

Date: February 5, 2013, 23:30

Facilitators' Draft

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

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

LIST OF TERMS

[Associated Traditional Knowledge] / [Traditional Knowledge Associated with Genetic Resources]

Option 1. "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.

Option 2. "Traditional Knowledge Associated with Genetic Resources" means substantive knowledge of the properties and uses of genetic resources held by indigenous peoples and local communities.

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.]

Genetic Resources

"Genetic Resources" are genetic material of actual or potential value. Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity.

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

[(j) 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.]

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 research center, 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, in particular the UN Declaration on the Rights of Indigenous Peoples.

The [intellectual property] [patent] system should provide certainty of rights for legitimate users¹ 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.

¹ This requires a definition.

POLICY OBJECTIVES

OBJECTIVE 1: Compliance with International/National laws relating to ABS [and disclosure]²

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 [requirements³ of the country providing⁴ 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 make proper decisions in granting intellectual property [patent] rights.

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 INSTRUMENT

1.1 This instrument shall [extend] apply to any [intellectual property] [patent] right 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, providers, and users of the resources.

2.2 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 of genetic resources and associated knowledge.

[ARTICLE 3] SCOPE OF INSTRUMENT

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].

DISCLOSURE PROTECTION

² Boxed and/or bolded headings are Facilitators text to enhance clarity in the document.
³ National law and requirements include customary norms.

OPTION 1

FORMALITIES REQUIREMENTS FOR DISCLOSURE

Triggers

Sub Option 1

3.2 Patent offices shall have a mandatory requirement for disclosure that applies to patent applications that claim inventions that:

(a) arise from the specific properties of this resource, [even where the inventor has altered the structure of the received material]; and

(b) the inventor possessed, or at least had contact which is sufficient enough to identify the properties of, the genetic resource relevant for the invention.

3.3 The disclosure requirement for traditional knowledge in this instrument will only apply to patent applications that claim inventions for which the inventor consciously derived the invention from traditional knowledge associated with genetic resources.

Sub-option 2

3.4 Intellectual property offices shall have a mandatory requirement for applications that involve the utilization of genetic resources, [their derivatives] and associated traditional knowledge.

Exclusions

3.5 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

3.6 [Intellectual property] [patent] offices shall require applicants 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

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

3.8 [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.

3.9 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.

3.10 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.

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

PCT and PLT

3.12 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

3.13 Parties [may] [shall] have legal, administrative or policy measures to provide the following sanctions and associated measures for [failure to disclose] [infringement of protection in this instrument] [false or misleading information]

3.14 Sanctions that affect a granted [intellectual property] [patent] right:

- (a) Compulsory licencing
- (b) Regulatory review, though if there is delay this results in extension of term
- (c) Render unenforceable the patent
- (d) Revocation only in case of fraud

3.15 Sanctions that affect granting of an [intellectual property] [patent] right or are outside the [intellectual property] [patent] system.

- (a) Prevent further processing of IP applications
- (b) Prevent or refuse granting of IP applications
- (c) Office can consider the application withdrawn
- (d) administrative sanctions
- (e) criminal sanctions
- (f) fines
- (g) adequate compensation for damages

- (h) effective, proportionate and dissuasive sanctions outside the field of patent law imposed on the patent applicant or holder
- (i) the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers
- (j) If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application.
- (k) no sanction within the patent system for failure to meet any mandatory disclosure requirement relating to genetic resources or traditional knowledge

OPTION 2

NO DISCLOSURE OF ABS INFORMATION

3.16 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.

3.17 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

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

3.20 There shall be minimum standards to harmonise the structure and content of such databases.

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

- 3.22 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

3.23 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.

3.24 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].

[ARTICLE 4] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

4.1 [Contracting Parties] [Countries] shall establish a coherent system and promote mutually supportive relationship between intellectual property rights involving the utilization of genetic resources, [their derivatives] and associated traditional knowledge and existing international agreements and treaties.

4.2 [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 and the TRIPS Agreement and, as the case may be, of regional agreements. PLT and PCT would need to be amended.

