

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

March 4, 2022, 10:30AM (Geneva Time)

|

[PREAMBLE

1. — ~~[Contribute to the prevention of unauthorized use of genetic resources and [traditional knowledge associated with genetic resources].]~~
2. — ~~[Minimize the erroneous granting of [IP] [patent] rights.]~~
3. — ~~[Reaffirming the important economic, scientific, cultural, and commercial value of genetic resources and [traditional knowledge associated with genetic resources].]~~
4. — ~~[Acknowledging the important contribution of the patent system to scientific research and development, innovation and economic development.]~~
5. — ~~[Stressing the need for Members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and [traditional knowledge associated with genetic resources].]~~
6. — Encourage respect for indigenous [people[s]] and local communities.
7. — ~~[The [intellectual property] [patent] system [shall]/[should] provide certainty of rights for legitimate users and providers of genetic resources and/or [traditional knowledge associated with genetic resources].]~~
8. — ~~[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 and [traditional knowledge associated with genetic resources].]~~
9. — ~~[Promote [transparency and] dissemination of information.]~~
10. — ~~[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.]~~
11. — ~~[Foster [patent] [industrial property] protection and the development of genetic resources and [traditional knowledge associated with genetic resources] and encourage international research leading to innovation.]~~
12. — ~~[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 associated with genetic resources]. Accordingly, disclosing the source would build mutual trust in the North—South—relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the [intellectual property] [patent] system.]~~
13. — ~~[[Ensure] [recommend] that no [patents] [intellectual property] on life forms, including human beings, are granted.]~~
14. — ~~[Recognize that those accessing genetic resources and [traditional knowledge associated with genetic resources] in a country [shall]/[should], where required, comply with that country's national law providing protection for the genetic resources and [traditional knowledge associated with genetic resources].]~~

~~15.— [[IP][Patent] offices [shall]/[should] have a mandatory requirement for disclosure, as elaborated in this international legal instrument, when patenting of genetic resources would cause harm to the interests of indigenous [people[s]] and local communities.]~~

~~16.— [Reaffirm, in accordance with the Convention on Biological Diversity, the sovereign rights of States over their [natural] [biological] resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]~~

ALT

~~16.— [Reaffirm, [in accordance] [consistent] [with the Convention on Biological Diversity], the sovereign rights of States over [their] [natural] [biological] [genetic] resources [within their jurisdiction other than those associated with human beings], and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]~~

~~17.— [Recognizing that the [IP][patent] system, which protects inventions and fosters innovation, intersects with the CBD and has a role to play in protecting genetic resources and traditional knowledge associated with genetic resources.]~~

~~18.— Ensure that patent offices have appropriate information available to them on genetic resources and traditional knowledge associated with genetic resources, which they need in order to make informed decisions, in terms of granting patents~~

~~19.— Reaffirm the stability and predictability of correctly granted patent rights.~~

~~20.— [Recognize that the erroneous granting of patents can be effectively addressed by improving databases for storing information related to genetic resources and non-secret traditional knowledge associated with genetic resources, which can thus be used to search prior rights and reference materials not only in the procedures of examination, but also in the proceedings of a procedure of invalidation against granted patents.]~~

[ALTERNATIVE PREAMBLE

1. *Recognizing and reaffirming* obligations set forth in the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) and Member States' commitment to achieving the ends of the UNDRIP¹;
2. *Acknowledging* the UN Sustainable Development Goals and Indigenous Peoples' commitment to sustainability and ethical use in relation to GRs and [Associated TK] traditional knowledge associated with genetic resources;
3. [Ensuring] [Desiring to ensure] respect for the ~~sovereign~~-rights of sovereign holders, ~~including and~~ indigenous ~~people[s]~~ and local communities entities over their genetic resources, and traditional knowledge associated with genetic resources;
4. *Recognizing* the principles of free and prior informed consent and mutually agreed terms in relation to access and utilization of genetic resources and traditional knowledge associated with genetic resources;
5. *Recognizing* the role of the [IP]/[patent] system in contributing to the protection of genetic resources, and traditional knowledge associated with genetic resources, including ~~[preventing misappropriation]~~ [contributing to the traceability of access to GRs / contributing to the traceability of utilization of GRs];
- ~~6. — *Desiring* the promotion of the [efficacy, transparency and] quality of the patent system in relation to genetic resources (GRs) and traditional knowledge associated with genetic resources [(Associated TK)];~~
- ~~7. — *[Recognizing that an international disclosure requirement related to GRs and TK associated with GRs in patent applications contributes to legal certainty and consistency and, therefore, has benefits for the patent system and for providers and users of such resources and knowledge.]*~~
6. *Acknowledging* the important contribution of the patent system to scientific research and development, innovation and economic development;
7. *Stressing* the need for Members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and traditional knowledge associated with genetic resources;
8. [Ensuring] mutual supportiveness with [Desiring to ensure coherence] with international agreements relating to the protection of genetic resources and/or traditional knowledge associated with genetic resources and those relating to [IP]/[patents];
9. *Emphasizing* the importance of [IP]/[Patent] Offices having access to the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of [IP]/[patent] rights;
10. *Recognizing* the role of databases for storing information related to genetic resources and non secret traditional knowledge associated with genetic resources, in preventing the erroneous granting of patents, pre and post grant;

