

WIPO/GRTKF/IC/SS/GE/23/4 ORIGINAL: ENGLISH DATE: SEPTEMBER 8, 2023

Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Geneva, September 4 to 8, 2023

DECISIONS

Adopted by the Committee

DECISION ON AGENDA ITEM 2:

ADOPTION OF THE AGENDA

The Chair submitted the draft agenda circulated as WIPO/GRTKF/IC/SS/GE/23/1 Prov. for adoption and it was adopted.

DECISION ON AGENDA ITEM 3:

PARTICIPATION OF INDIGENOUS AND LOCAL COMMUNITIES

The Committee took note of document WIPO/GRTKF/IC/SS/GE/23/INF/3.

The Committee strongly encouraged and called upon members of the Committee and all interested public and private entities to contribute to the WIPO Voluntary Fund for Accredited Indigenous and Local Communities.

DECISION ON AGENDA ITEM 4:

GENETIC RESOURCES

The Committee reviewed and revised the text of the Preamble and Articles 1 to 9 of document WIPO/GRTKF/IC/SS/GE/23/2. The agreed revisions are reflected in the text annexed to this document. The Committee decided that this text, as annexed to this document, be transmitted to the Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources as the substantive articles of the Basic Proposal for the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

The Committee agreed that the notes on each article, as contained in document WIPO/GRTKF/IC/43/5, be published separately as an information document for the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. These notes were prepared by Mr. Ian Goss in April 2019, when he was the Chair of the IGC.

The Committee took note of and held discussions on documents WIPO/GRTKF/IC/SS/GE/23/3. WIPO/GRTKF/IC/SS/GE/23/INF/2, WIPO/GRTKF/IC/SS/GE/23/INF/4, WIPO/GRTKF/IC/SS/GE/23/INF/5 and WIPO/GRTKF/IC/SS/GE/23/INF/6.

DECISION ON AGENDA ITEM 5:

ADOPTION OF A REPORT TO THE PREPARATORY COMMITTEE OF THE DIPLOMATIC CONFERENCE TO CONCLUDE AN INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

The Committee adopted its decisions on agenda items 2, 3 and 4 on September 8, 2023, and agreed that these decisions be transmitted to the Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

DECISION ON AGENDA ITEM 6:

ANY OTHER BUSINESS

There was no discussion under this item.

DECISION ON AGENDA ITEM 7: CLOSING OF THE SESSION

The Committee closed the session on September 8, 2023.

[Annex follows]

ANNEX

DRAFT

INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

September 8, 2023

The Parties to this instrument,

Desiring the promotion of the efficacy, transparency and quality of the patent system in relation to genetic resources and traditional knowledge associated with genetic resources,

Emphasizing the importance of patent offices having access to appropriate information on genetic resources and traditional knowledge associated with genetic resources to 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,

Recognizing the potential role of the patent system in contributing to the protection of genetic resources and traditional knowledge associated with genetic resources.

Recognizing that an international disclosure requirement related to genetic resources and traditional knowledge associated with genetic resources 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,

Recognizing that this instrument and other international instruments related to genetic resources and traditional knowledge associated with genetic resources should be mutually supportive,

Recognizing and reaffirming the role that the intellectual property system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of providers and users of genetic resources and traditional knowledge associated with genetic resources,

Acknowledging the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP),

Have agreed as follows:

ARTICLE 1 OBJECTIVES

The objectives of this instrument are to:

- (a) enhance the efficacy, transparency and quality of the patent system with regard to genetic resources and traditional knowledge associated with genetic resources, and
- (b) 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.

ARTICLE 2 LIST OF TERMS

For the purposes of this instrument:

"Applicant" means the person whom the records of the Office show, pursuant to the applicable law, as the person who is applying for the granting of a patent, or as another person who is filing or prosecuting the application.

"Application" means an application for granting of a patent.

"Contracting Party" means any State or intergovernmental organization party to this instrument.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in situ conditions.

"[Materially/Directly] based on" means that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or traditional knowledge associated with genetic resources.

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

"Genetic resources1" are genetic material of actual or potential value.

"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.

"Office" means the authority of a Contracting Party entrusted with the granting of patents.

"PCT" refers to the Patent Cooperation Treaty, 1970.

"Source of Genetic Resources" refers to any source from which the applicant has obtained the genetic resources, such as a research centre, gene bank, Indigenous Peoples and local communities, the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other *ex situ* collection or depository of genetic resources.

"Source of Traditional Knowledge Associated with Genetic Resources" means any source from which the applicant has obtained the traditional knowledge associated with genetic resources, such as scientific literature, publicly accessible databases, patent applications and patent publications.

