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Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources

(clean version)

LIST OF TERMS

[Traditional Knowledge Associated with Genetic Resources

Option 1

“Traditional knowledge associated with genetic resources” 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.]

Option 2

“Traditional knowledge associated with genetic resources” means substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by [rightful holders, including] indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]] [and where, but for the traditional knowledge, the invention would not have been made].]

[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.]

ALT

[“Country providing genetic resources” is the country that possesses the genetic resource and/or traditional knowledge in in situ or ex situ conditions and that provides the genetic resource and/or traditional knowledge.]

[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.]

[[Invention] Directly Based On

"[[Invention] Directly based on" means that the [invention] [must] make [immediate] use of the genetic resource, and depend on the specific properties of the resource of which the inventor [must] have had [physical] access.]

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].

[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] [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 [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 [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 [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]/[Direct] 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] [Budapest depository] 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], [patent owners, universities, farmers, and plant breeders].]

[Unauthorized Use

"Unauthorized use" is the acquisition of genetic resources, traditional knowledge associated with genetic resources without the consent of the competent authority in accordance with national legislation of the providing country.]

[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 [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

ALT

[“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 [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity] [and to make a new product, or a new method of use or manufacturing of a product.]]]

[PREAMBLE

[Ensure [encourage] respect for [sovereign rights] [the rights] of [rightful holders, including] indigenous [people[s]] and local communities [as well as [people[s]] partially or entirely under occupation] over their genetic resources, [their derivatives] and [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].]

[Contribute to the prevention of misappropriation of genetic resources, [their derivatives] and traditional knowledge associated with genetic resources.]

[Minimize the granting of erroneous [IP] [patent] rights.]

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 [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] [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 [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 [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 [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 [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.]

[I. GENERAL PROVISIONS]

[ARTICLE 1 OBJECTIVE[S]]

1 [The objectives of this instrument are to [enhance the [efficacy] and [transparency] of the [IP] [patent] system; and facilitate mutual supportiveness with international agreements relating to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

ALT 1

1 [The objectives of this instrument are to [enhance the [transparency] of the [IP] [patent] system to facilitate the possibility of ABS through the disclosure of country of origin or source of genetic resources in separate systems such as the CBD.]

ALT 2

1 [The objective of this instrument is to [promote][ensure][the effective protection of] [contribute to the prevention of] [prevent] the [misappropriation of] genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] [through the] [in the context of the] [IP] [patents] system by:]

- (a) Ensuring that [IP] [patent] offices have access to the appropriate information on genetic resources [their derivatives] and [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) [Ensuring] [promoting] [facilitating] [complementarity] [mutual supportiveness] with international agreements relating to the protection of genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] [and those relating to IP].

[ARTICLE 2] SUBJECT MATTER OF INSTRUMENT

2 This instrument applies to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].

[II. [MANDATORY] DISCLOSURE]

[ARTICLE 3] [DISCLOSURE REQUIREMENT]

3.1 Where the [subject matter] [claimed invention] within a [IP Rights] [patent] application [includes utilization of] [is directly based on] [is directly based on the utilization of]¹ genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] each Party shall/should require applicants to:

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

¹ Some members noted a need for a definition for this formulation in the list of terms.

- (b) [Provide relevant information, as required by national law, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]
- (c) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, 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 contents of the disclosure. [But [IP] [patent] offices [shall/should] provide guidance to [IP] [patent] applicants on how to meet disclosure requirement [formalities].]

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/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[, except for information related to privacy, business secrets, or other lawful confidentiality²,] publicly available at the time of application publication [or patent grant].]

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 In complying with the obligation set forth in Article 3, members may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument.

ALT

4.1 A [IP] [patent] disclosure requirement related to genetic resources [their derivatives] and [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];[/genetic resources when they are used as 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]] [entry into force of the Nagoya Protocol on October 12, 2014].

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

² An alternative formulation from the Nagoya Protocol Art. 14(2) is "without prejudice to the protection of confidential information".

**[ARTICLE 5]
SANCTIONS AND REMEDIES**

5 [Each [Party] [country] shall/should put in place appropriate, effective and proportionate legal and 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) *Suspending* 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) Other measures [including revocation and economic compensation for holders of genetic resources, their derivatives, and traditional knowledge associated with genetic resources including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]

ALT

5.1 Each Party shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures to address non-compliance with Article 3, [including preventing further processing of patent applications.]

[5.2 Material misstatements made with an intent to deceive the patent office regarding compliance with Article 3, shall be deemed perjury, lying to an official, or other similar infraction, and punishable as such in accordance with national law.]

5.3 [[Failure to fulfill the disclosure requirement] [incorrect or incomplete information], [in the absence of fraud], shall/should not affect the validity or enforceability of granted [IP] [patent] rights.]

**[ALTERNATIVES TO ARTICLES 1, 2, 3, 4 & 5
NO NEW DISCLOSURE REQUIREMENT]**

**ALT
[ARTICLE 1]
[OBJECTIVE]**

1 [The objective of this instrument is to prevent the grant of patent rights on inventions that are not novel, non-obvious, and industrially applicable.]

**ALT
[ARTICLE 2]
[SUBJECT MATTER]**

2 [This instrument shall/should apply to patent applications for inventions directly based on genetic resources, and traditional knowledge associated with genetic resources.]

