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# Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Eighteenth Session Geneva, May 9 to 13, 2011

# GLOSSARY OF KEY TERMS RELATED TO INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE

Document prepared by the Secretariat

- 1. At its seventeenth session, held from December 6 to 10, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided that the Secretariat should "prepare and make available, as an information document for IWG 2, a glossary on intellectual property and traditional knowledge as recommended by the first Intersessional Working Group in its Summary Report (WIPO/GRTKF/IC/17/8)". 1
- 2. The Second Intersessional Working Group (IWG 2) met from February 21 to 25, 2011 and "noted the "Glossary of Key Terms related to Intellectual Property and Traditional Knowledge" (WIPO/GRTKF/IWG/2/INF 2) and requested that it be transmitted as an information document to the next session of the IGC."<sup>2</sup>
- 3. This present document draws, as far as possible, from previous glossaries of the Committee and from existing United Nations and other international instruments. The document also takes into account definitions and glossaries which can be found in national and regional laws and draft laws, multilateral instruments, other organizations and processes and in dictionaries. Further, definitions are based on working documents of the Committee, other WIPO documents and documents of other work programs of WIPO. That said, the proposed definitions are not exhaustive. Other terms may also be

<sup>&</sup>lt;sup>1</sup> Draft Report of the Seventeenth Session of the Committee (WIPO/GRTKF/IC/17/12 Prov.)

<sup>&</sup>lt;sup>2</sup> Summary Report of the Second Intersessional Working Group (WIPO/GRTKF/IWG/2/2)

- relevant to intellectual property and traditional knowledge, and the terms selected may also be defined in other ways.
- 4. The selection of key terms has been based on the terms used most frequently in document WIPO/GRTKF/IC/18/5 and other related documents. The selection and proposed definitions contained in the Annex are without prejudice to any other glossary or definitions of key terms contained in previous documents of this Committee or in any other international, regional or national instrument or fora. The selection and proposed definitions of key terms are not intended to suggest that the selection of terms or their proposed definitions are necessarily agreed upon by participants in the Committee. This is an information document and the Committee is not requested to endorse or adopt either the selection of terms or their proposed definitions.
- 5. Pursuant to the decision of the Committee taken at its sixteenth session, a "Glossary of Key Terms Related to Intellectual Property and Genetic Resources" (WIPO/GRTKF/IC/17/INF/13) was prepared for the Committee's seventeenth session. Following the Third Intersessional Working Group that met from February 28 to March 4, 2011, this document has been reissued for the eighteenth session of the Committee as document WIPO/GRTKF/IC/18/INF/9. Some terms contained in the genetic resources glossary are also included in the present document, since they are related to traditional knowledge. In line with the decision of the Committee taken at its seventeenth session, the Secretariat has been commissioned "to prepare and make available, as an information document for the next session of the Committee, a glossary on intellectual property and traditional cultural expressions"3. This has been made available as document WIPO/GRTKF/IC/18/INF/7. The Committee might wish to consider whether the three glossaries should eventually be consolidated into one, noting that some terms are related to genetic resources, traditional knowledge and traditional cultural expressions.
  - 6. The Committee is invited to take note of this document and the Annex to it.

[Annex follows]

<sup>&</sup>lt;sup>3</sup> Draft Report of the Seventeenth Session of the Committee (WIPO/GRTKF/IC/17/12 Prov.)

#### ANNEX

GLOSSARY OF KEY TERMS RELATED TO INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE

## Access and Benefit-sharing (ABS)<sup>1</sup>

The Convention on Biological Diversity (CBD) has among its objectives "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity aims to "the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components". According to Article 3, the Protocol "shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge."

For plant genetic resources for food and agriculture, the International Treaty on Plant Genetic Resources (ITPGRFA) for Food and Agriculture of the Food and Agriculture Organization (FAO) requires in Article 1 the "fair and equitable sharing of the benefits arising out of" their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".

"Access" has been defined by Article 1 of the Andean Community Decision 391 as "the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things".

Article 4(2) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) provides that "(a) [t]he benefits of protection of traditional knowledge to which its holders are entitled include the fair and equitable sharing of benefits arising out of the commercial or industrial use of that traditional knowledge. (b) Use of traditional knowledge for non-commercial purposes need only give rise to non-monetary benefits, such as access to research outcomes and involvement of the source community in research and educational activities. (c) Those using traditional knowledge beyond its traditional context should mention its source, acknowledge its holders, and use it in a manner that respects the cultural values of its holders. (d) Legal means should be available to provide remedies for traditional knowledge holders in cases where the fair and equitable sharing of benefits as provided for in paragraphs 1 and 2 has not occurred, or where knowledge holders were not recognized as provided for by paragraph 3. (e) Customary laws within local communities may play an important role in sharing benefits that may arise from the use of traditional knowledge."

<sup>&</sup>lt;sup>1</sup> Glossary of Key Terms Related to Intellectual Property and Genetic Resources (WIPO/GRTKF/IC/18/INF/9), page 1 of Annex

#### **Beneficiaries**

Many stakeholders have emphasized that traditional knowledge are generally regarded as collectively originated and held, so that any rights and interests in this material should vest in communities rather than individuals. In some cases, however, individuals, such as traditional healers, might be regarded as the holders of traditional knowledge and as beneficiaries of protection.

Some national and regional laws for the protection of traditional knowledge provide rights directly to concerned peoples and communities.

Many rather vest rights in a governmental authority, often providing that proceeds from the granting of rights to use the traditional knowledge shall be applied towards educational, sustainable development, national heritage, social welfare or culture related programs.

Article 2 of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) provides that "[p]rotection of traditional knowledge should benefit the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context, who are associated with it and who identify with it in accordance with Article 1(3). Protection should accordingly benefit the indigenous and traditional communities themselves that hold traditional knowledge in this manner, as well as recognized individuals within these communities and peoples. Entitlement to the benefits of protection should, as far as possible and appropriate, take account of the customary protocols, understandings, laws and practices of these communities and peoples."

# **Biological Diversity<sup>2</sup>**

Article 2 of the CBD defines the term "biological diversity", often shortened to "biodiversity", as meaning the "variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems".

# Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines)<sup>3</sup>

The Bonn Guidelines were adopted in 2002 by the Conference of Parties of the CBD in order to provide guidance in respect of implementation of relevant provisions under Articles 8(j), 10(c), 15, 16 and 19 of the CBD related to access to genetic resources and benefit-sharing. The Guidelines are voluntary in nature and are addressed to a range of stakeholders<sup>4</sup>. They cover procedural and regulatory aspects, in particular, of prior informed consent, and identify monetary and non-monetary forms of benefit-sharing<sup>5</sup>.

<sup>&</sup>lt;sup>2</sup> ld

<sup>&</sup>lt;sup>3</sup> Id, page 3 of Annex

<sup>&</sup>lt;sup>4</sup> See Bonn Guidelines, Articles 1, 7(a) and 17 to 21

<sup>&</sup>lt;sup>5</sup> See Bonn Guidelines, Articles 24 to 50 and Appendix II

## **Codified Traditional Knowledge**

"Codified traditional knowledge" refers to "traditional knowledge which is in some systematic and structured form, in which the knowledge is ordered, organized, classified and categorized in some manner".

Article 1(2) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) provides that traditional knowledge "includes the know-how, skills, innovations, practices and learning [...] contained in codified knowledge systems passed between generations."

"In the field of traditional medicine, for example, the Traditional Medicine Team of the World Health Organization (WHO) distinguishes between (a) *codified* systems of traditional medicine, which have been disclosed in writing in ancient scriptures and are fully in the public domain, e.g. Ayurveda disclosed in ancient Sanskrit scriptures<sup>7</sup> or Traditional Chinese Medicine (TCM) disclosed in ancient Chinese medical texts<sup>8</sup>; and (b) *non-codified* traditional medicinal knowledge which has not been fixed in writing, often remains undisclosed by traditional knowledge holders, and is passed on in oral traditions from generation to generation. In South Asia, for example, the codified knowledge systems include the Ayurvedic system of medicine, which is codified in the 54 authoritative books of the Ayurvedic System, the Siddha system, as codified in 29 authoritative books, and the Unani Tibb tradition, as codified in 13 authoritative books<sup>9</sup>."