¹Outcome Document of the World Conference on Indigenous Peoples approved unanimously in 2014 by all 193 Member States of the UN General Assembly (G.A. Resolution A/RES/69/2,

11. *Reaffirming* the important economic, scientific, cultural, and commercial value of genetic resources and traditional knowledge associated with genetic resources;:-

12. *[Reaffirming* the [stability] need for reliability and predictability of granted [IP]/[patents] [IP]/[patent] rights, and recognizing the need for legal certainty with respect to disclosure requirements related to GRs and TK associated with GRs in [IP]/[patent] applications;:-]

13. *Recognizing and reaffirming* the role the [IP]/[patent] system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of stakeholders, providers, holders and users of genetic resources, and traditional knowledge associated with genetic resources;:-

[14. *Emphasizing that no [patents] [intellectual property] on life forms, including human beings, are to be granted;*]

154. *Reaffirming*, the sovereign rights of States over their natural resources, where applicable, and that the authority to determine access to genetic resources, in such cases, rests with the national governments and is subject to national legislation.]

[ARTICLE 1] DEFINITIONS

TERMS USED IN THE OPERATIVE ARTICLES

[Traditional Knowledge Associated with Genetic Resources

ALT 1

Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning, and is:

(a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];

(b) linked with, and is an integral part of, the cultural and social identity and traditional heritage of indigenous peoples, local communities and/or [other beneficiaries]; and

——(c) transmitted between or from generation to generation, whether consecutively or not.

~~“Traditional knowledge associated with genetic resources” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, [that subsist in] [that are associated with] genetic resources.~~

ALT 2

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

ALT 3

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

ALT 4

~~“Traditional Knowledge associated with genetic resources” has the meaning agreed upon in the WIPO IGC text on Protection of Traditional Knowledge.~~

[Country of Origin

“Country of origin” is the [first] country which possesses genetic resources in in-situ conditions.

ALT

“Country of origin” is the country which first possessed genetic resources in in-situ conditions and still possesses those genetic resources.]

[[Country Providing]][Providing Country]

“Country providing/Providing country” means, [[in accordance] [consistent] 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] [consistent] with the [Convention on Biological Diversity].]

[Erroneous Grant/Granting of Patents

Erroneous grant/granting of patents means the granting of patent rights on inventions that are not novel, that are obvious, or that are not industrially applicable.]

[[Invention] Directly Based On

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

ALT

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

Genetic Material

“Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.

ALT

“Genetic material” means any material of plant, animal, or microbial origin containing functional units of heredity.

Genetic Resources

“Genetic resources” are genetic material of actual or potential value.

ALT

“Genetic resources” means any material of plant, animal, or microbial origin containing functional units of heredity of actual or potential value, and includes derivatives and genetic information thereof.

[Source

ALT 1

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or botanical garden.]

ALT 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, [patent owners, universities, farmers, and plant breeders,] indigenous and local communities; and
- (ii) Secondary sources, including in particular ex-situ collections and [scientific literature].]

ALT 3

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or [botanical garden] or any other depository of genetic resources.]

[Utilization

“Utilization” of genetic resources means to conduct research and development, [conservation, collection, characterization, among others,] [including commercialization] on the genetic and/or biochemical composition of genetic resources, and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

ALT

[“Utilization” of genetic resources means to conduct research and development [outside of the traditional uses by the knowledge holders] [including commercialization] on the genetic and/or biochemical composition of genetic resources and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity] [and to make a new product, or a new method of use or manufacturing of a product.]]]

OTHER TERMS

[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 Providing Genetic Resources

[“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, [or taken from ex-situ sources,] which may or may not have originated in that country.]