4.3 The disclosure of source requirement enables the [contracting Parties] [countries] of relevant international agreements, including the CBD/ITPGRFA, the PCT, the PLT and the TRIPS Agreement to fulfill their respective obligations.

[ARTICLE 5] INTERNATIONAL COOPERATION

5.1 [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 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 6] TRANSBOUNDARY COOPERATION

6.1 [In instances where genetic resources and associated traditional knowledge associated with genetic resources [of indigenous peoples and local communities] is located in territories of different [Contracting Parties] [countries], those [[Contracting Parties] [Countries]] countries [shall] should co-operate by taking measures that are supportive of and do not run counter to the objectives of this instrument.]

[ARTICLE 7] TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

7.1 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.

Guiding Principles Objective 1

1.1. Roles and Rights of [States, Nations, Indigenous Peoples, Local Communities and right owners].

1.1.1 Option 1. Recognize [the wide variety of kinds of [ownership] arrangements pertaining to] [sovereign rights of States] over genetic resources [, their derivatives] and associated traditional knowledge [, including the sovereign rights of [States] nations and peoples, the rights of indigenous peoples and local communities, [as well as private property rights]] in accordance with domestic legislation [in patent applications].

1.1.2 Option 2. [Sovereign States have the authority to determine access to genetic resources in their jurisdiction. Subject to national legislation, persons accessing traditional knowledge associated with genetic resources from the knowledge [holder(s)] [owners] and applying that knowledge in the development of an invention should obtain approval from the knowledge [holder(s)] [owners] and seek their involvement.]

1.1.3 Option 3. To ensure respect for [the sovereign rights of peoples partially or entirely under occupation] over their genetic resources and associated traditional knowledge, including the principle of prior informed consent and mutually agreed terms and total and effective participation.

1.2 Respect for Rights of Indigenous Peoples and Local communities.

[Ensure respect for the principle of self determination of indigenous peoples and local communities, [including] as well as peoples partially or entirely under occupation] and their rights over genetic resources and associated traditional knowledge, including the principles of prior informed consent, mutually agreed terms, and full and effective participation, noting the United Nations Declaration on the Rights of Indigenous Peoples.]

1.3 Procedural Burden.

[To ensure that patent applicants are not burdened with unreasonable procedures for relevant conditions for access, use and benefit-sharing under national law] when seeking patent protection.]

1.4 [Transparency in ABS].

A requirement in national and international patent applications to disclose the source would increase transparency in access and benefit sharing with regard to genetic resources and traditional knowledge].

OBJECTIVE 2: Prevent [intellectual property rights] [patents] from being granted in error [in bad faith].

2.1 Prevent [intellectual property rights] [patents] involving the access and utilization of genetic resources, [their derivatives] and/or associated traditional knowledge from being granted [in bad faith]:

- (a) [[in error for inventions that are not novel [new] or inventive] [that do not satisfy the patentability criteria];
- (b) [where there is no prior informed consent, mutually agreed terms [and [/or] fair and equitable benefit-sharing, and disclosure of origin] or related national law and requirements are not satisfied; and
- (c) [or that was granted in violation of the inherent rights of the original owners].

Guiding Principles Objective 2

2.2. **Certainty of Rights.**

2.2.2 Option 2. The patent system should provide certainty of rights for users of genetic resources and traditional knowledge and shall not impose requirements that detract from legal certainty such as mandatory disclosure requirements relating to genetic resources and traditional knowledge.

2.3 **Compliance with Patentability Requirements.**

Patent applicants should not receive exclusive rights on inventions that are not new or inventive.

2.4 **[Compliance with disclosure, prior informed consent and fair and equitable benefit sharing requirements.]**

Intellectual property rights applicants should not receive exclusive rights where free, prior and informed consent and fair and equitable benefit-sharing requirements for accessing and using genetic resources [and their derivatives] [and their associated traditional knowledge] have not been met [ensuring free prior informed consent and fair and equitable benefit-sharing for indigenous peoples and local communities]

2.5 **[Disclosure Requirements.]**

Persons applying for [intellectual property rights] [patents] involving the use of genetic resources and/or associated traditional knowledge have a duty [of good faith and candor] to disclose in their applications [all background information] all relevant [known] information relating to the genetic resources [, their derivatives] and associated traditional knowledge, including the country of [source or] origin.]