Another distinction has been made, namely (i) traditional knowledge which has been codified, i.e., traditional knowledge which appears in written form, and which is in the public domain; and (ii) traditional knowledge which is not codified and which forms part of the oral traditions of indigenous communities.<sup>11</sup>

The "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found" (WIPO/GRTKF/IC/17/INF/9) discusses codified traditional knowledge and non-codified traditional knowledge further.

# Convention on Biological Diversity (CBD)<sup>12</sup>

An international convention adopted in June 1992 during the United Nations Conference on Environment and Development held in Rio de Janeiro, Brazil. According to Article 1 of the CBD, the Convention aims at "the conservation of biological diversity, the sustainable use of its

<sup>&</sup>lt;sup>6</sup> List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found (WIPO/GRTKF/IC/17/INF/9), para. 16 of Annex

<sup>&</sup>lt;sup>7</sup> Ayurveda is a codified system of traditional medicine which was disclosed in writing in the Vedic period when the Aryans compiled the four Vedas (1500-1800 B.C.) with maximum references in the *Rigveda* and the *Atharvaveda* 

<sup>&</sup>lt;sup>8</sup> Traditional Chinese Medicine was initially codified and disclosed in writing in the *Yellow Emperor's Canon of Medicine*, the first monumental classic establishing TCM. The Canon was compiled over several hundred years and appeared between 300 and 100 B.C.

<sup>&</sup>lt;sup>9</sup> In India the First Schedule of the Drugs and Cosmetics Act, No. 23 of 1940, as amended by the Drugs and Cosmetics (Amendment) Act No. 71 of 1986, specifies the authoritative books of the Ayurvedic, Siddha and Unani Tibb Systems

<sup>&</sup>lt;sup>10</sup> Inventory of Existing Online Databases Containing Traditional Knowledge Documentation Data (WIPO/GRTKF/IC/3/6), para. 8. Also see Karin Timmermans and Togi Hutadjulu, The TRIPs Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals, page 45

<sup>11</sup> Intervention of the Delegation of Canada. See Report of the Second Session (WIPO/GRTKF/IC/2/16), para. 131

<sup>&</sup>lt;sup>12</sup> See supra note 6, page 3 of Annex

components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding". It entered into force on December 29, 1993.

#### Custodian

Black's Law Dictionary defines "custodian" as "[a] person or institution that has charge or custody (of a child, property, papers, or other valuables)". A "custodian" is defined in the Oxford English Dictionary as "one who has the custody of a thing or person; a guardian, keeper."

The term "custodian" in the context of traditional knowledge refers to those communities, peoples, individuals and other entities which, according to customary laws and other practices, maintain, use and develop the traditional knowledge. It expresses a notion that is different from "ownership" as such, since it conveys a sense of responsibility to ensure that traditional knowledge is used in a way that is consistent with community values and customary law.

## **Customary Law and Protocol**

Black's Law Dictionary defines "customary law" as "[l]aw consisting of customs that are accepted as legal requirements or obligatory rules of conduct; practices and beliefs that are so vital and intrinsic a part of a social and economic system that they are treated as if they were laws."

Customary law has also been defined as "locally recognized principles, and more specific norms or rules, which are orally held and transmitted, and applied by community institutions to internally govern or guide all aspects of life." <sup>13</sup>

The ways in which customary laws are embodied differ from one another. For instance, the laws can be codified, written or oral, expressly articulated or implemented in traditional practices. Another important element is whether these laws are actually "formally" recognized by and/or linked to the national legal systems of the country in which a community resides. A decisive factor in determining whether certain customs do have status as law is whether they have been viewed by the community as having binding effect, or whether they simply describe actual practices.

Article 1(3)(iii) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) provides that "[p]rotection should be extended at least to that traditional knowledge which is: ... (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws." Article 2 provides that "[e]ntitlement to the benefits of protection should, as far as possible and appropriate, take account of the customary protocols, understandings, laws and practices of these communities and peoples." Article 4(2)(e) provides "[c]ustomary laws within local communities may play an important role in sharing benefits that may arise from the use of traditional knowledge."

<sup>&</sup>lt;sup>13</sup> Protection Rights over Traditional Knowledge: Implications of Customary Laws and Practices, Research Planning Workshop, Cusco, Peru, 20-25 May, 2005

## **Disclosed Traditional Knowledge**

"Disclosed traditional knowledge" refers to "[traditional knowledge which is accessible to persons beyond the indigenous or local community which is regarded as the 'holder' of the [traditional knowledge]. Such [traditional knowledge] might be widely accessible to the public and might be accessed through physical documentation, the internet and other kinds of telecommunication or recording. [Traditional knowledge] might be disclosed to third parties or to non-members of the indigenous and local communities from which [traditional knowledge] originates, with or without the authorization of the indigenous and local communities."

Article 8 of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) states that registers of traditional knowledge "should not compromise the status of hitherto undisclosed traditional knowledge or the interests of traditional knowledge holders in relation to undisclosed elements of their knowledge."

The "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found" (WIPO/GRTKF/IC/17/INF/9) discusses disclosed traditional knowledge and undisclosed traditional knowledge further.

## Disclosure Requirements<sup>15</sup>

Disclosure is part of the core rationale of patent law<sup>16</sup>. Patent law imposes a general obligation on patent applicants, as referred to in Article 5 of the Patent Cooperation Treaty (PCT), "to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". However, "disclosure requirements" are recently used as a general term for reforms made to patent law at the regional or national level, and proposals to reform international patent law, which would specifically oblige patent applicants to disclose several categories of information concerning traditional knowledge and/or genetic resources when these are used in developing the invention claimed in a patent or patent application.<sup>17</sup>

Three broad functions have been considered for disclosure methods relating to genetic resources and traditional knowledge:

- to disclose any genetic resources/traditional knowledge actually used in the course of developing the invention (a descriptive or transparency function, pertaining to the genetic resources/traditional knowledge itself and its relationship with the invention);
- to disclose the actual source of the genetic resources/traditional knowledge (a
  disclosure function, relating to where the genetic resources/traditional knowledge was
  obtained) this may concern the country of origin (to clarify under which jurisdiction the
  source material was obtained), or a more specific location (for instance, to ensure that
  genetic resources can be accessed, so as to ensure the invention can be duplicated or
  reproduced); and
- to provide an undertaking or evidence of prior informed consent (a compliance function, relating to the legitimacy of the acts of access to genetic resources/traditional knowledge source material) - this may entail showing that genetic resources/traditional

<sup>&</sup>lt;sup>14</sup> See supra note 6, para. 4 of Appendix

<sup>&</sup>lt;sup>15</sup> See supra note 1, pages 4-5 of Annex

<sup>&</sup>lt;sup>16</sup> See document WIPO/GA/32/8, Annex, page 32

<sup>&</sup>lt;sup>17</sup> For further information see document WIPO/GRTKF/IC/16/6, Annex I, pages 7 to 11 and WIPO, TK Division, database on national and regional legislative measures in patent law, available at: http://www.wipo.int/tk/en/laws/genetic.html

knowledge used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; or showing that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.<sup>18</sup>

At the invitation of the CBD Conference of Parties (COP), the Committee has prepared a technical study on this issue, as well as an examination of issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, which have been made available to the CBD.<sup>19</sup>

Several proposals on an international level have been made at the Committee.

The Swiss proposal to introduce a disclosure requirement in the PCT applying to both international and national applications and requiring the patent applicants to disclose the source of genetic resources and/or traditional knowledge.<sup>20</sup>

The proposal made by the European Union and its Member States includes an obligation to implement a mandatory requirement to disclose the country of origin or source of genetic resources for all international, regional and national patent applications.<sup>21</sup>

Alternative mechanisms to disclosure requirements have been proposed. <sup>22</sup>

Another current international initiative for a disclosure requirement is the proposed Article 29*bis* of the WTO TRIPS Agreement propounded by a number of countries.<sup>23</sup>

#### **Documentation**

Documenting traditional knowledge includes recording it, writing it down, taking pictures of it or filming it - anything that involves recording traditional knowledge in a way that preserves it and could make it available for others to learn about it. It is different from the traditional ways of preserving and passing on knowledge within the community. Documentation is especially important because it is often the way people beyond the traditional circle get access to traditional knowledge.<sup>24</sup>

The "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found" (WIPO/GRTKF/IC/17/INF/9) discusses documented traditional knowledge and non-documented traditional knowledge further.

Related Terms: Traditional Knowledge Digital Library (TKDL), Traditional Knowledge Resource Classification (TKRC), Register of Traditional Knowledge, WIPO Traditional Knowledge Toolkit.