ALT

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

[Derivative

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources[, even if it does not contain functional units of heredity].]

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].

Ex-Situ Conservation

“Ex-situ conservation” means the conservation of components of biological diversity outside their natural habitats.

[Misappropriation

“Misappropriation” is the [acquisition] [utilization] of genetic resources [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with national legislation] [of the country of origin or providing country].]

ALT

[“Misappropriation” is the use of genetic resources and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

[[Physical] Access

“[[Physical]/[Direct] access” to the genetic resource is its physical possession [or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property]].]

[Protected Genetic Resources

“Protected genetic resources” means, genetic resources that are protected either pursuant to an intellectual property right or other legal right. Once intellectual property rights in a genetic resource expire, the genetic resource should be in the public domain and not treated as a protected genetic resource.]

[Source of Traditional Knowledge Associated with Genetic Resources

“Source of Traditional Knowledge Associated with Genetic Resources” means any source from which the applicant has acquired the traditional knowledge associated with genetic resources, including indigenous and local communities, scientific literature, publicly accessible databases, and patent applications, and patent publications.^{2]}

[Unauthorized Use

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

² This phrase does not appear verbatim in the document, but was introduced contemporaneously with the global deletion of “associated traditional knowledge” from the text. Upon reflection, it was felt that the Member State which introduced the phrase should have the opportunity to clarify its continuing relevance to the text.

[I. [MANDATORY] DISCLOSURE]

[ARTICLE 2] [OBJECTIVE]

[The objective of this instrument is to contribute to the protection of genetic resources and traditional knowledge associated with genetic resources within the [IP] [patent] system by:

- (a) [Enhancing] [transparency], [efficacy] and quality in the [IP][patent] system in relation to genetic resources and/or traditional knowledge associated with genetic resources; and
- (b) [Ensuring] [Desiring to ensure] that [IP] [patent] offices have access to the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of [IP] [patent] rights.]

[ARTICLE 3] [SUBJECT MATTER OF INSTRUMENT]

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

ALT

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

[ARTICLE 4] [DISCLOSURE REQUIREMENT]

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

~~(a)–(d):~~

~~(b)–~~

~~(a)~~ Disclose the [providing country [that is the country of origin]] [country of origin [and]] [or [if unknown],] source of the genetic resources, [and, where applicable, the indigenous [peoples] or local communities from which the genetic resourcesGRs] and/or [traditional knowledge associated with genetic resources.] [were]/[was] obtained.

~~(c)–~~

~~(d)–~~

~~(e)(b)~~ [If the source and/or [providing country that is the country of origin] [country of origin] is not known to the ~~[patent]~~ applicant, make a declaration to that effect.]

4.2 In accordance with national law, a [Member State]/[Party] may require applicants to provide relevant information regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]

ALT 1

4.2 The disclosure requirement of Paragraph 1 shall not include a requirement to provide relevant information regarding compliance with ABS requirements, including PIC.

ALT 2

4.2 In accordance with national law, a [Member State]/[Party] may require applicants to provide relevant information regarding their entitlement to use the genetic resource.

4.3 The disclosure requirement [shall/should/may] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices [shall]/[should/may] provide guidance to [IP] [patent] applicants on how to meet the disclosure requirement.

4.4 Each [Member State]/[Party] [shall]/[should] make the information disclosed, that supports the disclosure requirement, publicly available³, except for information considered confidential.³

[ARTICLE 5] [EXCEPTIONS AND LIMITATIONS]

[In complying with the obligation set forth in Article 4, members may, in special cases, and in conjunction with Indigenous peoples and local communitiesPLGs, adopt justifiable exceptions and limitations necessary to protect the public interest and public health, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument, or mutual supportiveness with other instruments.]

[ALT

5.1 A [IP] [patent] disclosure requirement related to genetic resources and [traditional knowledge associated with genetic resources] [shall]/[should] not apply to the following:

- (a) [All [human genetic resources] [genetic resources taken from humans] [including human pathogens];]
- (b) [Derivatives];
- (c) [Commodities];[/genetic resources when they are used as commodities];
- (d) [Traditional knowledge and other information in the public domain];
- (e) [Genetic resources from areas beyond national jurisdictions [and economic zones]];
- (f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993]] [entry into force of the Nagoya Protocol on October 12, 2014]; -and

³ An alternative formulation from the Nagoya Protocol Art. 14(2) is “without prejudice to the protection of confidential information”.

