
Date: February 18, 2016

Facilitators' Text

Consolidated Document Relating to Intellectual Property and Genetic Resources

Rev. 1

DRAFT – WORK IN PROGRESS

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 [first] 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.]

[Directly Based On

"Directly based on" means that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of the resource to which the inventor must have had physical access or access to non-tangible genetic resources or associated traditional knowledge.]

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

Option 1

"Misappropriation" is the [acquisition] [utilization] of genetic resources, [their derivatives] [and] [or] [associated traditional knowledge] [traditional knowledge associated with

genetic resources] 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].]

Option 2

["Misappropriation" is the use of genetic resources, [their derivatives] and/or [associated traditional knowledge] [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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] 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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.].]~~

[Intellectual Property Office] [Patent Office]

["Intellectual property office"] ["Patent office"] means the authority of a Member State entrusted with the granting of [intellectual property rights] [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 a party that has acquired the genetic resources, the Multilateral System of in accordance with the CBD, the multilateral system established by ITPGRFA, indigenous and local communities; and~~

(ii) ~~Secondary other sources, including in particular such 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, [their derivatives] 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 shall/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, [their derivatives] 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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]. 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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] in a country shall/should, where required, comply with that country's national law providing protection for the genetic resources, [their derivatives] 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 [natural] [biological] resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]

Recognize that genetic resources in the form found in nature are not inventions and therefore no patent rights should be granted to such genetic resources.

POLICY OBJECTIVE[S] OBJECTIVES

[The objectivepolicy objectives of this instrument isare tocontribute:

(a) Enhance the efficacy and transparency of the [IP] [international patent] system;

(b) 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:];

Ensuring that [IP] [patent] offices have access(c) Facilitate [complementarity] [mutual supportiveness] with relevant international agreements relating to the appropriate information on genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] to preventand the IP system; and

(d) Minimize the granting of erroneous [IP] [patent] rights;

a. [Enhancing transparency in the [IP][patent] [and access and benefit sharing] system]; and;

b. [Ensuring] [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/should apply to any [IP] [patent] right or [application] [claimed invention] [derived from] [the utilization of] [directly based on] genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].]~~ 1.1 This instrument applies to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

[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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] that were not invented by the patent applicant or patentee or do not have an inventive step over genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]].]~~

[ARTICLE 3] [DISCLOSURE REQUIREMENT]

3.1 — ~~Where the [subject matter] [claimed invention] within a [IP Rights] [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]~~ the subject matter of this instrument, each Party shall/should require applicants to:

(a) Disclose the [providing country that is the country of origin [and]] [or if unknown,] the source of the genetic resources, [their derivatives] 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.].]

If the source and/or country of origin is not known, the applicant may make a declaration to that effect.

3.2 — ~~The disclosure requirement [shall/should] [does] not place an obligation on the [IP] [patent] offices to verify the [veracity of the] contents of the~~

disclosure. ~~[But [IP] [patent] offices are shall, upon request, be required to provide effective guidance to [IP] [patent] applicants on how to meet~~comply with disclosure requirement formalities.

~~3.3 requirements, and to provide an opportunity for applicants to obtain from [Patent] [IP] [patent] offices a positive decision that should, if appropriate, notify disclosure requirements have been met.]~~
~~of origin information to~~

~~3.3 — A simple notification procedure shall/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/NP/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.]~~

3.4 — [Each Party shall/should make the information disclosed ~~publically~~publicly available at the time of publication.]

3.5 — ~~[Genetic resources and [their derivatives] as found in nature or isolated therefrom shall/should not be considered as [inventions] [IP] and therefore no [IP] [patent] rights shall/should 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 [human genetic resources] [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 jurisdictions [and economic zones]]; and
- (f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993].]

4.2.4.2 [Use of genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] that has been acquired by means deemed lawful in the country of origin is not misappropriation.]

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

[ARTICLE 4]
[ENTRY INTO FORCE AND TRANSITIONAL MEASURES]

4.1 [Member States shall/should not impose the disclosure requirement in this instrument on [IP] [patent] applications filed before entry into force of this instrument[, subject to national laws that existed prior to this instrument].]

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

5.1 The [PCT] and [PLT] shall/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/should 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/should put in place appropriate, effective and proportionate legal and/or administrative measures to address non-compliance with paragraph 3.1 ~~[-]~~ [including dispute resolution mechanisms]. Subject to national legislation, sanctions and remedies ~~[shall/should]~~ [may] ~~[include, inter alia]~~ consist of:

- (a) Pre-Grant.
 - (i) Preventing further processing of [IP] [patent] applications until the disclosure requirements are met.
 - (ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].
 - (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) Allowing third parties to dispute the validity of a patent by submitting prior art with regard to inventions that include genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources].
 - ~~(iii)~~(iv) Other measures [including revocation] may be considered depending on the circumstances of the case, in accordance with national law.]]

6.2 ~~[Failure to fulfill]~~ A party may consider revocation of a patent as a sanction for willful, repeated or fraudulent failure to comply with the disclosure requirement, ~~[.]~~

6.3 ~~[Failure to examine a patent application in the absence of fraud], shall/a timely manner should not affect~~ result in an adjustment of the term of the validity or enforceability of granted ~~[IP] [patent] rights.] patent to compensate the patentee for delays.]~~

[ARTICLE 7] [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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

[DEFENSIVE MEASURES¹]

[ARTICLE 8] [DUE DILIGENCE]

8.1 Member states shall/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 shall/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/should not be obliged to establish such databases.

(b) Such databases shall/should be accessible to potential patent licensees to confirm lawful chain of title of protected genetic resources upon which a patent is based.]

¹ Facilitators Note. Members should note that some members consider Defensive Measure as an alternative option to Disclosure while some other members consider them as a complementary option to Disclosure.

**[ARTICLE 9]
[PREVENTION OF THE ERRONEOUS GRANT OF PATENTS AND
VOLUNTARY CODES OF CONDUCT]**

9.1 Member States shall/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 [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] where, under national law, those genetic resources, [their derivatives] and [associated traditional knowledge] [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, [their derivatives] and [associated traditional knowledge] [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, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].]
- d. Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases of genetic resources, [their derivatives] and [associated traditional knowledge] [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 information associated with genetic resources, [their derivatives] -and [associated traditional knowledge] [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 shall/should comply with minimum standards and structure of content.
- (b) Appropriate safeguards shall/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, [their derivatives] and non-secret [associated traditional knowledge] [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] [with] 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 shall/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 shall/should encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group shall/should] develop a set of guidelines for [the search and examination of applications related to genetic resources, [their derivatives] 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 [shall/should]] [WIPO shall/should] develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO [shall/should] 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.]