<sup>&</sup>lt;sup>18</sup> See WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge, WIPO Publication No. 786(E), page 65

<sup>&</sup>lt;sup>19</sup> WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge, WIPO Publication No. 786(E); WIPO/GA/32/8 ("Examination of Issues regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications"), 2005

<sup>&</sup>lt;sup>20</sup> See document WIPO/GRTKF/IC/11/10 (Swiss Proposal) and document WIPO/GRTKF/IC/16/6 Annex, page 13

<sup>&</sup>lt;sup>21</sup> See document WIPO/GRTKF/IC/8/11 (EU Proposal) and document WIPO/GRTKF/IC/16/6 Annex, page 14

<sup>&</sup>lt;sup>22</sup> See document WIPO/GRTKF/IC/9/13 (Alternative Proposal)

<sup>&</sup>lt;sup>23</sup> See document TN/C/W/52

<sup>&</sup>lt;sup>24</sup> Report on the Toolkit for Managing Intellectual Property when Documenting Traditional Knowledge and Genetic Resources (WIPO/GRTKF/IC/5/5), page 4 of Annex

## Farmers' Rights

Article 9.1 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture recognizes "the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centers of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world."

Article 9.2 defines "farmers' rights" as "(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture".

Article 2 of the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer defines the term as "the rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the FAO International Undertaking on Plant Genetic Resources."

# Food and Agriculture Organization (FAO)<sup>25</sup>

A United Nations specialized agency committed to defeating hunger and poverty at the international level. The Organization's mandate includes "raising levels of nutrition, improving agricultural productivity, bettering the lives of rural populations and contributing to the growth of the world economy" <sup>26</sup>.

## **Indigenous and Local Communities**

The term "indigenous and local communities" has been the subject of considerable discussion and study. There is no universal, standard definition of "indigenous and local communities".

The term "indigenous and local communities" is used in the Convention on Biological Diversity. For instance, Article 8(j) states that "[e]ach 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; ...". The same term is used in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

<sup>&</sup>lt;sup>25</sup> See supra note 1, page 6 of Annex

<sup>&</sup>lt;sup>26</sup> http://www.fao.org/about/mission-gov/en/

The Convention on Biological Diversity uses the term "indigenous and local communities" in recognition of communities that have a long association with the lands and waters that they have traditionally live on or used.<sup>27</sup>

This term is also used in the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Article 5.1 states that "[e]ach Contracting Party ... shall in particular, as appropriate: ... (d) Promote in situ conservation of wild crop relatives and wild plants for food production, including in protected areas, by supporting, inter alia, the efforts of indigenous and local communities...".

Other legal instruments use different terms:

"Local or traditional community" is used in the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore. Article 2.1 states that "*'community'*, where the context so permits, includes a local or traditional community."

"Local and indigenous communities" is used in Article 9.1 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture: "[t]he Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world...".

"Local communities" is used in Article 5.1 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture: "[e]ach Contracting Party ... shall in particular, as appropriate: ... (c) Promote or support, as appropriate, farmers and local communities' efforts to manage and conserve on-farm their plant genetic resources for food and agriculture...".

Article 1 of the Decision 391 on Access to Genetic Resources of Andean Community defines "native, Afro-American or local community" as "a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them."

Article 7.III of the Brazilian Provisional Act No. 2,186-16, dated August 23, 2001, defines "local community" as a "human group, including descendants of Quilombo communities, differentiated by its cultural conditions, which is, traditionally, organized along successive generations and with its own customs, and preserves its social and economic institutions."

Different terms are used in "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5), such as "indigenous and local community" (Article 1(2)), "traditional or indigenous community or people" (Article 1(3)), "indigenous and traditional community" (Article 2) and "local community" (Article 4(2)).

# Indigenous Knowledge (IK)

"Indigenous knowledge" is used to describe "knowledge held and used by communities, peoples and nations that are 'indigenous'". <sup>28</sup> In this sense, "indigenous knowledge" would be the

<sup>&</sup>lt;sup>27</sup> The Concept of Local Communities, Background paper prepared by the Secretariat of the Permanent Forum on Indigenous Issues for the Expert Workshop on the Dissaggregation of Data (PFII/2004/WS.1/3/Add.1). Also see UNEP/CBD/WS-CB/LAC/1/INF/5

<sup>&</sup>lt;sup>28</sup> It is also mentioned that "indigenous knowledge" is also used to refer to knowledge that is itself "indigenous". In this sense, the terms "TK" and "indigenous knowledge" may be interchangeable. See WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) "Intellectual Property Needs and Expectations of

traditional knowledge of indigenous peoples. Indigenous knowledge is, therefore, a part of the traditional knowledge category, but traditional knowledge is not necessarily indigenous.<sup>29</sup>

## **Indigenous Peoples**

The term "indigenous peoples" has been the subject of considerable discussion and study. There is no universal, standard definition of "indigenous peoples".

The United Nations Declaration on the Rights of Indigenous Peoples acknowledges the equal human rights of indigenous peoples against cultural discrimination and seeks to promote mutual respect and harmonious relations between the indigenous peoples and States. However, there is no definition of "indigenous peoples".

The description of the concept of "indigenous" in the Study of the Problem of Discrimination Against Indigenous Populations, prepared by Special Rapporteur of the United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities, Mr. J. Martínez Cobo, is regarded as an acceptable working definition by many indigenous peoples and their representative organizations. The Study understands indigenous communities, peoples and nations as "those which, having a historical continuity with 'pre-invasion' and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those countries, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identities, as the basis of their continued existence as peoples, in accordance with their own cultural pattern, social institutions and legal systems."

The UNEP Glossary of Biodiversity Terms defines "indigenous people" as "people whose ancestors inhabited a place or country when persons from another culture or ethnic background arrived on the scene and dominated them through conquest, settlement, or other means and who today live more in conformity with their own social, economic, and cultural customs and traditions than with those of the country of which they now form a part. (Also: 'native peoples' or 'tribal peoples.')" 30

The Peruvian Law No. 27811 of 24 July, 2002, Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources defines "indigenous peoples" as "aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. These include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. The term 'indigenous' shall encompass, and may be used as a synonym of, 'aboriginal', 'traditional', 'ethnic', 'ancestral', 'native' or other such word form."

"Aboriginal people" is a related term. The Oxford Dictionary defines "aboriginal" as (1) "[...] of peoples, plants, and animals: inhabiting or existing in a land from earliest times; strictly native, indigenous"; (2) "[...] inhabiting or occupying a country before the arrival of European colonists

[Footnote continued from previous page]

Traditional Knowledge", page 23-24. Also see List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found (WIPO/GRTKF/IC/17/INF/9), para. 41 of Annex

<sup>&</sup>lt;sup>29</sup> See WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) "Intellectual Property Needs and Expectations of Traditional Knowledge", page 23. Also see List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found (WIPO/GRTKF/IC/17/INF/9), para. 41 of Annex

<sup>&</sup>lt;sup>30</sup> UNEP Glossary of Biodiversity Terms. It is available at http://www.unep-wcmc.org/reception/glossaryF-L.htm

and those whom they introduced"; and (3) "[...] of, relating to, or characteristic of the Aborigines of Australia or their languages".

Section 35 of the Constitution of Canada states that "[...] Aboriginal Peoples of Canada includes the Indian, Inuit and Métis peoples of Canada." The 1996 Canadian Royal Commission on Aboriginal People self-defined their focus group as: "... organic political and cultural entities that stem historically from the original peoples of North America...".

# Intellectual Property Guidelines for Access and Benefit-sharing<sup>31</sup>

From its first session, the Committee supported a task which would lead to the development by WIPO of Intellectual Property Guidelines for Access and Benefit-sharing. It was proposed that the Guidelines be based on a systemic survey of actual and model contractual agreements in the form of the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements<sup>32</sup>.

A first draft<sup>33</sup> was prepared taking into account the operational principles identified by the Committee for the development of such Guidelines<sup>34</sup>. This draft was later updated for purposes of the seventeenth session of the Committee<sup>35</sup>.

The purpose of the Intellectual Property Guidelines for Access and Benefit-sharing is to serve both providers and recipients of genetic resources when they negotiate, develop and draft the IP elements of mutually agreed terms for access to genetic resources and benefit-sharing. They illustrate the practical IP issues that providers and recipients are likely to face when negotiating an agreement, contract or licence. The diversity of national law and of the practical interests of providers and recipients are likely to lead to a wide range of choices when actual provisions are negotiated and drafted. Guidelines may therefore support providers and recipients in ensuring that access and benefit-sharing is on equitable, mutually agreed terms, but does not prescribe one template or set of choices.

