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Facilitators' Draft

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

INTELLECTUAL PROPERTY AND THE PROTECTION OF GENETIC RESOURCES [THEIR DERIVATIVES] AND ASSOCIATED TRADITIONAL KNOWLEDGE: NEGOTIATING TEXT

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 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].

[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

Option 1 . "Country of origin" is the country which possesses those genetic resources in in-situ conditions.

Option 2. Country Providing/Providing Country - 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" 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.

Option 3. "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.

Genetic Resources Associated with Traditional Knowledge

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 of genetic resources or associated traditional without the consent of those who are authorized to give consent to such acquisition.

[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.

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] including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].

PREAMBLE

[Ensure respect for the rights of indigenous [peoples] and local communities over their genetic resources and associated traditional knowledge, 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.]

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.

Recognize the role the intellectual property 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.

Promote transparency and dissemination of information.

[A global and compulsory system creates a level playing field for industry and the commercial exploitation of 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 industrial property development of genetic resources and associated traditional knowledge 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 patent system.

POLICY OBJECTIVES

OBJECTIVE 1: Compliance with International/National laws relating to ABS [and disclosure]

Ensure [applications for intellectual property rights [patents] utilizing genetic resources [their derivatives] and associated traditional knowledge] [those accessing [and/or using]] genetic resources [,their derivatives] and associated traditional knowledge comply with [international rights and national legislations [national law and relevant conditions for [requirements of the country providing for prior informed consent, mutually agreed terms, fair and equitable] access and benefit-sharing [and disclosure of origin.]

OBJECTIVE 2: Ensuring intellectual property [patent] offices have the required information to / and make proper decisions in granting intellectual property [patent] rights.

Option 1

Recognise the need for patent offices to have access to appropriate information on genetic resources and associated traditional knowledge needed to make informed decisions to prevent grant of patents that do not comply with novelty, inventiveness or industrial applicability.

Option 2

Ensure that [[intellectual property] [Patent] offices] [should] have [access to] [all] the appropriate information [on genetic resources, [their derivatives] and/or associated traditional knowledge] needed to make proper and informed decisions in granting [intellectual property rights] [patents], to prevent granting of erroneous patents, [prevent misappropriation and enhance transparency in the patent system.]

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

1.1 [Protection under this instrument] [This international legal instrument][shall] [extend] apply to any [intellectual property] [patent] right or application derived from [utilization of] genetic resources, [their derivatives] and associated traditional knowledge.]

[ARTICLE 2]
[BENEFICIARIES

2.1 [Effective ABS systems implemented in national laws should be beneficial to the public, resource holders, supplier countries, indigenous and local communities, providers, and users of the resources.]

2.2 [This instrument should apply to] [Protection] [Measures] related to the compliance with existing rules of access and benefit-sharing derived from the utilization [for the protection] of genetic resources, [their derivatives] and associated traditional knowledge shall be for the benefit of country providing such resources and knowledge [of origin of genetic resources] and indigenous peoples and local communities who develop, use and maintain the genetic resources and associated traditional knowledge.

[2.3 The beneficiaries of genetic resources and associated traditional knowledge under this instrument shall have the right to authorize or deny [access to the] [use] [utilization] of genetic resources and associated traditional knowledge.]]

[ARTICLE 3]
[SCOPE OF [INSTRUMENT] [PROTECTION]] [LEGAL OBLIGATIONS]

Option 1

3.1 The scope of this instrument is [to provide measures for the [intellectual property] [patent] system to support compliance with ABS regimes through [the disclosure of] information on genetic resources, [derivatives], and [associated traditional knowledge] and] [the provision of information to patent offices to [prevent] [grant of erroneous patents] [misappropriation]] and to enhance transparency in the [intellectual property] [patent] system.

Options 2

3.2 Member states may consider implementing national laws outside the patent system to regulate conduct and manage access to genetic materials.

DISCLOSURE PROTECTION

OPTION 1

FORMALITIES REQUIREMENTS FOR DISCLOSURE

Trigger

3.3 Intellectual property offices shall have a [disclosure] [mandatory] requirement for [patent] intellectual property rights] applications that [involve] [arising from] [directly based on] utilization of genetic resources, [derivatives] and associated traditional knowledge.

[Exclusions

3.4 A patent disclosure requirement related to genetic resources [their derivatives] and associated traditional knowledge 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
(f) all genetic resources acquired before the national implementations of the Convention on Biological Diversity and 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.]

