

Introduction to Consolidated Document Relating to Intellectual Property and Genetic Resources (35/4)

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Changes from Consolidated Document 30/4
to 35/4 (2014 to 2016)

Structure of Consolidated Document 30/4 (2014)

- List of terms
- [Preamble]
- Policy objective[s]
- [Article 1] Subject matter of instrument
- [Article 2] [Disclosure requirement]
- [Article 3] [Exceptions and limitations]
- [Article 4] [Relationship with [PCT] and [PLT]]
- [Article 5] Sanctions and remedies
- [Article 6] [No new disclosure requirement]
- [Defensive measures]
- [Article 7] [Due diligence]
- [Article 8] [Prevention of the erroneous grant of patents and voluntary codes of conduct]
- [Article 9] Relationship with international agreements
- [Article 10] International cooperation
- [Article 11] Transboundary cooperation
- [Article 12] Technical assistance, cooperation and capacity building

Structure of Consolidated Document 35/4 (2016)

- List of terms
- [Preamble]
- **[I. General Provisions]**
- [Article 1] Objective[s]
- [Article 2] Subject matter of instrument
- **[II. [Mandatory] Disclosure]**
- [Article 3] [Disclosure requirement]
- [Article 4] [Exceptions and limitations]
- [Article 5] Sanctions and remedies
- **[Alternative to Articles 1, 2, 3, 4 & 5 No New Disclosure Requirements]**
- Alt [Article 1] [Objective]
- Alt [Article 3] [No new disclosure requirement]
- **[III. Defensive measures/Defensive measures complementary to mandatory disclosure]**
- [Article 6] [Due diligence]
- [Article 7] [[Prevention of the [erroneous] grant of patents] [Prevention of the granting of patents which do not comply with the requirements for patentability of the invention] and voluntary codes of conduct]
- **[IV. Final Provisions]**
- [Article 8] Relationship with international agreements
- [Article 9] International cooperation
- [Article 10] Transboundary cooperation
- [Article 11] Technical assistance, cooperation and capacity building

Consolidated document 35/4: No focus on List of Terms or Preamble (few changes)

- Global change: “associated traditional knowledge” to “traditional knowledge associated with genetic resources”
- List of Terms
 - Added: “invention directly based on”, “unauthorized use,” protected genetic resources”
 - Alternatives provided: “country providing genetic resources,” “utilization”
 - Deleted: “international certificate of compliance.”
 - Need to determine which terms need to be defined, whether to use definitions consistent with other agreements
- Preamble (additions included)
 - “contribute to the prevention of misappropriation of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources.]];And
 - [Minimize the granting of erroneous [IP] [patent] rights.]

[ARTICLE 1 OBJECTIVE[S]]

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

ALT 1

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

ALT 2

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

- (a) Ensuring that [IP] [patent] offices have access to the appropriate information on genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] to prevent the granting of [erroneous] [IP] [patent] rights;
- (b) [Enhancing transparency in the [IP][patent] [and access and benefit sharing] system]; and,
- (c) [Ensuring] [promoting] [facilitating] [complementarity] [mutual supportiveness] with international agreements relating to the protection of genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] [and those relating to IP].

Objectives: Key Points

Focus on IP/Patent system

- Enhance the transparency of the [IP] [patent] system relating to GRs and TK associated with GRs.
- Facilitate mutual supportiveness with international agreements relating to GRs and TK associated with GRs.
- Facilitate the possibility of ABS through the disclosure of country of origin or source of GRs in separate systems such as the CBD.
- Ensure that IP/patent offices have access to the appropriate information on GRs and TK associated with GRs to prevent the granting of erroneous IP/patent rights.

Two Approaches: Subject Matter

[ARTICLE 2] SUBJECT MATTER OF INSTRUMENT

2 This instrument applies to genetic resources, [their derivatives] 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].]

Two Broad Approaches Reflected in 35/4:

- **Disclosure Requirement**

- Inclusion of a disclosure requirement (voluntary or mandatory) within IP/patent legislation relating to information (e.g., about the country of origin or source of GRs and TK associated with GRs) in applications, where the subject matter/claimed invention includes utilization of/is directly based on/utilizes GRs and TK associated with GRs.

- **Defensive Measures**

- Focuses on measures such as databases, voluntary codes and guidelines for IP/patent offices, third party dispute mechanisms and due diligence regimes within patent offices under national laws with a view to preventing the grant of erroneous patents.
- Does not envision a new, mandatory disclosure requirement; disclosure only for preventing grant of erroneous patents, not for facilitating ABS compliance.
- Some delegations view defensive measure as complementary to a disclosure requirement.