2.6 **Mutual Trust:**

[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.]

2.7 **Patents on Life Forms⁵**

2.7.1 Option 1. Ensure that no patents on life and life forms are granted for genetic resources and associated traditional knowledge.

2.7.2 Option 2. Enhance the availability of patent protection for life forms and new uses for known substances in order to create benefits and support benefit-sharing from the use of genetic resources and associated traditional knowledge.

Guiding Principles Objective 3

⁵ Where one or more options are presented on any issue, it is understood the possibility remains for there to be a **no** option on the issue.

3.1 Prior Art

[Intellectual property] [Patent] offices should [must] consider all relevant prior art [[as far as known to the applicant] relating to genetic resources, [their derivatives] and associated traditional knowledge] when assessing [the eligibility for grant of [intellectual property rights]] [the patentability of an invention] [a patent].

3.2 Applicant(s) Disclosure Requirement

3.2.1 Option 1. [Intellectual property] [Patent] an applicant[s] [should] must disclose all background information of genetic resources, [their derivatives] and associated traditional knowledge relevant for determining the eligibility conditions. Such information shall include confirmation through the mandatory disclosure requirements that prior informed consent has been obtained and access has been granted on mutually agreed terms which can be made through an internationally recognized certificate of compliance.

3.2.2 Option 2. Technical prior art: Disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges in the establishment of prior art with regard to inventions that somehow relate to these resources or this knowledge, including use of databases of traditional knowledge that is prior art.

3.2.3 Option 3. Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing technical information related to new inventions, where appropriate and where publicly available, so as to enrich the total body of technical knowledge accessible to the public.

3.3 Traceability

Disclosing the source in patent applications would allow the providers of genetic resources and traditional knowledge to keep track of the use of their resources or knowledge in research and development resulting in patentable inventions.

3.4 Rights of traditional knowledge holders

There is a need to recognize that some holders of traditional knowledge may not want their knowledge documented.

OBJECTIVE 4: Relationship between international, [regional] agreements, instruments and treaties

4.1 Option 1. [Establish a] [Recognize] the coherent and mutually supportive [system] relationship between [intellectual property rights] [patents] involving the utilization of genetic resources, their [derivatives] and/or associated traditional knowledge and [existing] relevant international [and regional] [agreements and treaties] instruments, [including ensure consistency with international legal standards in the promotion and protection of the [collective] rights of indigenous peoples.]

4.2 Option 2. [Promote a mutually supportive relationship] [Promotion of cooperation] with relevant international agreements [and processes].

Guiding Principles Objective 4

4.3 Respect and Consistency.

4.3.1 [Promote respect for [and seek consistency with] other relevant international [and regional] instruments [and processes].

4.3.2 The work of the IGC should not prejudice the work pursued in other fora.]

4.4 **Cooperation, Awareness and Information Sharing/Linkage CBD/ ITPGRFA.**

Promote [cooperation] [awareness and information sharing] with relevant international [and regional] instruments [and processes] [and support, in particular, the implementation 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 of Biological Diversity and ITPGRFA.]

OBJECTIVE 5: Role of Intellectual Property System in promoting innovation and knowledge, technology transfer.

5.1 Recognize [and maintain] [strengthen] the role of the [intellectual property] [patent] system 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 [in a manner conducive to social, cultural and economic welfare wellbeing and development [while]:

(a) [contributing] ensuring to the protection of genetic resources, [their derivatives] and[/or] associated traditional knowledge.

(b) preventing the adverse effects of the [intellectual property] [patent] system on the [indigenous peoples] indigenous and local communities' [customs, beliefs and rights, traditional knowledge] laws, practices, knowledge systems and rights with the aim of recognizing and protecting the rights of [indigenous peoples] indigenous and local communities to use, develop, create and protect their knowledge and innovation in relation to genetic resources].