Contents of Disclosure

3.5 [Intellectual property] [patent] offices shall require applicants [in good faith] to disclose

(a) [Provider country]
(b) [Source in provider country]
(c) [Internationally Recognised Certificate of Compliance, or evidence of compliance, with ABS requirements, including PIC where relevant]
(d) [Certificate of origin]
(e) [Country of origin]
(f) [If Country of origin not known, information on the source that the inventor had physical access to]
(g) [Statement that origin is not known]
(h) [Statement that source is not known]
(i) [Primary source, or if not known, the secondary source]
(j) [Written and oral information regarding traditional knowledge associated with genetic resources, [their derivatives] for enabling search and examination of the intellectual property application including the details of the holder of the TK]
(k) [a copy of the standard material transfer agreement stipulated in the ITPGRFA if access to genetic resources has been provided in pursuance the ITPGRFA]

Actions of the Office

3.6 The disclosure requirement shall not place an obligation on the [intellectual property] [patent] offices to verify the contents of the disclosure.

3.7 [Intellectual property] [patent] offices or other relevant authorities shall put in place an adequate information dissemination system to enable an opportunity by relevant authorities for other [Contracting Parties] [Countries], indigenous and local communities or any other interested parties to take appropriate actions regarding ABS rules or submit information relevant to search and examination of an intellectual property application.

3.8 A simple notification procedure should be introduced to be followed by the patent offices every time they 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 patent offices should send the available information.

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

3.10 Patent offices receiving patent applications containing disclosures should inform the competent government agency that the respective State is declared as the source.

Relationship between PCT and PLT

3.11 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.

Sanctions and Remedies

Sub-Option 1

3.12 Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance under this international legal instrument and to ensure that accessible and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available.

Sub-Option 2

3.13 Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance under this international legal instrument and to ensure that accessible and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available. Such measures shall include at least:

(a) Publication of judicial ruling regarding failure to disclose, and
(b) Prevent further processing of IP applications, and
(c) Prevent or refuse granting of IP applications, and
(d) Office can consider the application [withdrawn] [lapsed] [nullified]

Members may, but shall not be obliged to, apply more extensive sanctions.

Sub-Option 3

3.14 Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted under this international legal instrument and to ensure that accessible and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available. Such measures shall include:

(a) Publication of judicial ruling regarding failure to disclose
(b) Prevent further processing of IP applications
(c) Prevent or refuse granting of IP applications
(d) Office can consider the application withdrawn

Failure to fulfill the disclosure requirement shall not affect the validity or enforceability of granted patents.

OPTION 2

NO DISCLOSURE REQUIREMENT

3.15 Patent disclosure requirements shall not include a mandatory disclosure relating to genetic resources [, their derivatives and associated traditional knowledge] unless such disclosure is material to the patentability criteria of novelty, inventive step or enablement.

[3.16 Patent applicants shall be under no requirement to disclose the source, origin or other information relating to genetic resources [unless such information is material to the patentability requirements of novelty, inventive step or enablement.]

DEFENSIVE PROTECTION

[3.17 Establishment of databases of TK and GR that are accessible to IP offices [to

(a) avoid granting of erroneous patents
(b) [ensure the free prior informed consent]
(c) ensure transparency, traceability and mutual trust taking into account access and benefit sharing arrangements as provided for under the CBD and the Nagoya Protocol.]]

3.18 Each country has responsibility for [codifying oral information], compiling and maintaining such databases.

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

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

3.21 The content of the databases will be

(a) [in languages that can be understood by patent examiners]
(b) [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]
(c) relevant written and oral [information] prior art relating to genetic resources, [their derivatives] and associated traditional knowledge
(d) information related to genetic resources, [their derivatives] and associated traditional knowledge

3.22 Such databases would [ensure the free prior informed consent] avoid the erroneous granting of patents for genetic resources and related traditional knowledge and ensure transparency, traceability [and mutual trust taking into account access and benefit sharing arrangements as provided for under the CBD and the Nagoya Protocol.]

3.23 National [intellectual property] [patent] offices [shall] should develop appropriate and adequate guidelines for the purpose of conducting search and examination of [intellectual property] [patent] applications relating to genetic resource, [their derivatives] and associated traditional knowledge considering existing prior art accessible to the examiners, as appropriate [and additional information provided by the applicants, as well as accessible to the examiners].

3.24 Establishment of an international gateway on traditional knowledge.