[ARTICLE 3]
[DISCLOSURE REQUIREMENT]

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

- (a) Disclose the [providing country that is the country of origin] [country of origin [and]] [or [if unknown],] source of the genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources.]
- (b) [Provide relevant information, as required by national law, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]
- (c) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, a declaration to that effect.]

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

3.3 A simple notification procedure shall/should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.]

3.4 [Each Party shall/should make the information disclosed[, except for information related to privacy, business secrets, or other lawful confidentiality²,] publicly available at the time of application publication [or patent grant].]

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

[ARTICLE 4]
[EXCEPTIONS AND LIMITATIONS]

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

ALT

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

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

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

**[ARTICLE 5]
SANCTIONS AND REMEDIES**

5 [Each [Party] [country] shall/should put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with paragraph 3.1[, including dispute resolution mechanisms]. Subject to national legislation, sanctions and remedies [shall/should] [may] [include, inter alia] consist of:

- (a) Pre-Grant.
 - (i) Suspending further processing of [IP] [patent] applications until the disclosure requirements are met.
 - (ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].
 - (iii) Preventing or refusing to grant an [IP right] [patent].

- (b) [Post-Grant].
 - (i) Publication of judicial rulings regarding failure to disclose.
 - (ii) [Fines or adequate compensation for damages, including payment of royalties.]
 - (iii) Other measures [including revocation, restorative justice, and economic compensation for holders of genetic resources, their derivatives, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]

ALT

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

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

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

Disclosure: Key Issues (not new)

- Nature of the disclosure requirement: Should disclosure requirements be mandatory or voluntary (depends on nature of the instrument)?
- In addition to GRs, should the instrument also apply to derivatives and TK associated with GRs?
- What should trigger disclosure, “utilization of” subject matter, “directly based on” subject matter, or “directly based on the utilization of” subject matter?
- What should be the content of disclosure? For example, should it be the origin and/or source of the GR, and information regarding compliance with access and benefit-sharing requirements including prior informed consent?
- Should there be exceptions and limitations to a disclosure requirement, and if so, which ones?
- Should issues concerning IP/patent subject matter eligibility for GRs and/or derivatives as found in nature and/or isolated therefrom be addressed in this instrument, and, if so, where would this be better addressed, in the preamble or in the main body of the instrument?
- What should be the consequence of non-compliance? Should non-compliance affect the validity of a granted patent and, if so, what would the permissible condition for revocation be?

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

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

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

**ALT
[ARTICLE 3]
[NO NEW DISCLOSURE REQUIREMENT]**

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

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

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

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

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

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

Defensive Measures (Articles 6 & 7)

[ARTICLE 6] [DUE DILIGENCE

- 6 Member states 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 be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law. However, member states shall/should not be obliged to establish such databases.
- (b) Such databases shall/should be accessible to potential patent licensees [and potential investors] to confirm lawful chain of title of [protected] genetic resources upon which a patent is based.]

[ARTICLE 7]
[[PREVENTION OF THE [ERRONEOUS] GRANT OF PATENTS] [PREVENTION OF THE GRANTING OF PATENTS WHICH DO NOT COMPLY WITH THE REQUIREMENTS FOR PATENTABILITY OF THE INVENTION] AND VOLUNTARY CODES OF CONDUCT

7.1 Member States shall/should:

- a. Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted [erroneously] with regard to claimed inventions that include genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] where, under national law, those genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]:
 - (i) anticipate a claimed invention (no novelty); or
 - (ii) obviate a claimed invention (obvious or no inventive step).
- b. Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].
- c. [Encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines for users regarding the protection of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]
- d. Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for use by patent offices.]

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

**[ARTICLE 7]
[[PREVENTION OF THE [ERRONEOUS] GRANT OF PATENTS] [PREVENTION OF THE
GRANTING OF PATENTS WHICH DO NOT COMPLY WITH THE REQUIREMENTS FOR
PATENTABILITY OF THE INVENTION] AND VOLUNTARY CODES OF CONDUCT**

Cont.

Database Search Systems

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

(a) With a view towards interoperability, databases shall/should comply with minimum standards and structure of content.

(b) Appropriate safeguards [such as filters] shall/should be developed in accordance with national law.

(a) These databases will be accessible to patent offices [and other approved users].

WIPO Portal Site

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

[ARTICLE 8]
RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

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

ALT

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

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

8.3 [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.]]

[8.4 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, [their derivatives] and [traditional knowledge associated with genetic resources]. [The amendments shall/should also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]]

[ARTICLE 9]
INTERNATIONAL COOPERATION

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

ALT

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

[ARTICLE 10]
TRANSBOUNDARY COOPERATION

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

[ARTICLE 11]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

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