Guiding Principles Objective 5

5.2 **Maintaining Incentive for Innovation** [Maintain the incentives for innovation provided by the intellectual property system.] [Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources, [their derivatives] and/or associated traditional knowledge [and in the protection of traditional knowledge, genetic resources, [their derivatives] and/or associated traditional knowledge and traditional cultural expressions and fair and equitable sharing of benefits arising from their use.]

5.3 **Legal Certainty**

[Promote] To [strengthen legal] certainty and [clarity] [scope] of intellectual property rights [, noting the relationship with genetic resources, [their derivatives] and/or associated traditional knowledge and obligations with respect to the protection of traditional knowledge [beneficiaries] [of indigenous peoples and local communities], genetic resources, [their derivatives] and/or associated traditional knowledge and traditional cultural expressions and certainty and clarity for prior informed consent and fair and equitable benefit-sharing].

5.4 **Protect Creativity and Reward for Investment**

5.4.1 Option 1. To protect from national and international biopiracy, creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the

[indigenous peoples and local communities, [and] traditional knowledge [holders] [owners]]
[traditional knowledge beneficiaries].

5.4.2 Option 2. Protect creativity and reward [public, private and community] investments [and ensure prior informed consent and fair and equitable benefit-sharing, mutually agreed terms] [made in developing a new invention [which has been developed in full compliance with national laws and requirements, including the principles of prior informed consent, fair and equitable benefit-sharing, mutually agreed terms].

5.5 Transparency

Promote transparency and dissemination of information [by disclosing country of origin of genetic resources] [, where not in contrast with public morality and/or order public,] [and providing sufficient protection] by:

- (a) [publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public;
 - (b) disclosing country of origin and publishing and disclosing technical information related to new inventions, [where appropriate and where publicly available], so as to enrich the total body of technical knowledge accessible to the public; and
 - (c) increase legal certainty and trust between users and providers
- of genetic resources and traditional knowledge through a mandatory disclosure of origin or source.]

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

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

[ARTICLE 2] [[BENEFITS] / BENEFICIARIES [OF THE PROPOSALS]] [OBJECTIVES]

2.2 Parties shall respect the rights of indigenous and local communities in the traditional knowledge associated with genetic resources, [their derivatives] in accordance with the [domestic]/national legislation and existing international agreements and treaties, in particular 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 and ITPGRFA.

2.3 The beneficiaries of genetic resources and associated traditional knowledge under this instrument shall have the following exclusive rights that:

- (a) arise out of the existence of knowledge (de facto rights);
- (b) are inalienable and in perpetuity as long as knowledge exist;
- (c) are intergenerational, i.e., passed on to future generations; and
- (d) to authorize or deny access to the use of genetic resources and associated knowledge.

OPTION 2

2.4 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.

**[ARTICLE 3]
[SCOPE [OF [LEGAL] PROTECTION]]
[[MANDATORY] DISCLOSURE REQUIREMENTS]**

LEGAL PROTECTION

3.1 [The [Contracting Parties] [Countries] shall provide legal protection to genetic resources and associated traditional knowledge as a unique knowledge system that has the following characteristics:

- (a) Traditional knowledge, genetic resources, landscapes, cultural and spiritual values and customary laws, are inextricably linked and together maintain the integrity of knowledge systems.
- (b) Genetic resources and biodiversity cannot be separated from traditional knowledge as intangible and tangible components cannot be separated.
- (c) Genetic resources and associated traditional knowledge is part of the collective, ancestral, territorial, spiritual, cultural and intellectual heritage.
- (d) Genetic resources and associated traditional knowledge is transmitted from generation to generation in diverse forms and is inalienable, indivisible and imprescriptible.

3.2 No registration of knowledge is required for rights to be legally recognized].

3.3 [Contracting Parties] [Countries] shall provide in [their national intellectual property] [patent] legislation a mandatory disclosure requirement. The disclosure requirement should be mandatory. This implies that it should be implemented in a legally binding and universal manner.

3.4 Check Point:

- (a) Option 1. [Contracting Parties] [Countries] shall appoint national intellectual property offices as a checkpoint for disclosure of the country of origin and source of genetic resources, [their derivatives] and associated traditional knowledge [and for their monitoring.]
- (b) Option 2. The patent system must provide for a mandatory disclosure requirement ensuring that the IP Offices becomes a key checkpoint for disclosure [and monitoring] of the utilization of genetic resources and/or associated TK (in line with Article 17 of the CBD Nagoya Protocol).