¹ The definition of "genetic resources" is, in line with the manner in which the term is understood in the context of the CBD, not intended to include "human genetic resources".

ARTICLE 3 DISCLOSURE REQUIREMENT

- 3.1 Where the claimed invention in a patent application is [materially/directly] based on genetic resources, each Contracting Party shall require applicants to disclose:
 - (a) the country of origin of the genetic resources, or,
 - (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the genetic resources.
- 3.2 Where the claimed invention in a patent application is [materially/directly] based on traditional knowledge associated with genetic resources, each Contracting Party shall require applicants to disclose:
 - (a) the Indigenous Peoples or local community that provided the traditional knowledge associated with genetic resources, or,
 - (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the traditional knowledge associated with genetic resources.
- 3.3 In cases where none of the information in paragraphs 3.1 and/or 3.2 is known to the applicant, each Contracting Party shall require the applicant to make a declaration to that effect.
- 3.4 Offices shall provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for patent applicants to rectify a failure to include the minimum information referred to in paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect.
- 3.5 Contracting Parties shall not place an obligation on Offices to verify the authenticity of the disclosure.
- 3.6 Each Contracting Party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information.

ARTICLE 4 EXCEPTIONS AND LIMITATIONS

In complying with the obligation set forth in Article 3, Contracting Parties 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 or mutual supportiveness with other instruments.

ARTICLE 5 NON-RETROACTIVITY

Contracting Parties shall not impose the obligations of this instrument in relation to patent applications which have been filed prior to that Contracting Party's ratification of or accession to this instrument, subject to national laws that existed prior to such ratification or accession.

ARTICLE 6 SANCTIONS AND REMEDIES

- 6.1 Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address an applicant's failure to provide the information required in Article 3 of this instrument.
- 6.2 Each Contracting Party shall provide an applicant an opportunity to rectify a failure to include the minimum information detailed in Article 3 before implementing sanctions or directing remedies.
- 6.3 Subject to Article 6.4, no Contracting Party shall revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument.
- 6.4 Each Contracting Party may provide for post grant sanctions or remedies where there has been fraudulent intent in regard to the disclosure requirement in Article 3 of this instrument, in accordance with its national law.
- 6.5 Without prejudice to non-compliance as a result of a fraudulent intention as addressed under Article 6.4, Contracting Parties shall put in place adequate dispute mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions, in accordance with national law.

ARTICLE 7 INFORMATION SYSTEMS

- 7.1 Contracting Parties may establish information systems (such as databases) of genetic resources and traditional knowledge associated with genetic resources, in consultation, where applicable, with Indigenous Peoples and local communities and other stakeholders, taking into account their national circumstances.
- 7.2 Contracting Parties should, with appropriate safeguards developed in consultation, where applicable, with Indigenous Peoples and local communities and other stakeholders, make such information systems accessible to Offices for the purposes of search and examination of patent applications. Such access to the information systems may be subject to authorization, where applicable, by the Contracting Parties establishing the information systems.
- 7.3 In regard to such information systems, the Assembly of the Contracting Parties may establish one or more technical working groups to:
 - (a) Develop minimum interoperability standards and structures of information systems content;
 - (b) Develop guidelines relating to safeguards;
 - (c) Develop principles and modalities related to the sharing of relevant information related to genetic resources and traditional knowledge associated with genetic resources, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge associated with genetic resources, and how WIPO Members should cooperate in the sharing of such information;
 - (d) Make recommendations as to the possible establishment of an online portal to be hosted by the International Bureau of WIPO through which Offices would be able to directly access and retrieve data from such national and regional information systems, subject to appropriate safeguards; and,
 - (e) Address any other related issue.

ARTICLE 8 RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument shall be implemented in a mutually supportive manner with other international agreements relevant to this instrument.²

² Agreed Statement to Article 8: The Contracting Parties request the Assembly of the International Patent Cooperation Union to consider the need for amendments to the Regulations under the PCT and/or the Administrative Instructions thereunder with a view towards providing an opportunity for applicants who file an international application under the PCT designating a PCT Contracting State which, under its applicable national law, requires the disclosure of GRs and Associated TK, to comply with any formality requirements related to such disclosure requirement either upon filing of the international application, with effect for all such Contracting States, or subsequently, upon entry into the national phase before an Office of any such Contracting State.

ARTICLE 9 REVIEW

The Contracting Parties commit to a review of the scope and contents of this instrument, addressing issues such as the possible extension of the disclosure requirement in Article 3 to other areas of intellectual property and to derivatives and addressing other issues arising from new and emerging technologies that are relevant for the application of this instrument, no later than four years after the entry into force of this instrument.

[End of Annex and the document]