their genetic resources and traditional knowledge connected with it, and puts forward the concept of prior informed consent and access and benefit sharing when utilising such resources;
- many member countries of the Convention on Biological Diversity have not yet set up mechanisms how to access genetic resources under their control and how to get prior informed consent;

Mindful that

- the patent system is intended to encourage inventors to disclose their inventions to the public in return for a monopoly period in which patent owners may prevent others from practising the invention, and that an invention is a solution to a technical problem;
- patents should only be granted for inventions which are new, not obvious and capable of industrial application, and should contain disclosure of the invention sufficient to enable the skilled person in the art to work the invention;
- the patent system cannot prevent unlawful use of genetic material or traditional knowledge in research, development, marketing of products, or trade;

Supporting that users of genetic material and traditional knowledge connected with it comply with the requirements of the Convention on Biological Diversity and national laws in this respect.

Resolves:

- 1) Traditional knowledge in the public domain should be treated as other information in the public domain for the assessment of patentability of inventions.
- 2) The patent system is not suitable to control whether the requirements of the Convention on Biological Diversity are met, in particular since research results and products in commerce and trade need not be covered by patents.
- 3) If national laws require a declaration of the source of genetic material and traditional knowledge in patent applications, such laws should:
 - only require that the patent applicant to the best of his knowledge identifies the source from which the inventor obtained the genetic material or the information based on traditional knowledge;
 - entitle the applicant to rectify any failure to indicate the source or add any later information obtained on the origin of the genetic material.

- 4) Ways and means other than patent applications should be developed to deal with prior informed consent and access and benefit sharing concerning genetic resources and traditional knowledge connected with it.