OPTION 2

3.5 [Contracting Parties] [Countries] may provide in their national patent legislation a mandatory disclosure requirement.

OPTION 3

3.6 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.

3.7 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.

Types of [intellectual property] [patent] right applications relevant to disclosure requirements/[Trigger points]

Sub-option 1

3.8 The invention must be directly based on the specific genetic resources. [in the claimed invention and] In such circumstances

- (a) The invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource;
- (b) The inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention; and [or]
- (c) [If the applicant is aware that the invention is directly based on traditional knowledge associated with genetic resources, that is, the inventor must consciously derive the invention from this knowledge].

Sub-option 2

3.9 The application involves genetic resources, [their derivatives] and associated traditional knowledge.

Sub-Option 3

3.10 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.

Content of the Disclosure

Sub-option 1

3.12 Parties shall require applicants to disclose The country providing such resources and the source in the country providing the genetic resources and/or [their derivatives] and associated traditional knowledge.

3.13 Parties shall also require that applicants provide a copy of an internationally recognized certificate of compliance (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent

and access and fair equitable benefit-sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the Convention on Biological Diversity.

Sub-option 2

3.14 Mandatory disclosure of information in the patent application of the following:

- (a) The applicant should declare the country of origin, or if not known, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him.
- (b) In the exceptional case that both the country of origin and the source are unknown to the applicant this should be declared accordingly.

Sub-option 3

3.15 Patent applicants must declare the primary source to fulfill the requirement, if they have information about this primary source at hand, whereas a secondary source may only be declared if patent applicants have no information at hand about the primary source. In case the source is unknown this must be confirmed by the patent applicant.

Sub-option 4

3.16 Country of origin and source of genetic resources, [their derivatives] and associated traditional knowledge.

3.17 Prior informed consent, either by the certificate of origin or by any other document issued in accordance with the domestic law of country of origin. In case the country of origin is not identifiable even after making reasonable efforts, certificate of evidence issued in accordance with the domestic law of country providing the genetic resources.

3.18. Evidence of benefit sharing under mutually agreed terms entered with the beneficiaries as define in Article 2 in accordance with their domestic legislation.

3.19 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.

Sub-Option 5

3.20 Mandatory disclosure requirements shall be met by providing an internationally recognized certificate of compliance as described 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.

Sub-Option 6

3.21 The patent application shall include information on the country from which the inventor collected or received the genetic resources and/or associated traditional knowledge (the providing country). If it follows from the national law in the providing country that access to genetic resources or traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

3.22 If the providing country is not the same as the country of origin of the genetic resources and/or the associated traditional knowledge, the application shall also state the country of origin. For genetic resources, the country of origin means the country from which material was

collected from its natural environment and, for associated traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to genetic resources or associated traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

3.23 If the information set out in paragraphs 1 and 2 is not known to the applicant, the applicant shall state the immediate source from which the inventor collected or received the genetic resources and/or associated traditional knowledge.

3.24 If access to genetic resources has been provided in pursuance of Article 12.2 and Article 12.3 of the ITPGRFA, a copy of the standard material transfer agreement stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs. If the applicant has obtained an internationally recognized certificate of compliance as mentioned in Article 17.4 of the Nagoya Protocol on Access and Fair and Equitable Sharing of Benefits Arising from the Utilization of Genetic Resources to the Convention on Biological Diversity that covers the genetic resources the invention concerns or uses, a copy of the certificate shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.

Actions of the [intellectual property] [patent] office

Sub-option 1

3.25 Put in place an adequate information dissemination system to enable an opportunity by relevant authorities from other [Contracting Parties] [Countries], indigenous and local communities or any other interested parties to submit information relevant to search and examination of an intellectual property application pending before national intellectual property offices in order to better assess compliance with the eligibility criteria for the grant of intellectual property rights.