Further, nothing in such Guidelines should be interpreted to affect the sovereign rights of States over their natural resources, including their entitlement to set terms and conditions on access and benefit-sharing. Guidelines would be voluntary and illustrative only. They would be no substitute for relevant international, regional or national legislation<sup>36</sup>.

Traditional knowledge is often associated with genetic resources, and this can provide valuable insights into how genetic resources can be preserved, maintained, and used for the benefit of humanity.<sup>37</sup> The Guidelines also apply to traditional knowledge associated with genetic resources.

<sup>&</sup>lt;sup>31</sup> See supra note 1, pages 7-8 of Annex

<sup>&</sup>lt;sup>32</sup> See document WIPO/GRTKF/IC/2/3, para. 133, also see Glossary of Key Terms Related to Intellectual Property and Genetic Resources (WIPO/GRTKF/IC/18/INF/9), page 4 of Annex

<sup>&</sup>lt;sup>33</sup> See document WIPO/GRTKF/IC/7/9 (Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing)

<sup>&</sup>lt;sup>34</sup> See operational principles in document WIPO/GRTKF/IC/2/3, Section V.B, page 50

<sup>&</sup>lt;sup>35</sup> See document WIPO/GRTKF/IC/17/INF/12 (Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing: Updated version)

<sup>&</sup>lt;sup>36</sup> Id

<sup>&</sup>lt;sup>37</sup> Id, page 4 of Annex

## **International Patent Classification (IPC)**

International Patent Classification (IPC) is defined as "a hierarchical system in which the whole area of technology is divided into a range of sections, classes, subclasses and groups. The Classification is a language independent tool indispensable for the retrieval of patent documents in the search for 'prior art'."<sup>38</sup>

The IPC was established by the Strasbourg Agreement Concerning the International Patent Classification, 1971. Article 2(1)(a) provides that "[t]he Classification comprises: (i) the text which was established pursuant to the provisions of the European Convention on the International Classification of Patents for Invention of December 19, 1954 (hereinafter designated as the "European Convention"), and which came into force and was published by the Secretary General of the Council of Europe on September 1, 1968; (ii) the amendments which have entered into force pursuant to Article 2(2) of the European Convention prior to the entry into force of this Agreement; (iii) the amendments made thereafter in accordance with Article 5 which enter into force pursuant to the provisions of Article 6."

# Inventive Step<sup>39</sup>

Inventive step (also referred to as "non-obviousness") is one of the criteria of patentability and relates to the question of whether the invention would have been obvious to a person having ordinary skill in the art<sup>40</sup>.

According to article 33 of the PCT, a claimed invention shall be considered to involve an inventive step "if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art".

Article 56 of the European Patent Convention and Section 35 U.S.C. 103 provide for similar definitions. Section 35 U.S.C. 103 uses the equivalent term "non-obvious subject matter".

# Licensing Agreements<sup>41</sup>

Licensing agreements are described as agreements setting out certain permitted use of materials or rights that the provider is entitled to grant, such as agreements to license the use of genetic resources as research tools, or to license the use of associated traditional knowledge or other IP rights. 42

# Material Transfer Agreements (MTAs)<sup>43</sup>

Material Transfer Agreements are agreements in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms

<sup>38</sup> WIPO PATENTSCOPE Glossary

<sup>&</sup>lt;sup>39</sup> See supra note 1, page 8 of Annex

<sup>&</sup>lt;sup>40</sup> WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 20

<sup>&</sup>lt;sup>41</sup> See supra note 1, page 9 of Annex

<sup>42</sup> See document WIPO/GRTKF/IC/17/INF/12

<sup>&</sup>lt;sup>43</sup> See supra note 1, page 9 of Annex

and cell cultures to exchange of materials from a provider to a recipient and setting conditions for access to public germplasm collections, seed banks or *in situ* genetic resources<sup>44</sup>.

WIPO has developed the Database of Biodiversity-related Access and Benefit-sharing Agreements containing contractual clauses related to the transfer and use of genetic resources. 45

The FAO has developed and adopted in 2006 a Standard Material Transfer Agreement (SMTA) as required for the implementation of the ITPGRFA.<sup>46</sup> Appendix I of the Bonn Guidelines suggests elements for material transfer agreements.

## Minimum Documentation PCT<sup>47</sup>

According to the WIPO PCT Glossary, the Minimum documentation could be described as "The documents in which the International Searching Authority must search for relevant prior art. It also applies to International Preliminary Examining Authorities for examination purposes. The documentation comprises certain published patent documents and non-patent literature contained in a list published by the International Bureau. The Minimum Documentation is set out by the PCT Regulations Rule 34". 48

In the PCT International Search Guidelines, the international search minimum documentation is defined as "a document collection that is systematically arranged (or otherwise systematically accessible) for search purposes according to the subject matter content of the documents, which are primarily patent documents supplemented by a number of articles from periodicals and other items of non-patent literature". <sup>49</sup>

In February of 2003, at the seventh session of the Meeting of International Authorities under the PCT, there was agreement in principle that Traditional Knowledge documentation should be included in the non-patent literature part of the PCT Minimum Documentation<sup>50</sup>. For instance, the Indian Journal of Traditional Knowledge and the Korean Journal of Traditional Knowledge are identified as non-patent literature in the "PCT Minimum Documentation – List of Periodicals: Periodicals to Be Used for Search and Examination".

## Misappropriation

In the field of intellectual property, Black's Law Dictionary defines "misappropriation" as "the common-law tort of using the noncopyrightable information or ideas that an organization collects and disseminates for a profit to compete unfairly against that organization, or copying a work whose creator has not yet claimed or been granted exclusive rights in the work. [...] The elements of misappropriation are: (1) the plaintiff must have invested time, money, or effort to extract the information, (2) the defendant must have taken the information with no similar investment, and (3) the plaintiff must have suffered a competitive injury because of the taking."

<sup>44</sup> See supra note 35

<sup>&</sup>lt;sup>45</sup> Available at: http://www.wipo.int/tk/en/databases/contracts/index.html

<sup>&</sup>lt;sup>46</sup> Available at: ftp://ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf

<sup>&</sup>lt;sup>47</sup> See supra note 1, page 9 of Annex

<sup>&</sup>lt;sup>48</sup> Available at: http://www.wipo.int/pct/en/texts/glossary.html#M

<sup>&</sup>lt;sup>49</sup> Para IX-2.1, PCT International Search Guidelines (as in force from 18 September 1998)

<sup>&</sup>lt;sup>50</sup> PCT Minimum Documentation, document PCT/MIA/9/4

The tort of misappropriation is part of unfair competition law in the common law system.

Misappropriation thus entails the wrongful or dishonest use or borrowing of someone's property, and is often used to found action in cases where no property right as such has been infringed. Misappropriation may refer to wrongful borrowing or to the fraudulent appropriation of funds or property entrusted to someone's care but actually owned by someone else.

Article 3 of draft law "A Legal Framework for the Protection of Traditional Knowledge In Sri Lanka", 2009 defines "misappropriation" as "(i) acquisition, appropriation or use of traditional knowledge in violation of the provisions of this Act, (ii) deriving benefits from acquisition, appropriation or use of traditional knowledge where the person who acquires, appropriates or uses traditional knowledge is aware of or could not have been unaware of or is negligent to become aware of the fact that the traditional knowledge was acquired, appropriated or used by any unfair means and (iii) any commercial activity contrary to honest practices that results in unfair or inequitable benefits from traditional knowledge."<sup>51</sup>

Article 3(1) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) defines "acts of misappropriation" as "any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge." It also states that "filn particular, legal means should be provided to prevent: (i) acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach or inducement of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means: (ii) acquisition of traditional knowledge or exercising control over it in violation of legal measures that require prior informed consent as a condition of access to the knowledge, and use of traditional knowledge that violates terms that were mutually agreed as a condition of prior informed consent concerning access to that knowledge; (iii) false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over traditional knowledge-related subject matter when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access; (iv) if traditional knowledge has been accessed, commercial or industrial use of traditional knowledge without just and appropriate compensation to the recognized holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on its user, and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge; and (v) willful offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge and is contrary to ordre public or morality."