- (g) [Genetic resources and traditional knowledge associated with genetic resources necessary to protect human, animal or plant life or health [including public health] or to avoid serious prejudice to the environment].

~~5.2— [[Member States]/[Parties] [shall]/[should] not impose the disclosure requirement in this instrument on [IP] [patent] applications filed [or having a priority date] before entry into force of this instrument[, subject to national laws that existed prior to this instrument]]~~

ARTICLE X
NON-RETROACTIVITY

[[Member States]/[Parties] [shall]/[should] not impose the disclosure requirement in this instrument on [IP] [patent] applications filed [or having a priority date] prior to that [Member State's]/[Party's] ratification of or accession to this instrument, [, subject to [national laws]] national disclosure requirements relating to GRs and associated TK] that existed prior to such ratification or accession.]

ARTICLE XX
RECIPROCITY

Contracting Parties may *choose to* apply the disclosure requirement specified in Article 4 only to the genetic resources and traditional knowledge associated with genetic resources of Parties to this Instrument.

**[ARTICLE 6]
[SANCTIONS AND REMEDIES]**

6.1 [Each [Member State]/[Party] [shall]/[should] put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with the disclosure requirement of Article 4.

[Member States]/[Parties] shall develop these measures in conjunction with the Indigenous peoples and local communities PLCs concerned, where applicable.

6.2 Such measures [should/shall/may] include pre and/or post grant measures.

ALT

[6.2 Subject to national legislation, such measures [shall/should] [may] [include, inter alia] consist of:

(a) Pre-Grant.

~~_____~~ Suspending ~~further processing the grant~~ of [IP] [patent] applications until the disclosure requirements are met.

~~(i)~~ _____

~~(i)(ii)~~ A [IP] [patent] office considering the application withdrawn [in accordance with national law].

~~(ii)(iii)~~ Preventing or refusing to grant an [IP right] [patent].

~~(iii)(iv)~~ Providing an opportunity for [IP] [patent] applicants to supplement the [IP] [patent] application with additional information to disclose the source or origin of any genetic resource or traditional knowledge used. Since such information is irrelevant to how to make and use the invention, there would be no impact upon the filing date of the application and no fee required for its submission after the filing date of the application.

(b) [Post-Grant.

(i) Publication of judicial rulings regarding failure to disclose.

(ii) [Fines or adequate compensation for damages, including payment of royalties.]

(iii) Other measures [including revocation, restorative justice, and economic compensation for holders of genetic resources, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]]

6.3 Revocation of [an IP right] [a patent] as a sanction for non-compliance with Article 4 may be provided under national law for willful or deliberate instances of refusal to comply, but only after the [IP right] [patent] holder has been offered the opportunity to reach a mutually satisfactory resolution with relevant parties, as defined under national law, and such negotiations have failed.

ALT

6.3 Failure to fulfill the disclosure requirement [shall]/[should] not affect the validity or enforceability of granted [IP] [patent] rights.

6.4 [IP] [patent] offices [shall]/[should/may] provide an opportunity, within a reasonable time, for applicants [or IP right holders][patentees] to correct any disclosures that are erroneous or incorrect.

6.54 [Member States]/[Parties] [shall]/[should] put in place adequate dispute resolution mechanisms.]

**[II. ALTERNATIVES TO ARTICLES 2-6
NO NEW DISCLOSURE REQUIREMENT]**

**ALT
[ARTICLE 2]
[OBJECTIVE]**

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

ALT

The objectives of this instrument are to:

- (a) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources, which could protect Indigenous peoples and local communities from the limitations of the traditional use of genetic resources and their traditional knowledge associated with genetic resources that might result from the erroneous patenting thereof;
- (b) ensure that patent offices have the appropriate available information on genetic resources and traditional knowledge associated resources needed to make informed decisions on granting patents; and
- (c) preserve a rich and accessible public domain in order to foster creativity and innovation.]

**ALT
[ARTICLE 3]
[SUBJECT MATTER OF INSTRUMENT]**

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

**ALT
[ARTICLE 4]
[DISCLOSURE]**

4.1 Patent applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources and [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

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

(a) include within a specification of any patent application and any patent issuing thereon a statement specifying that the invention was made using the genetic resource and other relevant information, and

[(b) obtain consent for uses not encompassed within the permit agreement or license.]]

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

4.4 [Where access to a genetic resource or [traditional knowledge associated with genetic resources] is not necessary to make or use the invention, information regarding the source or origin of genetic resource or the [traditional knowledge associated with the genetic resource] can be provided at any time after the filing date of the application and without payment of a fee.]