3.26 That the intellectual property offices while examining the intellectual property application ascertain whether the applicant has comply with the mandatory disclosure requirements as per clause 1(a) of this Article and take necessary measures as mandated in this instrument in case of non compliance.

3.27 That the national [intellectual property] [patent] officers [shall] should not grant patents on life forms , or parts thereof, in the form of biological or genetic resources as they are found in nature, that are only isolated or characterized as such, as well as [their derivatives] and associated traditional knowledge.

Sub-option 2

3.28 Parties shall publish information disclosed jointly with the publication of the application or the grant of patent, whichever is made first.

Relationship between PCT and PLT⁶

Sub-option 1

3.29 Amend relevant provisions of the PCT and PLT. to include a mandatory disclosure requirement of the origin and source of the genetic resources.

Sub-option 2

⁶ Where one or more options are presented on any issue, it is understood the possibility remains for there to be a **no** option on the issue.

3.30 Amend relevant provisions of the PCT and PLT, in particular Rules 4.17, 26ter and 51bis, to include a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and associated traditional knowledge. The amendments shall also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.

Sub-option 3

3.31 Amend the PCT Regulations to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications (proposals for specific wording are contained in document WIPO/GRTKF/IC/20/INF/10 Appendix 1). The proposals thus leave it up to the national legislator to decide whether such a requirement is to be introduced in the national patent legislation.

3.32 Based on the reference to the PCT contained in Article 6.1 of WIPO's Patent Law Treaty (PLT), the proposed amendment to the PCT would also apply to the PLT. Accordingly, the [Contracting Parties] [Countries] of the PLT would also explicitly be enabled to require in their national patent laws that the patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications.

Sub-option 4

3.33 Amend the PCT and PLT to reflect a mandatory disclosure requirement of the origin of the genetic resource, incorporation of the "internationally recognized certificate of compliance" as stipulated in the Nagoya Protocol and any other submission that may be tabled by member countries.

Sub-option 5

3.34 [Contracting Parties] [Countries] of the PCT shall take steps to amend the guidelines for search and examination procedures for patent applications to ensure that they take into account the disclosure of the origin of genetic resources, [their derivatives] and associated traditional knowledge. The provision is applicable to regional patent authorities as well as the international search and examination authorities under the PCT.

Data Base Inventory

3.35 [WIPO begin developing an inventory of databases with [requesting] the assistance of Member States and information resources on genetic resources and associated traditional knowledge but at the same time maintaining protection of indigenous sources where such cultural protocols exist to ensure the prior informed consent of the indigenous peoples and local communities.]

Information systems on GR for defensive protection

OPTION 1

3.36 Develop a database related to genetic resources and to traditional knowledge accessible by examiners worldwide in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge.

3.37 A summary, which has been written in a language which every examiner can understand, be attached to documents written in indigenous languages.

3.38 Each country to assess and compile the information concerning genetic resources and the related traditional knowledge under its own responsibility.

- 3.39 An all-in-one consolidated system or multiple systems easily searchable with one click.
- 3.40 Searchable databases should be in the possession of, and maintained by, each participating WIPO member states. The database will be composed of a WIPO portal site as well as databases of WIPO member states, which are linked to this portal site.
- 3.41 The WIPO portal site is only accessible to patent offices and other registered IP addresses.

OPTION 2

- 3.42 Collect genetic resources and associated traditional knowledge into databases.
- 3.43 There is a minimum standard to harmonize the structure and content of these databases.
- 3.44 WIPO administers a system to access the local, regional and national databases of genetic resources and associated traditional knowledge.
- 3.45 Establishment of an international gateway on traditional knowledge.

OPTION 3

- 3.46 Make available 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.
- 3.47 Put in place an adequate information dissemination system to enable an opportunity by relevant authorities from other [Contracting Parties] [Countries], indigenous and local communities or any other interested parties to submit information relevant to search and examination of an [intellectual property] [patent] application pending before national [intellectual property] [patent] offices in order to better assess compliance with the eligibility criteria for the grant of intellectual property rights.
- 3.48 That the national intellectual property offices [shall] should consider all relevant written and oral [information] prior art relating to genetic resources, [their derivatives] and associated traditional knowledge which is available to them, regardless of the language, from all countries when conducting search and examination for determining the eligibility criteria for granting of [intellectual property] [patent] rights.

