

Date: February 7, 2014 (4:00 p.m.)

**Consolidated Document Relating to Intellectual Property and
Genetic Resources
Rev. 2**

LIST OF TERMS

[Associated Traditional Knowledge]

"Associated Traditional knowledge" means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, that [subsist in] [that are associated with] genetic resources.]

[Traditional Knowledge Associated with Genetic Resources]

"Traditional Knowledge Associated with Genetic Resources" means substantive knowledge of the properties and uses of genetic resources and their [derivatives] held by indigenous [people[s] and local communities [and which directly leads to a claimed [invention] [intellectual property]].]

[Biotechnology]

"Biotechnology" [as defined in Article 2 of the Convention on Biological Diversity] means any technological application that uses biological systems, living organisms or [derivatives] thereof, to make or modify products or processes for specific use.]

[Country of Origin]

"Country of origin" is the country which possesses genetic resources in in-situ conditions.]

[[Country Providing] [Providing Country]

"Country Providing/Providing Country" means, [in accordance with Article 5 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], a [providing country] [country providing] that is the country of origin or that has acquired the genetic resources and/or that has accessed the traditional knowledge in accordance with the [Convention on Biological Diversity].]

[Country providing genetic resources]

"Country providing genetic resources" is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.]

[Derivative]

"Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.]

Ex-Situ conservation

"Ex-Situ conservation" means the conservation of components of biological diversity outside their natural habitats.

Genetic Material

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic Resources

"Genetic Resources" are genetic material of actual or potential value.

In situ conditions

"In situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties [Article 2, CBD].

[Internationally Recognized Certificate of Compliance

"Internationally recognized certificate of compliance" shall mean the instrument foreseen in Article 17.2 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.]

[Member State

"Member State" refers to a member state of the World Intellectual Property Organization].

[Misappropriation

"Misappropriation" is the [acquisition] [utilization] of genetic resources [and] [or] associated traditional knowledge without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [[in accordance with national legislation] [of the country of origin or providing country]].]

Alt

["Misappropriation" is the use of genetic resources and/or traditional knowledge associated with genetic resources of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources and associated traditional knowledge that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources and associated traditional knowledge failure to take reasonable protective measures, is not misappropriation.]

[Patent Office]

"Patent Office" means the authority of a Member State entrusted with the granting of patents.

[[Physical] Access

"[Physical] access to the genetic resource" is its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property].]

[Source

Option 1. "Source" refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, gene bank or botanical garden.

[Option 2 . "Source" should be understood in its broadest sense possible:

- (i) Primary sources, including in particular [Contracting Parties] [Countries] providing genetic resources, the Multilateral System of ITPGRFA, indigenous and local communities; and
- (ii) Secondary sources, including in particular ex situ collections and scientific literature.]]

[Utilization

"Utilization of Genetic Resources" means to conduct research and development [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

[PREAMBLE]

[Ensure [encourage] respect for [sovereign rights] [the rights] of indigenous people[s] and local communities [as well as people[s] partially or entirely under occupation] over their genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources], including the principle of [prior informed consent and mutually agreed terms] and total and effective participation in accordance with international [agreements and] declarations [, in particular the UN Declaration on the Rights of Indigenous Peoples.]

Encourage respect for indigenous people[s] and local communities

[The [intellectual property] [patent] system should provide certainty of rights for legitimate users and providers of genetic resources, [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

[Recognize the role the [intellectual property] [patent] system plays in promoting innovation, [transfer and dissemination of technology] to the mutual advantage of stakeholders, providers, holders and users of genetic resources, their [derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

[Promote transparency and dissemination of information.]

[A global and compulsory system creates a level playing field for industry and the commercial exploitation of [intellectual property] [patents], and also facilitates the possibilities [under Article 15(7) of the CBD] for the sharing of the benefits arising from the use of genetic resources.]

[Foster [patent] [industrial property] *protection and the* development of genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources] and encourage international research leading to innovation.]

[The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing. All of these stakeholders may be providers and/or users of genetic resources and traditional knowledge. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual **supportiveness between the access and benefit sharing system and the [intellectual property] [patent] system.**]

[[Ensure] [recommend] that no [patents] [intellectual property] on life forms, including human beings, are granted.]