<sup>&</sup>lt;sup>51</sup> Working Document-Version 01- January 2009 "A Legal Framework For The Protection Of Traditional Knowledge In Sri Lanka" is available at http://www.wipo.int/wipolex/en/details.jsp?id=7425

## Misuse<sup>52</sup>

In the field of patents, Black's Law Dictionary defines "misuse" as "the use of a patent either to improperly extend the granted monopoly to nonpatented goods or to violate antitrust laws."

Dictionaries define misuse as a wrong, incorrect or improper use, or misapplication. Misuse may also refer to improper or excessive use, or to acts which change the inherent purpose or function of something.

# Mutually Agreed Terms (MAT)<sup>53</sup>

Besides recognizing the authority of national governments to determine access to genetic resources, Article 15 of the CBD provides that "access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article". The Executive Secretary of the CBD has noted that "contracts are the most common way of recording "mutually agreed terms". The Bonn Guidelines indicate some basic requirements for mutually agreed terms in Articles 41 to 44.

Article 18 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity specifically deals with compliance with mutually agreed terms, providing that "1. In the implementation of Article 6, paragraph 3 (g)(i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including: (a) The jurisdiction to which they will subject any dispute resolution processes; (b) The applicable law; and/or (c) Options for alternative dispute resolution, such as mediation or arbitration. 2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms. 3. Each Party shall take effective measures, as appropriate, regarding: (a) Access to justice; and (b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards. 4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol."

Article 4(1)(c) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTK/IC/18/5) provides that "[m]easures and mechanisms for implementing the principle of prior informed consent should be understandable, appropriate, and not burdensome for all relevant stakeholders, in particular for traditional knowledge holders; should ensure clarity and legal certainty; and should provide for mutually agreed terms for the equitable sharing of benefits arising from any agreed use of that knowledge."

It was proposed to add the term "misuse" in the text of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) by some Delegations, such as the Delegation of Indonesia and the Delegation of Mexico. However, the Delegation of Australia noted that misuse was a term that was used in the CBD context within the draft negotiating text for an international regime on access and benefit sharing of genetic resources and associated traditional knowledge. It was used to refer to acts that were contrary to mutually agreed terms, while misappropriation referred specifically to acquisition without prior informed consent. It called for further discussion as to the meaning of these terms in the context of the Committee and in relation to intellectual property rather than access to traditional knowledge associated with genetic resources

<sup>&</sup>lt;sup>53</sup> See supra note 1, page 10 of Annex

<sup>&</sup>lt;sup>54</sup> Article 15.4, CBD

<sup>55</sup> See document UNEP/CBD/COP/4/22, para. 32

# Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

A protocol was adopted in October 2010 during the tenth meeting of the Conference of the Parties (COP 10) held in Nagoya, Japan. According to Article 1, the Protocol aims to "the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components". The Secretary-General of the United Nations will be the Depositary of the Protocol and will open it for signature at the United Nations Headquarters in New York from 2 February 2011 to 1 February 2012.

Several articles are specifically related to traditional knowledge associated with genetic resources, such as Article 3 (Access to Traditional Knowledge Associated with Genetic Resources), Article 12 (Traditional Knowledge Associated with Genetic Resources), and Article 16 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing for Traditional Knowledge Associated with Genetic Resources).

## Novelty<sup>56</sup>

Novelty is one of the criteria of patentability in any examination as to substance. An invention is new if it is not anticipated by prior art<sup>57</sup>.

According to Article 33 of the PCT, novelty is defined as follows: "For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations". Rule 64.1(a) of the Regulations under the PCT defines "prior art" as "everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior to the relevant date".

Article 54 of the EPC defines "Novelty" as follows: "An invention shall be considered to be new if it does not form part of the state of the art. The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application".

Section 35 of the U.S.C.102 [Conditions for patentability; novelty and loss of right to patent] defines the concept of novelty as follows: "A person shall be entitled to a patent unless — the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, ...".

#### **Patent**

A patent is defined as "a document which describes an invention which can be manufactured, used, and sold with the authorization of the owner of the patent. An invention is a solution to a specific technical problem. A patent document normally contains at least one claim, the full text of the description of the invention, and bibliographic information such as the applicant's name. The protection given by a patent is limited in time (generally 15 to 20 years from filing or grant). It

<sup>&</sup>lt;sup>56</sup> See supra note 1, page 10 of Annex

<sup>&</sup>lt;sup>57</sup> WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 19

is also limited territorially to the country or countries concerned. A patent is an agreement between an inventor and a country. The agreement permits the owner to exclude others from making, using or selling the claimed invention."<sup>58</sup>

Article 27.1 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement states that "[...] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [...] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

#### Prior Art<sup>59</sup>

Prior art is, in general, all the knowledge that existed prior to the relevant filing or priority date of a patent application, whether it existed by way of written and oral disclosure. In some legal instruments there is a differentiation between printed publications, oral disclosures and prior use and where the publications or disclosure occurred.<sup>60</sup>

For the purposes of the PCT, prior art is defined by Rule 33.1 of the PCT Regulations as "everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e. that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date".

In the case of Europe, Article 54(2) of the EPC defines the equivalent term "the state of the art" as comprising "everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of the European patent application". With reference to this provision of the EPC, the Guidelines for Examination in the European Patent Office (EPO) emphasize that "[t]he width of this definition should be noted. There are no restrictions whatever as to the geographical location where, or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information. However certain specific exclusions exist (see IV, 8)". 61

Section 35 of the U.S.C. 102 defines prior art indirectly through the concept of novelty as anything "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, ...".

Section 29 of Japanese Patent Law indirectly defines "prior art" as "(i) inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application; (ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application".

<sup>&</sup>lt;sup>58</sup> WIPO PATENTSCOPE Glossary

<sup>&</sup>lt;sup>59</sup> See supra note 1, pages 10-11 of Annex

<sup>&</sup>lt;sup>60</sup> WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 19

<sup>&</sup>lt;sup>61</sup> See Guidelines for Examination in the European Patent Office, Part C, Chapter IV, para 5.1

## Prior and Informed Consent (PIC)<sup>62</sup>

A right or principle of "prior and informed consent" (PIC) or sometimes "free, prior informed consent" (FPIC) is referred to or implied in several international instruments, particularly in the environmental field, such as Article 6(4) of the Basel Convention on the transboundary movement of hazardous wastes, 1989, and the CBD.

In respect to access to genetic resources, the CBD states in Article 15(5) CBD that it "shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party".

Article 16(1) of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity provides that "[e]ach Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located."

The notion was originally derived from medical ethics in which a patient has the right to decide whether or not to undergo a medical treatment after being fully informed about the risks and benefits of that particular treatment. For instance, the Universal Declaration on the Human Genome and Human Rights of 1997 states in Article 5 that in all cases of research, treatment or diagnosis affecting an individual's genome the potential risks and benefits should be assessed and "the prior, free and informed consent of the person concerned shall be obtained". Article 6 of the UNESCO Declaration on Bioethics and Human Rights of 2005 requires the "prior, free and informed consent of the person concerned" when it comes to "preventive, diagnostic and therapeutic medical intervention" or "scientific research".

Article 4(1) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTK/IC/18/5) provides that "(a) The principle of prior informed consent should govern any access of traditional knowledge from its traditional holders, subject to these principles and relevant national laws. (b) The holder of traditional knowledge shall be entitled to grant prior informed consent for access to traditional knowledge, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation. (c) Measures and mechanisms for implementing the principle of prior informed consent should be understandable, appropriate, and not burdensome for all relevant stakeholders, in particular for traditional knowledge holders; should ensure clarity and legal certainty; and should provide for mutually agreed terms for the equitable sharing of benefits arising from any agreed use of that knowledge."

### **Protection**

"Protection" in the work of the Committee has tended to refer to protection of traditional knowledge against some form of unauthorized use by third parties. <sup>63</sup> Two forms of protection have been developed and applied.

<sup>&</sup>lt;sup>62</sup> See supra note 1, page 11 of Annex

<sup>&</sup>lt;sup>63</sup> Overview of Activities and Outcomes of the Intergovernmental Committee (WIPO/GRTKF/IC/5/12), para. 20

#### Positive Protection

Two aspects of positive protection of traditional knowledge by intellectual property rights are explored, one concerned with preventing unauthorized use and the other concerned with active exploitation of traditional knowledge by the originating community itself. Besides, the use of non-intellectual property approaches for the positive protection of traditional knowledge can be complementary to the use of intellectual property rights and could be used in conjunction with intellectual property protection. For instance, positive protection of TK may prevent others from gaining illegitimate access to TK or using it for commercial gain without equitably sharing the benefits, but it may also be used by TK holders to build up their own enterprises based on their TK.