OPTION 4

- 3.49 Develop databases related to genetic resources, [their derivatives] and associated traditional knowledge accessible to relevant competent authorities and other parties [indigenous peoples and local communities] in order to [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.
- 3.50 Efforts should be made to codify the oral information related to genetic resources, [their derivatives] and associated traditional knowledge for the purpose of enhancing the development of databases.

[Additional and Complementary Protection Measures/Guidelines or recommendations on defensive protection]

OPTION 1

3.51 That the 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].

OPTION 2

3.52 Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account the disclosure of the origin of genetic resources.

3.53 Use of available databases on genetic resources and/or associated traditional knowledge.

Patents on life forms and naturally occurring genetic resources⁷

3.54 Option 1. No intellectual property rights shall be granted to genetic resources that naturally occur in situ and ex situ.

3.55 Option 2. Enhance the availability of patent protection for life forms and new uses for known substances in order to create benefits and support benefit sharing from the use of genetic resources and associated traditional knowledge.

3.56 Option 3. That the national [intellectual property] [patent] offices [shall] should not grant patents on life forms, or parts thereof, in the form of biological or genetic resources as they are found in nature, that are only isolated or characterized as such, as well as [their derivatives] and associated traditional knowledge.

[ARTICLE 4] [PROPOSAL ON COMPLEMENTARY] [PROTECTION] MEASURES

OPTION 1

4.1 [Contracting Parties] [countries] may facilitate access to information, including information made available in databases, relating to genetic resources, [their derivatives] and associated traditional knowledge with the intellectual property offices of [Contracting Parties] [countries] to this instrument.

4.2 [Contracting Parties] [countries] shall ensure that:

- (a) Confidentiality of such information provided to the intellectual property offices as stated in clause [1.1.] is maintained by the such offices and the applicants who have access to such information, in accordance with [domestic] international rights and law national legislation or contractual obligation [, except where the information is cited as prior art during the examination of a patent application].

⁷ Where one or more options are presented on any issue, it is understood the possibility remains for there to be a **no** option on the issue.

- (b) Any violation of the same shall be considered as an act of unfair competition and a violation of contractual obligations or an infringement of the protection provided in this instrument and be subjected to sanction as provided in this instrument.]
- (c) They share information and best practices in tech transfer and contracts related to genetic resources through WIPO databases for such information and further develop guidelines for model contractual provisions.
- (d) They share information on intellectual property guidelines for access and equitable benefit-sharing and request WIPO to conduct a study on licensing practices on genetic resources.

OPTION 2

4.3 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.

OPTION 3

4.4 Establish a publicly available list of government agencies competent to receive information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge. Patent offices receiving patent applications containing such declaration could inform the competent government agency that the respective State is declared as the source. WIPO could, in close collaboration with the CBD/ITPGRFA, consider the possible establishment of such a list of competent government agencies.

[ARTICLE 8] SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS

OPTION 1

8.1 Sanctions that go to the status of a granted patent right

Sub-Option 1

8.2 Patents granted without disclosing country of origin or source shall be subject to issuing of mandatory licenses, as foreseen in Article 31 of the TRIPS Agreement.

Sub-Option 2

8.3 Countries which revoke patents for failure to disclose the source of origin of a genetic resource or failure to comply with ABS laws shall pay adequate remuneration to both the country of origin and the patent holder.

Sub-Option 3

8.4 Any patent relating to genetic resources or traditional knowledge, the commercialization of which is subject to regulatory review, shall be entitled to extension of the term of the patent to compensate for delays caused by such regulatory review. Such patent term restoration shall be made available for a period that corresponds to the period of delay in commercialization caused by the regulatory review.

Sub-Option 4

8.5 Any patent relating to genetic resources or traditional knowledge whose grant is unduly delayed by the imposition of a mandatory disclosure requirement relating to the same shall be entitled to an extension of the patent term. Such patent term extension, corresponds to any period of delay in patent grant caused by the imposition of such mandatory disclosure requirements.