4.5 The disclosure of the [geographic location] where the genetic material was obtained [shall]/[should]/[may][does] not place an obligation on the patent office to verify the contents of the disclosure. But patent offices [shall]/[should] provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect.

4.6 Failure to examine a patent application in a timely manner shall result in an adjustment of the term of the granted patent to compensate the patentee for administrative delays.]

[III. [DEFENSIVE]/[COMPLEMENTARY] MEASURES]

[ARTICLE 7] [DUE DILIGENCE]

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

(a) A database ~~[[shall]/[should]]~~ may be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law. ~~However, [member states]/[parties] [shall]/[should] not be obliged to establish such databases.~~

(b) Such databases can be accessed in accordance with national law and with appropriate safeguards, by stakeholders [shall]/[should] be accessible to potential [patent] [IP rights] licensees [and potential investors] to confirm lawful chain of title of [protected] genetic resources upon which a [patent][IP right] is based.]]

~~(b)(c) Where databases are to be utilized as part of a due diligence mechanism, the creation of said databases and the rules governing access, uses, and the application of safeguards, should be developed and implemented in conjunction with indigenous peoples and local communities and in accordance with their laws, customs, and protocols.~~

[ARTICLE 8] [[PREVENTION OF THE [ERRONEOUS]⁴ GRANT OF [IP RIGHTS]/[PATENTS] AND VOLUNTARY CODES OF CONDUCT]

8.1 [Member States]/[Parties] [shall]/[should]:

- (a) Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted [erroneously] with regard to claimed inventions that include genetic resources 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 for users regarding the protection of genetic resources and [traditional knowledge associated with genetic resources].]

⁴ A Member State requested to change this title to "Protection of the Demand of the Patents". However, the facilitators do not understand the meaning of this proposal and request clarification before such a change is made.

- (d) Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases containing [information associated with] genetic resources and [traditional knowledge associated with genetic resources] for use by patent offices] [with appropriate safeguards].

[8.2 As a complement to the disclosure obligation provided for in Article 4, and in the implementation of this instrument, the [Member State]/[Party] may consider the use of databases on traditional knowledge and genetic resources in accordance with its needs, priorities, and safeguards as may be required under national laws and special circumstances.]

ALT

8.1 Databases on genetic resources may be established in accordance with national law, in consultation with the relevant stakeholders, and with appropriate safeguards, for the purposes of search and examination of [IP]/[patent] applications.

8.2 The databases should be accessible to [IP]/[patent] offices and other approved users to aid in the prevention of the erroneous grant of [IP]/[patents].

Database Search Systems

8.3 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources and [traditional knowledge associated with genetic resources] for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:

- (a) With a view towards interoperability, databases [shall]/[should] comply with minimum standards and structure of content.
- (b) Appropriate safeguards [such as filters] [shall]/[should] be developed in accordance with national law.
- (c) These databases will be accessible to patent offices [and other approved users].

WIPO Portal Site

8.4 [Member States]/[Parties] [shall]/[should] establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources and non-secret [traditional knowledge associated with genetic resources] within their territory. The WIPO portal site will enable an examiner [and the public] to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards [such as filters].]

8.5 [Member States]/[Parties] should provide effective, legal, policy or administrative measures, as appropriate and in accordance with national law, to implement and administer the WIPO portal.]

[IV. FINAL PROVISIONS]

[ARTICLE 9] [PREVENTIVE MEASURES FOR PROTECTION]

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

[ARTICLE 10] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

10.1 This instrument [shall]/[should] establish a mutually supportive relationship [between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources and [traditional knowledge associated with genetic resources] and] [with] relevant [existing] international agreements and treaties.

ALT

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

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

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

[10.4 The [PCT] and [PLT] [shall]/[should] be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources and [traditional knowledge associated with genetic resources]. [The amendments [shall]/[should] also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]]

[ARTICLE 11] INTERNATIONAL COOPERATION

[[Relevant WIPO bodies [shall]/[should] encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group [shall]/[should] develop a set of guidelines for [the search and examination of applications related to genetic resources and [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

ALT

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

[ARTICLE 12]
TRANSBOUNDARY COOPERATION

[In instances where the same genetic resources and [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties [shall]/[should] endeavor to cooperate, as appropriate, with the involvement of indigenous [people[s]] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

[ARTICLE 13]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

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

[End of Annex and of Document]