## **Defensive Protection**

Defensive protection refers to a set of strategies to ensure that third parties do not gain illegitimate or unfounded intellectual property rights over traditional knowledge subject matter and related genetic resources. 66 Defensive protection of traditional knowledge includes measures to preempt or to invalidate patents that illegitimately claim pre-existing traditional knowledge as inventions.

#### Preservation

Preservation has two broad elements – first, the preservation of the living cultural and social context of traditional knowledge, so that the customary framework for developing, passing on and governing access to traditional knowledge is maintained; and second, the preservation of traditional knowledge in a fixed form, such as when traditional technical know-how or medicinal knowledge is documented. Preservation may have the goal of assisting the survival of the traditional knowledge for future generations of the original community and ensuring its continuity within an essentially traditional or customary framework, or the goal of making traditional knowledge available to a wider public (including scholars and researchers), in recognition of its importance as part of the collective cultural heritage of humanity.<sup>67</sup>

## Public Domain<sup>68</sup>

In general, a work is considered to be in the public domain if there is no legal restriction for its use by the public.<sup>69</sup>

Black's Law Dictionary defines the public domain as "[t]he universe of inventions and creative works that are not protected by intellectual-property rights and are therefore available for anyone to use without charge. When copyright, trademark, patent, or trade-secret rights are lost or expire, the intellectual property they had protected becomes part of the public domain and can be appropriated by anyone without liability for infringement".

 $<sup>^{64}</sup>$  Id, paras. 21 and 22

<sup>65</sup> ld, paras, 21

<sup>66</sup> ld, paras. 28

<sup>67</sup> Id, para. 19

<sup>&</sup>lt;sup>68</sup> See supra note 1, page 12 of Annex

<sup>69</sup> See document SCP/13/5

The public domain has been defined in the field of copyright and related rights as "the scope of those works and objects of related rights that can be used and exploited by everyone without authorization, and without the obligation to pay remuneration to the owners of copyright and related rights concerned — as a rule because of the expiry of their term of protection, or due to the absence of an international treaty ensuring protection for them in the given country". <sup>70</sup>

In general, the public domain in relation to patent law consists of knowledge, ideas and innovations over which no person or organization has any proprietary rights. Knowledge, ideas and innovations are in the public domain if there are no legal restrictions of use (varying in different legislations and forming, therefore, different public domains), after expiration of patents (regularly 20 years), in consequence of non renewal, after revocation and after invalidation of patents.<sup>71</sup>

The role, contours and boundaries of the "public domain" are under active discussion in several forums, including in WIPO and this Committee. Document WIPO/GRTKF/IC/7/INF/8 discusses the meanings of the "public domain" in relation to traditional knowledge further.<sup>72</sup>

## **Publicly Available**

The experts at the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing discussed the terms "public domain" and "publicly available" with special reference to traditional knowledge associated with genetic resources: "The term public domain, which is used to indicate free availability, has been taken out of context and applied to [traditional knowledge] associated with genetic resources that is publicly available. The common understanding of publicly available does not mean available for free. The common understanding of public availability could mean that there is a condition to impose mutually agreed terms such as paying for access. [Traditional knowledge] has often been deemed to be in the public domain and hence freely available once it has been accessed and removed from its particular cultural context and disseminated. But it cannot be assumed that [traditional knowledge] associated with genetic resources that has been made available publicly does not belong to anyone. Within the concept of public availability, prior informed consent from a [traditional knowledge] holder that is identifiable, could still be required, as well as provisions of benefit-sharing made applicable, including when a change in use is discernible from any earlier prior informed consent provided. When a holder is not identifiable, beneficiaries could still be decided for example by the State."<sup>73</sup>

The term "already readily available" is used in Article 6(2) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTK/IC/18/5), reading as "[i]n particular national authorities may exclude from the principle of prior informed consent the fair use of traditional knowledge which is already readily available to the general public, provided that users

<sup>&</sup>lt;sup>70</sup> WIPO publication "Guide to the Copyright and Related Rights Treaties by WIPO and Glossary of Copyright and Related Rights Terms"

<sup>71</sup> See supra note 69

<sup>&</sup>lt;sup>72</sup> See document WIPO/GRTK/IC/17/INF/8 "Note on Meanings of the Term 'Public Domain' in the Intellectual Property System, with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore"

<sup>&</sup>lt;sup>73</sup> See UNEP/CBD/WG-ABS/8/2, Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing

of that traditional knowledge provide equitable compensation for industrial and commercial uses of that traditional knowledge."

The "Note on Meanings of the Term 'Public Domain' in the Intellectual Property System, with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore" (WIPO/GRTK/IC/17/INF/8) discusses the meanings of the term "public domain" in relation to traditional knowledge and traditional cultural expressions further.<sup>74</sup>

## **Registers of Traditional Knowledge**

Registers can be analyzed from many different perspectives. According to their legal nature, registers can be termed either declarative or constitutive, depending upon the system under which they are established.<sup>75</sup>

A declaratory regime relating to TK recognizes that the rights over TK do not arise due to any act of government but rather are based upon pre–existing rights, including ancestral, customary, moral and human rights. In the case of declarative registers, although registration does not affect the existence of such rights, it may be used to assist patent officials in analyzing prior art, and to support challenges to patents granted which may have directly or indirectly made use of TK. In circumstances where these registers are organized in an electronic form and available through the Internet, it is important to establish a mechanism that ensures that entry dates of TK are valid when carrying out searches related to novelty and inventiveness. A third function that these registers may have is to facilitate benefit–sharing between users and providers.<sup>76</sup>

Constitutive registers form part of a legal regime which seeks to grant rights over traditional knowledge. Constitutive registers will record the granting of rights (i.e. exclusive property rights) to the TK holder as a means to ensure their moral, economic and legal interests are protected and recognized. Most model constitutive registers are conceived as public in nature, run by a national entity and under a law or regulation which clearly determines how valid registration of TK can take place and be formally recognized and accepted. As such they may be more controversial and difficult to design and face some critical challenges and questions in moving from concept to practice. <sup>77</sup>

As an example of a national law, Article 16 of the Peruvian Law N° 27811 "Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources" provides that "[t]he purposes of the Registers of Collective Knowledge of Indigenous Peoples shall be the following, as the case may be: (a) to preserve and safeguard the collective knowledge of indigenous peoples and their rights therein; (b) to provide INDECOPI with such information as enables it to defend the interests of indigenous peoples where their collective knowledge is concerned."<sup>78</sup> Article 15 also provides that "[t]he collective knowledge of

<sup>&</sup>lt;sup>74</sup> See Note on Meanings of the Term "Public Domain" in the Intellectual Property System, with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore (WIPO/GRTK/IC/17/INF/8)

<sup>&</sup>lt;sup>75</sup>The Role of Registers & Databases in the Protection of Traditional Knowledge: A Comparative Analysis. UNU-IAS Report, January 2004, page 32

<sup>&</sup>lt;sup>76</sup> Id

<sup>&</sup>lt;sup>77</sup> Ic

<sup>&</sup>lt;sup>78</sup> Article 16 of Law N° 27811, Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources. The law is available at http://www.wipo.int/wipolex/en/details.jsp?id=3420

indigenous peoples may be entered in three types of register: (a) Public National Register of Collective Knowledge of Indigenous Peoples; (b) Confidential National Register of Collective Knowledge of Indigenous Peoples; (c) Local Registers of Collective Knowledge of Indigenous Peoples."

Article 8.2 of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) states that registers of traditional knowledge "[i]n the interests of transparency, certainty and the conservation of traditional knowledge, relevant national authorities may maintain registers or other records of traditional knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of traditional knowledge holders. Such registers may be associated with specific forms of protection, and should not compromise the status of hitherto undisclosed traditional knowledge or the interests of traditional knowledge holders in relation to undisclosed elements of their knowledge."

#### Sui Generis

Black's Law Dictionary defines "sui generis" as "[Latin "of its own kind"] Of its own kind or class; unique or peculiar. The term is used in intellectual-property law to describe a regime designed to protect rights that fall outside the traditional patent, trademark, copyright, and trade-secret doctrines. For example, a database may not be protected by copyright law if its content is not original, but it could be protected by a sui generis statute designed for that purpose."