[Recognize that those accessing genetic resources and associated traditional knowledge in a country should, where required, comply with that's country's national law providing protection for the genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources]].

[[IP][Patent] offices shall/should have a mandatory requirement for disclosure, as elaborated in this international legal instrument, when patenting of genetic resources would cause harm to the interests of indigenous people[s] and local communities].

[Reaffirm, in accordance with the Convention of Biological Diversity, the sovereign rights of States over their biological resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]

POLICY OBJECTIVE[S]

[The objective of this instrument is to [contribute to the prevention of] [prevent] the [misappropriation] of genetic resources [their derivatives] and associated traditional knowledge [traditional knowledge associated with genetic resources] [through the] [in the context of the] [IP] Patents] Rights] system] by:]

- a. ensuring that [IP] [Patent] Offices have access to the appropriate information on genetic resources [their derivatives] and associated traditional knowledge [traditional knowledge associated with genetic resources] to prevent the granting of erroneous [IP] [Patent] Rights;
- b. [enhancing transparency in the [IP][Patent] [and access and benefit sharing] system]; and
- c. Promoting/facilitating [complementarity] [mutual supportiveness] with international agreements relating to the protection of genetic resources [their derivatives] and/or associated traditional knowledge [traditional knowledge associated with genetic resources] [and those relating to IP].

**[ARTICLE 1]
SUBJECT MATTER OF INSTRUMENT**

1.1 [This international legal instrument shall apply to any [IP] [Patent] right or [application] [claimed invention] [derived from [utilization of] [inventions directly based on] genetic resources, [their derivatives] and associated traditional knowledge [traditional knowledge associated with genetic resources]. [This instrument applies to genetic resources and associated traditional knowledge.]

**[ARTICLE 2]
SCOPE OF INSTRUMENT**

2.1 [This instrument provides measures to support the prevention of misappropriation of genetic resources, [genetic parts and components], [their derivatives] and associated traditional knowledge [traditional knowledge associated with genetic resources] through the [IP] [Patent] system.] [, including to prevent the patenting of genetic resources and associated traditional knowledge that were not invented by the patent applicant or patentee or do not have an inventive step over genetic resources and traditional knowledge associated with genetic resources.]

**[ARTICLE 3]
[DISCLOSURE REQUIREMENTS]**

3.1 Where the claimed invention within a [IP Rights] [Patent] application [includes utilization of] [is directly based on] [is consciously derived from the] genetic resources [their derivatives] and/or associated traditional knowledge [traditional knowledge associated with genetic resources] each Party shall require applicants to:

- (a) Disclose the country of origin and [or if unknown,] source of the genetic resources and/or associated traditional knowledge [traditional knowledge associated with genetic resources].
- (b) [Provide relevant information, as required by the national law of the [IP] [Patent] Office, regarding compliance with ABS requirements, including PIC, [in particular from indigenous people[s] and local communities], where appropriate.]
- (c) If the source and/or country of origin is not known, a declaration to that effect.

3.2 The disclosure requirement [shall] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But IP [Patent] offices are required to provide effective guidance to [IP] [Patent] applicants on how to meet disclosure requirements, and to provide an opportunity for applicants to obtain from patent offices a positive decision that disclosure requirements have been met.]

3.3 A simple notification procedure should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices should send the available information.]

3.4 Each Party shall make the information disclosed publically available at the time of publication.

3.5 [Genetic resources and their [derivatives] as found in nature or isolated therefrom shall not be considered as [inventions] [IP] and therefore no [IP] [Patent] rights shall be granted.]]

**[ARTICLE 4]
[EXCEPTIONS AND LIMITATIONS]**

4.1 A [IP] [Patent] disclosure requirement related to genetic resources [their derivatives] and associated traditional knowledge [traditional knowledge associated with genetic resources] shall/should not apply to the following:

- (a) all genetic resources taken from humans [including human pathogens];
- (b) [derivatives];
- (c) [commodities];
- (d) [traditional knowledge in the public domain];
- (e) genetic resources from areas beyond national jurisdiction [and economic zones]; and
- (f) all genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993].

4.2 [Member States should not impose the disclosure requirement in this instrument on [IP] [Patent] applications filed before entry into force of this instrument, subject to national law.]

