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Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 1

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 [peoples] 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.]

[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]].]

[[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 respect for [sovereign rights] [the rights] of indigenous [peoples] and local communities [as well as [peoples] 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 peoples 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 that no [patents] [intellectual property] on life forms, including human beings, are granted.]]

Recognize that those accessing genetic resources and associated tk in a country should comply with that's country's national law providing protection for the gr and associated tk

Patent offices shall 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 [peoples] and local communities

POLICY OBJECTIVE

Prevent the misappropriation of genetic resources [their derivatives] and associated traditional Knowledge through the IP Rights system by:

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

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

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

**[ARTICLE 2]
SCOPE OF INSTRUMENT**

2.1 This instrument provides measures to support the prevention of misappropriation of genetic resources [their derivatives] and associated traditional knowledge through the [IP] [Patent] system.

[DISCLOSURE REQUIREMENTS]

3.1 Where the claims within a [Patent] [IP Rights] application [include] [are directly based on] [utilization of] genetic resources [their derivatives] and/or associated traditional knowledge each Party shall require applicants to:

- (a) Disclose the source and [country of origin] of the claimed genetic resources and/or associated traditional knowledge.
- (b) Provide relevant information, as required by national laws, regarding compliance with ABS requirements, including PIC, 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 not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure.

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

Sanctions and Remedies

3.4 [Each [Party] [country] shall put in place appropriate, effective and proportionate measures to address non-compliance with paragraph 3.1, including dispute resolution mechanisms. Sanctions and remedies may include:

(a) **Pre-Grant.**

- (i) Preventing further processing of [patent] [intellectual property] applications until the requirements are met.
- (ii) Preventing or refuse granting of [patent] [intellectual property] applications.
- (iii) A [patent] [intellectual property] office] can consider the application withdrawn.
- (iv) A [patent] [intellectual property] office] can invite the applicant to comply within a time limit.

(b) **Post-Grant.**

- (i) Fines or adequate compensation for damages, including payment of royalties.
- (ii) In the case of an applicant being found to have knowingly submitted false or fraudulent information, revocation may be considered, in accordance with national law.
- (iii) Other measures including revocation may be considered depending on the circumstances of the case, in accordance with national law.

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

[Exclusions

3.6 A [patent] [intellectual property] disclosure requirement related to genetic resources [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] shall not apply to the following:

- (a) all human genetic resources including human pathogens;
- (b) [derivatives];
- (c) commodities;
- (d) traditional knowledge in the public domain;
- (e) genetic resources found outside of national jurisdictions [and economic zones]; and
- (f) all genetic resources acquired before the national implementations of [the Convention on Biological Diversity.]

[Relationship with [PCT] and [PLT]

3.7 The [PCT] and [PLT] will 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.]

[NO NEW DISCLOSURE REQUIREMENT]

4.1 Patent [intellectual property] 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.]

[DEFENSIVE MEASURES]

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

5.1 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 regarding the protection of the use of genetic resources and traditional knowledge associated with genetic resources.
- d. facilitate, as appropriate, the creation, exchange and dissemination of, and access to, databases of and/or regarding genetic resources and traditional knowledge associated with genetic resources, with a view to supporting the measures mentioned in Paragraphs 5.1(a).

Due Diligence

5.2 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.
- (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.

DATABASE SEARCH SYSTEMS

5.3 Members are encouraged to establish databases of [traditional knowledge] [associated traditional knowledge] [traditional knowledge associated with genetic resources] and genetic resources that are accessible to [intellectual property] [patent] offices.

5.4 Each country has responsibility for [codifying oral information], compiling and maintaining such databases, in accordance with national law.

5.5 There shall be minimum standards to harmonize the structure and content of such databases.

5.6 These databases will be accessible [only to [intellectual property] [patent] offices and other registered IP addresses] [to any interested parties].

5.7 The content of the databases will

- (a) be [in languages that can be understood by patent examiners]
- (b) contain [written and oral information regarding traditional knowledge associated with genetic resources, [their derivatives] for enabling search and examination of the [intellectual property] [patent] application including the details of the holder of the TK].

DATABASE SEARCH SYSTEM AT WIPO PORTAL SITE

5.8 Member States shall establish a database search system, which will be composed of a WIPO portal site as well as databases of WIPO Members, which are linked to this portal site.

- (a) Each WIPO Member State will, as it deems necessary, collect information on genetic resources and non-secret traditional knowledge associated with genetic resources within its territory and store this information in its database/databases (either adapted from an existing database or newly created). In developing national databases, Member States should consult with relevant. A simple text search function should be provided in the databases of each WIPO member. For countries that are not able to develop such search programs, technical assistance can be provided by the WIPO.
- (b) The WIPO portal site will be equipped with two basic functions: (i) a function which enables an examiner to directly access the national databases and (ii) a function which enables an examiner to retrieve data from the accessed databases functions.

**[ARTICLE 6]
RELATIONSHIP WITH INTERNATIONAL AGREEMENTS**

6.1 [[Contracting Parties] [Countries] shall 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 existing international agreements and treaties, [but will not create a hierarchy between such international agreements and treaties, nor impose any of the obligations established under other international agreements or treaties upon any [party][country] that is not a [member] [party] to such international agreements or treaties].]

6.2 [[Contracting Parties] [Countries] shall support, in particular, the implementation of the [Convention on Biological Diversity] [(including communication with its Clearing House)] and [the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity], the ITPGRFA, [Article 31 of the UN Declaration on the Rights of Indigenous Peoples] and the TRIPS Agreement and, as the case may be, of regional agreements.]

**[ARTICLE 7]
INTERNATIONAL COOPERATION**

7.1 [[Relevant WIPO bodies to encourage Patent Cooperation Treaty members to develop a set of guidelines for the [search and examination] administrative disclosure of origin or source by the international search and examination authorities under the Patent Cooperation Treaty including additional information arising from the disclosure requirement as provided in this instrument.][WIPO could, in close collaboration with the [CBD]/ITPGRFA, consider the possible establishment of such a list of competent government agencies.]]

**[ARTICLE 8]
TRANSBOUNDARY COOPERATION**

8.1 [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 endeavor to cooperate, as appropriate, with the involvement of indigenous [peoples] 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 9]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING**

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

[End of Annex and of Document]