A *sui generis* system is a system specifically designed to address the needs and concerns of a particular issue. Calls for a *sui generis system* for the protection of traditional knowledge and traditional cultural expressions are being heard. This could mean a system entirely distinct from the current intellectual property system, such as a system based on customary law, or alternatively a system with new intellectual property, or intellectual property-like rights.

There are already several examples of *sui generis* intellectual property rights, such as plant breeders' rights - as reflected in the International Convention on the Protection of New Varieties of Plants, 1991 ("the UPOV Convention") - and the intellectual property protection of integrated circuits - as reflected in the Treaty on Intellectual Property in respect of Integrated circuits, 1989 ("The Washington Treaty"), among others. Peruvian Law No. 27811 of 24 July, 2002, Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources is a *sui generis* regime for the protection of collective knowledge of indigenous peoples that is connected with biological resources.

"The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) also embody *sui generis* approaches.

# Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore

A protocol was adopted by member states of the African Regional Intellectual Property Organization (ARIPO) in August 2010 during the Diplomatic Conference held in Swakopmund, Namibia. According to Article 1.1, this Protocol aims: "(a) to protect traditional knowledge holders against any infringement of their rights as recognized by this Protocol; and (b) to protect expressions of folklore against misappropriation, misuse and unlawful exploitation beyond their traditional context". The Protocol will enter into force when six Member States of the ARIPO either deposit instruments of ratification or instruments of accession.

## Traditional Ecological Knowledge/Traditional Environmental Knowledge (TEK)

The Dene Cultural Institute defines "traditional environmental knowledge" as "a body of knowledge and beliefs transmitted through oral tradition and first-hand observation. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use. Ecological aspects are closely tied to social and spiritual aspects of the knowledge system. The quantity and quality of TEK varies among community members, depending on gender, age, social status, intellectual capability, and profession (hunter, spiritual leader, healer, etc.). With its roots firmly in the past, TEK is both cumulative and dynamic, building upon the experience of earlier generations and adapting to the new technological and socioeconomic changes of the present." To

Traditional ecological knowledge is also defined as "a cumulative body of knowledge and beliefs, handed down through generations by cultural transmission, about the relationship of living beings (including humans) with one another and with their environment. Further, TEK is an attribute of societies with historical continuity in resource use practices; by and large, these are non-industrial or less technologically advanced societies, many of them indigenous or tribal."

#### **Traditional Context**

"Traditional" means that traditional knowledge is developed according to the rules, protocols and customs of a certain community, and not that it is old. In other words, the adjective "traditional" qualifies the method of creating traditional knowledge and not the knowledge itself.<sup>81</sup>

As indicated in the "Elements of a *Sui Generis* System for the Protection of Traditional Knowledge" (WIPO/GRTKF/IC/4/8), traditional knowledge is "traditional" because it is created in a manner that reflects the traditions of the communities. "Traditional", therefore, does not necessarily relate to the nature of the knowledge but to the way in which the knowledge is created, preserved and disseminated. 82

Article 1(3) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) provides that "[p]rotection should be extended at least to that traditional knowledge which is: (i) generated, preserved and transmitted in a traditional and intergenerational context; (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility". 83

<sup>&</sup>lt;sup>79</sup> Also see Marc G. Stevenson. "Indigenous Knowledge in Environmental Assessments", 49 ARCTIC 278 (1996), page 281

<sup>&</sup>lt;sup>80</sup> Fikret Berkes, Traditional Ecological Knowledge in Perspective. Traditional Ecological Knowledge: Concepts and Cases. International Program on Traditional Ecological Knowledge and International Development Research Centre, Ottawa

<sup>&</sup>lt;sup>81</sup> Nino Pires de Carvalho, From the Shaman's Hut to the Patent Office: A Road Under Construction. Chapter 18 of Biodiversity and the Law, page 244

<sup>82</sup> Elements of a Sui Generis System for the Protection of Traditional Knowledge (WIPO/GRTKF/IC/4/8), para. 27

<sup>83</sup> Article 1(3) of The Protection of Traditional Knowledge: Revised Objectives and Principles (WIPO/GRTKF/IC/18/5)

# Traditional Knowledge (TK)84

In the context of the Committee, "traditional knowledge" is used in a narrow sense (traditional knowledge *stricto sensu*) to refer to knowledge as such, in particular the "content 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, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources." The scope of traditional knowledge that would be eligible for legal protection has been further defined as traditional knowledge which is:

- "(i) generated, preserved and transmitted in a traditional and intergenerational context;
- (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and
- (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws."

#### Traditional Knowledge Associated with Genetic Resources

The term "traditional knowledge associated with genetic resources" is used in the Convention on Biological Diversity.

Some experts at the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing suggested that "traditional knowledge associated with genetic resources" refers to "traditional knowledge which is specific or general in its relationship to genetic resources".<sup>87</sup>

Some molecules/properties/active ingredients of genetic resources may be identified in genetic materials without the support of traditional knowledge and others with the support of traditional knowledge. Although in most cases genetic resources seem to have associated traditional knowledge, it was also recognized that not all genetic resources have associated traditional

<sup>&</sup>lt;sup>84</sup> "Traditional knowledge", as a broad description of subject matter, generally includes the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities (traditional knowledge in a general sense or *lato sensu*). In other words, traditional knowledge in a general sense embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with traditional knowledge

<sup>&</sup>lt;sup>85</sup> Articles 1(1) and 1(2) of The Protection of Traditional Knowledge: Revised Objectives and Principles (WIPO/GRTKF/IC/18/5)

<sup>86</sup> See supra note 83

<sup>&</sup>lt;sup>87</sup> See UNEP/CBD/WG-ABS/8/2, Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing, para.12 of Annex

<sup>88</sup> Id, para.6 of Annex

knowledge. Article 37 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization provides that "[p]ermission to access genetic resources does not necessarily imply permission to use associated knowledge and vice versa."

## Traditional Knowledge Digital Library (TKDL)

The Traditional Knowledge Digital Library (TKDL) is a collaborative project between the Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology, and the Department of AYUSH, Ministry of Health and Family Welfare, of India, and is being implemented at CSIR. An inter-disciplinary team of Traditional Medicine (Ayurveda, Unani, Siddha and Yoga) experts, patent examiners, IT experts, scientists and technical officers were involved in the creation of TKDL for Indian Systems of Medicine. The TKDL project involves documentation of the traditional knowledge available in public domain in the form of existing literature related to Ayurveda, Unani, Siddha and Yoga, in digitized format in five international languages which are English, German, French, Japanese and Spanish. The TKDL provides information on traditional knowledge existing in the country, in languages and format understandable by patent examiners at International Patent Offices (IPOs), so as to prevent the grant of wrong patents.<sup>90</sup>

The TKDL has a dual objective. In the first place, it seeks to prevent the granting of patents over products developed utilizing traditional knowledge where there has been little, if any, inventive step. Second, it seeks to act as a bridge between modern science and traditional knowledge, and can be used for catalyzing advanced research based on information on traditional knowledge for developing novel drugs. The TKDL is intended to act as a bridge between ancient Sanskrit Slokas and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners. It is expected that the gap on lack of prior art knowledge be minimized. The database will have sufficient details on definitions, principles, and concepts to minimize the possibility of patenting "inventions" for minor/insignificant modifications. <sup>91</sup>

## Traditional Knowledge Resource Classification (TKRC)

The Traditional Knowledge Resource Classification (TKRC) is an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval which identifies about 5,000 sub–groups of traditional knowledge against one group in international patent classification (IPC). The TKRC has been developed for the Indian Systems of medicine (Ayurveda, Unani, Siddha and Yoga). The TKRC has gained international recognition and linked with the IPC. It is likely to facilitate greater awareness on the traditional knowledge systems by leveraging the modern system of dissemination i.e. Information Technology, in particular, the Internet and Web technologies. It is anticipated that TKRC structure and details will create interest in those countries that are concerned about prevention of grant of wrong patents for non-original discoveries relating to traditional knowledge systems.

Related Term: International Patent Classification (IPC)

<sup>89</sup> Id, para.7 of Annex

<sup>90</sup> More information is available at http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng

<sup>&</sup>lt;sup>91</sup> See supra note 75, page 18

<sup>&</sup>lt;sup>92</sup> Id

<sup>93</sup> More information is available at http://www.tkdl.res.in/tkdl/langdefault/common/TKRC.asp?GL=Eng

## **Traditional Knowledge Holder**

Black's Law Dictionary defines "holder" as "a person who has legal possession of a negotiable instrument and is entitled to receive payment on it."