**[ARTICLE 5]
RELATIONSHIP WITH [PCT] AND [PLT]**

5.1 The [PCT] and [PLT] should be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]. The amendments shall also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.

**[ARTICLE 6]
SANCTIONS AND REMEDIES**

6.1 [Each [Party] [country] shall put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with paragraph 3.1. Subject to national legislation, sanctions and remedies [shall] [may] include, inter alia:

- (a) Pre-Grant.
 - (i) Preventing further processing of [IP] [Patent] applications until the requirements are met.
 - (ii) A [IP] [Patent] office considering the application withdrawn.
 - (iii) Preventing or refusing to grant an [IP Right] [Patent].
- (b) [Post-Grant].
 - (i) Publication of judicial rulings regarding failure to disclose.
 - (ii) [Fines or adequate compensation for damages, including payment of royalties.]
 - (iii) Other measures [including revocation] may be considered depending on the circumstances of the case.]

6.2 [Failure to fulfill the disclosure requirement, [in the absence of fraud], shall not affect the validity or enforceability of granted [IP] [Patent] rights.]

[NO NEW DISCLOSURE REQUIREMENT]

7.1 [IP] [Patent] applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention.] Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources and associated traditional knowledge, for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

DEFENSIVE MEASURES¹

[DUE DILIGENCE]

8.1 Member states should encourage or establish a fair and reasonable due diligence system to ascertain that protected genetic resources have been accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements.

- (a) A database should be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law. However, member states shall not be obliged to establish such data bases.
- (b) Such databases should be accessible to potential patent licencees to confirm lawful chain of title of protected genetic resources upon which a patent is based.]

PREVENTION OF THE ERRONEOUS GRANT OF PATENTS AND VOLUNTARY CODES OF CONDUCT

9.1 Member States should:

- a. provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted erroneously with regard to claimed inventions that include genetic resources and traditional knowledge associated with genetic resources where, under national law, those genetic resources and traditional knowledge associated with genetic resources:
 - (i) anticipate a claimed invention (no novelty); or
 - (ii) obviate a claimed invention (obvious or no inventive step).
- b. provide legal, policy or administrative measures, as appropriate and in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include genetic resources and traditional knowledge associated with genetic resources.
- c. [encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines for users regarding the protection of genetic resources and traditional knowledge associated with genetic resources.]

¹ Facilitators Note. Members should note that some members consider Defensive Measure as an alternative option to Disclosure.

- d. Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases of genetic resources and traditional knowledge associated with genetic resources for use by patent offices.

DATABASE SEARCH SYSTEMS

9.2 Members are encouraged to facilitate the establishment of databases of genetic resources and traditional knowledge associated with genetic resources for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:

- (a) With a view towards interoperability, databases should comply with minimum standards and structure of content.
- (b) Appropriate safeguards should be developed in accordance with national law.
- (c) These databases will be accessible to patent offices and other approved users.

WIPO PORTAL SITE

9.3 Member States shall/should establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources and non-secret traditional knowledge associated with genetic resources within their territory. The WIPO portal site will enable an examiner to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards.

[ARTICLE 10]

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

10.1 This instrument shall/should establish a mutually supportive relationship between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] and relevant existing international agreements and treaties.

10.2 This instrument shall/should complement and is not intended to modify other agreements on related subject matter, and should support in particular, Article 31 of the UN Declaration on the Rights of Indigenous Peoples.

[ARTICLE 11]

INTERNATIONAL COOPERATION

11.1 [[Relevant WIPO bodies should encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group should] develop a set of guidelines for [the search and examination of applications related to genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

[ARTICLE 12]
TRANSBOUNDARY COOPERATION

12.1 [In instances where the same genetic resources [, their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties shall/should endeavor to cooperate, as appropriate, with the involvement of indigenous people[s] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

[ARTICLE 13]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

13.1 [Relevant WIPO bodies [should] [shall]] [WIPO should] develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO [should] [shall] provide technical assistance, cooperation, capacity building and financial support, subject to budgetary resources, for developing countries in particular the least developed countries to implement the obligations under this instrument.]

[End of Annex and of Document]