Sub-Option 5

8.6 [Contracting parties] [Countries] shall ensure, in accordance with their legal systems, adequate criminal, civil and administrative enforcement procedures and dispute resolution mechanisms are available under their laws against the willful infringement of the protection provided to genetic resources, [their derivatives] and associated traditional knowledge under this instrument.

8.7 [Contracting Parties] [Countries] shall provide that administrative and/or judicial authorities have the right to:

- (a) Revoke intellectual property rights; and
- (b) Render unenforceable intellectual property rights when the applicant has either failed to comply with the obligations of mandatory disclosure requirements as provided in this instrument or provided false or fraudulent information.

8.8 Where a dispute arises in relation to mutually agreed terms between users, beneficiaries and providers of genetic resources, [their derivatives] and associated with genetic resources each Party may be entitled to refer the issue to an alternative dispute resolution mechanism recognized by domestic legislation.

Sub-Option 6

8.9 Countries may take other measures and sanctions, including revocation, against the violation of the mandatory disclosure requirements.

Sub-Option 7

8.10 Administration and/or judicial authorities shall have the right to revoke, subject to Article 32 of the TRIPS Agreement, or render unenforceable a patent.

Sub-Option 8

8.11 If it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, such failure to comply with the requirement may only be a ground for revocation or invalidation of the granted patent in the case of fraudulent intention (Article 10 PLT).

OPTION 2

8.12 Sanctions of an administrative character or that are outside the [intellectual property] [patent] system.

Sub-option 1

8.13 The patent system should provide certainty of rights for users of genetic resources and traditional knowledge and shall not impose requirements that detract from legal certainty.

Sub-option 2

8.14 [Contracting parties] [Countries] shall ensure, in accordance with their legal systems, adequate criminal, civil and administrative enforcement procedures and dispute resolution

mechanisms are available under their laws against the willful infringement of the protection provided to genetic resources, [their derivatives] and associated traditional knowledge under this instrument.

8.15 [Contracting Parties] [Countries] shall provide that administrative and/or judicial authorities have the right to:

- (a) Prevent the further processing of the intellectual property applications.
- (b) Prevent the granting of intellectual property rights.

Sub-option 3

8.16 Patent applications shall not be processed without completion of such requirements.

Sub-option 4

8.17 Countries shall impose sanctions, which shall include administrative sanctions, criminal sanctions, fines and adequate compensation for damages.

Sub-option 5

8.18 Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.

8.19 It must be left to the individual [Contracting State] country to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.

Sub-option 7

8.20 Administration and/or judicial authorities shall have the right to prevent (a) the further processing of an application or (b) the granting of a patent

Sub-option 8

8.21 [Contracting Parties] [Countries] shall, in accordance with their national legal systems, provide for adequate measures for the refusal of patent applications on the grounds of non-compliance and willful infringement of the protection of genetic resources, [their derivatives] and associated traditional knowledge, in pursuance of the applicable provisions of these regulations.

Sub-option 9

8.22 If the national law applicable by the designated office requires the declaration of the source of genetic resources or traditional knowledge, the proposed amended Rule 51bis.3(a) of the PCT regulations requires the designated office to invite the applicant, at the beginning of the national phase, to comply with this requirement within a time limit which shall not be less than two months from the date of the invitation. [Appendix I of 20/INF/10.]

8.23 If the patent applicant does not comply with this invitation within the set time limit, the designated Office may refuse the application or consider it withdrawn on the grounds of this non-compliance.

8.24 Furthermore, if it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, such failure to comply with the requirement may not be a ground for revocation or invalidation of the granted patent. However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.

Sub-option 10

8.25 There shall be no sanction within the patent system for failure to meet any mandatory disclosure requirement relating to genetic resources or traditional knowledge nor shall failure to meet such requirements cause delay in processing or grant of the patent.

OPTION 3

8.26 If it is discovered after the grant of a patent that the applicant failed to disclose the information required or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD/ITPGRFA, [parties] Countries shall impose sanctions, which shall include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. [Parties] Countries may take other measures and sanctions, including revocation, against the violation of the mandatory disclosure requirements.

[End of Annex and of Document]