WIPO uses this term to refer to all persons who create, originate, develop and preserve traditional knowledge in a traditional setting and context. Indigenous communities, peoples and nations are traditional knowledge holders, but not all traditional knowledge holders are indigenous. <sup>94</sup> In this context, "traditional knowledge" refers to both traditional knowledge *stricto sensu* and traditional cultural expressions.

As indicated in the "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found (WIPO/GRTKF/IC/17/INF/9)", "[traditional knowledge] is, in general, developed collectively and/or regarded as belonged collectively to an indigenous or local community or to groups of individuals within such a community. [...] Nonetheless, a particular individual member of a community, such as a certain traditional healer or individual farmer, might hold specific knowledge."

The "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found" (WIPO/GRTKF/IC/17/INF/9) discusses collective traditional knowledge and individual traditional knowledge further.

#### **Traditional Medicine**

WHO defines the term as "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses"<sup>96</sup>.

WHO also defines "traditional medicine" as "including diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness". 97

## Traditional Knowledge-based Creation or Innovation / Traditional Knowledge "as such"

This term refers to "innovations and creations based on traditional knowledge 'as such', developed and innovated beyond a 'traditional context'"<sup>98</sup>.

"Traditional knowledge 'as such'" refers to "knowledge systems, creations and innovations which have generally been transmitted from generation to generation; are generally regarded as

<sup>&</sup>lt;sup>94</sup> WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) "Intellectual Property Needs and Expectations of Traditional Knowledge", page 26.

<sup>&</sup>lt;sup>95</sup> See supra note 6, paras. 43 and 44 of Annex

<sup>&</sup>lt;sup>96</sup> WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine (WHO/EDM/TRM/2000.1), page 1

<sup>&</sup>lt;sup>97</sup> WHO Traditional Medicine Strategy 2002-2005, page 7

<sup>98</sup> See supra note 6, para. 37 of Annex

pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment." <sup>99</sup>

The "List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found" (WIPO/GRTKF/IC/17/INF/9) discusses traditional knowledge "as such" and traditional knowledge-based creation and innovation further.

#### **Unfair Competition**

Black's Law Dictionary defines "unfair competition" as "[d]ishonest or fraudulent rivalry in trade and commerce; esp., the practice of endeavoring to pass off one's own goods or products in the market for those of another by means of imitating or counterfeiting the name, brand, size, shape, or other distinctive characteristic of the article or its packaging".

Paragraph 2 of Article 10bis of the Paris Convention for the Protection of Industrial Property provides that "[a]ny act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition". Paragraph 3 of Article 10bis further provides that "[t]he following in particular shall be prohibited: (i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor; (ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor; (iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods."

## **United Nations Declaration on the Rights of Indigenous Peoples**

The United Nations General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples in 2007. The Declaration acknowledges the equal human rights of indigenous peoples against cultural discrimination and seeks to promote mutual respect and harmonious relations between the indigenous peoples and States.

In relation to traditional knowledge, traditional cultural expressions and genetic resources, Article 31.1 states that: "[i]ndigenous 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." Article 31.2 further provides that "[i]n conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights."

On traditional medicine, Article 24 provides that "[i]ndigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals."

<sup>99</sup> See supra note 94

## **Use of Traditional Knowledge**

Traditional knowledge can be used for different purposes. The use of traditional knowledge includes commercial or industrial use, customary use, fair use, household use and public health use of traditional medicine, and research and educational use.

#### Commercial Use

Black's Law Dictionary defines "commercial use" as "[a] use that is connected with or furthers an ongoing profit-making activity". "Non-commercial use" is defined as "[a] use for private pleasure or business purposes that non involving the generation of income or bestowing a reward or other compensation".

#### Customary Use

The Pacific Regional Framework defines customary use as "the use of traditional knowledge or expressions of culture in accordance with the customary laws and practices of the traditional owners."

General Guiding Principle (h) of "The Protection of Traditional Knowledge: Revised Objectives and Principles" (WIPO/GRTKF/IC/18/5) and "The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles" (WIPO/GRTKF/IC/17/4) indicates that customary use should be respected. The term "continuing customary use" refers to the persistence and living nature in the use of traditional knowledge and/or traditional cultural expressions by indigenous communities in accordance with their own customary laws and practices.

## Fair Use

In the field of copyright, Black's Law Dictionary defines "fair use" as "[a] reasonable and limited use of a copyrighted work without the author's permission, such as quoting from a book in a book review or using parts of it in a parody. Fair use is a defense to an infringement claim, depending on the following statutory factors: (1) the purpose and character of the use, (2) the nature of the copyrighted work, (3) the amount of the work used, and (4) the economic impact of the use."

## Household Use and Public Health Use

Black's Law Dictionary defines "household" as "[b]elong to the house or family; domestic".

Paragraph 1 of Doha Declaration on the TRIPS Agreement and Public Health recognize "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". Paragraph 5(c) further states that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

## Research and Educational Use

In the field of patents, Black's Law Dictionary defines "experimental-use defense" as "[a] defense to a claim of patent infringement raised when the construction and use of the patented invention was for scientific purposes only. While still recognized, this defense is narrowly construed and today may apply only to research that tests the inventor's claims."

It is to be noted that, although intellectual property rights are exclusive rights, certain exceptions and limitations to the exclusive rights are provided. For example, in the field of patents, a number of countries provide in their national legislations for certain exceptions and limitations to the exclusive rights, including, but not limited to:

- a) acts done for private and non-commercial use;
- b) acts done only for experimental purposes or research purposes.

Article 6 of The Protection of Traditional Knowledge: Revised Objectives and Principles provides that "[t]he application and implementation of protection of traditional knowledge should not adversely affect: (i) the continued availability of traditional knowledge for the customary practice, exchange, use and transmission of traditional knowledge by traditional knowledge holders; (ii) the use of traditional medicine for household purposes; use in government hospitals, especially by traditional knowledge holders attached to such hospitals; or use for other public health purposes. 2. In particular national authorities may exclude from the principle of prior informed consent the fair use of traditional knowledge which is already readily available to the general public, provided that users of that traditional knowledge provide equitable compensation for industrial and commercial uses of that traditional knowledge."

In relation to fair and equitable benefit-sharing, Article 6.2 of the Protection of Traditional Knowledge: Revised Objectives and Principles provides that "Use of traditional knowledge for non-commercial purposes need only give rise to non-monetary benefits, such as access to research outcomes and involvement of the source community in research and educational activities."

## **WIPO Traditional Knowledge Toolkit**

Documentation programs can raise intellectual property questions for holders of traditional knowledge and custodians of genetic resources. Conscious consideration of intellectual property implications is particularly important during the documentation process. The WIPO Traditional Knowledge Toolkit focuses on management of intellectual property concerns during the documentation process, and also takes the documentation process as a starting point for a more beneficial management of traditional knowledge as a community's intellectual and cultural asset. The WIPO Traditional Knowledge Toolkit is structured according to three phases of documentation, namely before documentation, during documentation and after documentation, so as to illustrate more clearly the diverse intellectual property issues that arise at each stage of documentation.

This toolkit is especially designed to be used by holders of traditional knowledge or custodians of biological resources, especially indigenous and local communities and their representatives. Others might also find the toolkit useful, such as an institution which undertakes documentation of traditional knowledge and biological resources (a museum, archive, genebank, botanical garden, etc.); a legal or policy advisor of such custodians of biological resources and traditional knowledge holders; a research institution (university, participatory breeding program, etc.); a government or public sector agency undertaking documentation projects; or a private sector partner. 103

<sup>100</sup> See supra note 24, para. 1

<sup>&</sup>lt;sup>101</sup> Id, para. 2

<sup>&</sup>lt;sup>102</sup> Draft Outline of an Intellectual Property Management Toolkit for Documentation of Traditional Knowledge (WIPO/GRTKF/IC/4/5), page 4 of Annex

<sup>103</sup> Id, page 5 of Annex

Intellectual property rights and other legal tools may be available to protect the knowledge when it is documented, but only if the right steps are taken during documentation. The toolkit will help to assess the intellectual property options, plan and implement intellectual property choices and strategies when documenting traditional knowledge or biological resources.

[End of Annex and of document]

<sup>&</sup>lt;sup>104</sup> Id, page 5 of Annex