ALT
[ARTICLE 3]
[NO NEW DISCLOSURE REQUIREMENT]

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

3.2 [Where the subject matter of an invention is made using genetic resources obtained from an entity having a legal right over the genetic resource [(including a patent owner)], that entity may in the permit agreement or license granting the applicant access to the genetic resource or the right to use the genetic resource, require a patent applicant to:

- (a) include within the specification of a patent application and any patent issuing thereon a statement specifying that the invention was made using the genetic resource and other relevant information, and
- (b) obtain consent for uses not encompassed within the permit agreement or license.]

3.3 [Patent offices shall/should publish the entire disclosure of the patent on the Internet, on the date of the patent grant and shall/should strive to make the contents of the patent application publicly accessible over the Internet as well.]

3.4 [Where access to a genetic resource or traditional knowledge associated with genetic resources is not necessary to make or use the invention, information regarding the source or origin of genetic resource or the traditional knowledge associated with the genetic resource³ can be provided at any time after the filing date of the application.]

3.5 [Failure to examine a patent application in a timely manner shall/should result in an adjustment of the term of the granted patent to compensate the patentee for delays. Applicants shall/should be provided an opportunity to correct any incorrect or erroneous disclosures.]

**[III. DEFENSIVE MEASURES/
 DEFENSIVE MEASURES COMPLEMENTARY TO MANDATORY
 DISCLOSURE⁴]**

**[ARTICLE 6]
 [DUE DILIGENCE]**

6 Member states shall/should encourage or establish a fair and reasonable due diligence system to ascertain that [protected]⁵ genetic resources have been accessed in accordance with [applicable] access and benefit sharing legislation or regulatory requirements.

³ The facilitator's reviewed the definition of "Source of Associated Traditional Knowledge". That Phrase does not appear verbatim in the document, but may have been intended for this provision and is thus reproduced here as "Source of Traditional Knowledge Associated with Genetic Resources" means any source from which the applicant has acquired the traditional knowledge associated with genetic resources, including indigenous and local communities, scientific literature, publicly accessible databases, and patent applications, and patent publications."

⁴ Facilitators Note. Members should note that some members consider Defensive Measures as an alternative option to Disclosure while some other members consider them as a complementary option to Disclosure.

⁵"Protected Genetic resources" means, genetic resources that are protected either pursuant to an intellectual property right or other legal right. Once intellectual property rights in a genetic resource expire, the genetic resource should be in the public domain and not treated as a protected genetic resource.] Several Member States expressed a difficulty in

[Footnote continued on next page]

- (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 [and potential investors] to confirm lawful chain of title of protected genetic resources upon which a patent is based.]

[ARTICLE 7]

[PREVENTION OF THE [ERRONEOUS]⁶ GRANT OF PATENTS AND VOLUNTARY CODES OF CONDUCT

7.1 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 [traditional knowledge associated with genetic resources] where, under national law, those genetic resources, [their derivatives] 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, [their derivatives] 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, [their derivatives] and [traditional knowledge associated with genetic resources].]
- d. Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for use by patent offices.]

Database Search Systems

7.2 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources, [their derivatives] 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 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.

[Footnote continued from previous page]

understanding the meaning of this definition. As the facilitators also struggled with it, it is requested the proponents provide greater clarity before it is included in the list of terms.

⁶ A Member State requested to change this title to "Protection of the Demand of the Patents". However, the facilitators do not understand the meaning of this proposal and request clarification before such changes made.

ALT

As a complement to the disclosure obligation provided for in Article 3, and in the implementation of this instrument, the Contracting State may consider the use of databases on traditional knowledge and genetic resources in accordance with their needs, priorities, and safeguards as may be required under national laws and special circumstances.⁷

WIPO Portal Site

7.3 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 [traditional knowledge associated with genetic resources] within their territory. The WIPO portal site will enable an examiner [and the public] to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards [such as filters].]

[IV. FINAL PROVISIONS]

[ARTICLE 8]

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

8.1 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 [traditional knowledge associated with genetic resources] and] [with] relevant [existing] international agreements and treaties.

ALT

8.1 [This instrument should be consistent with international IP agreements. Members recognize the coherent relationships between policies that promote the granting of patents involving the utilization of genetic resources and/or traditional knowledge associated with genetic resources and policies that promote the conservation of biological diversity, promote access to genetic resources, and the sharing of the benefits of such genetic resources.]

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

ALT

8.2 [No provision in this instrument shall be interpreted as harming, or being to the detriment of the rights of indigenous people enshrined in the United Nations declaration on the rights of indigenous people. In the case of a conflict of laws, the rights of indigenous people enshrined in such declaration shall prevail and any interpretation shall be guided by the provisions of such declaration.]]

[8.3 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 [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.]]

⁷ Unclear if this is intended to be an addition or an alternative.

**[ARTICLE 9]
INTERNATIONAL COOPERATION**

9 [[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 [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

ALT

9 [Patent examination authorities should share information related to sources of information related to genetic resources and/or traditional knowledge, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge. WIPO Members should cooperate in the sharing of information related to genetic resources and knowledge, including traditional knowledge, regarding the use of genetic resources.]

**[ARTICLE 10]
TRANSBOUNDARY COOPERATION**

10 [In instances where the same genetic resources [, their derivatives] and [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 11]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING**

11 [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.]