

**Diplomatic Conference to Conclude an International Legal Instrument
Relating to Intellectual Property, Genetic Resources and Traditional
Knowledge Associated with Genetic Resources**

Geneva, May 13 to 24, 2024

BASIC PROPOSAL FOR AN INTERNATIONAL LEGAL INSTRUMENT RELATING TO
INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL
KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

prepared by the Secretariat

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 Convention on Biological Diversity, 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 Instrument².

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.

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 10 GENERAL PRINCIPLES ON IMPLEMENTATION

10.1 Contracting Parties undertake to adopt the measures necessary to ensure the application of this Instrument.

10.2 Nothing shall prevent Contracting Parties from determining the appropriate method of implementing the provisions of this Instrument within their own legal systems and practices.

ARTICLE 11 ASSEMBLY

11.1 The Contracting Parties shall have an Assembly:

- (a) Each Contracting Party shall be represented in the Assembly by one delegate who may be assisted by alternate delegates, advisors and experts.
- (b) The expenses of each delegation shall be borne by the Contracting Party that has appointed the delegation. The Assembly may ask the International Bureau of WIPO to grant financial assistance to facilitate the participation of delegations of Contracting Parties that are regarded as developing countries or that are countries in transition to a market economy.

11.2 The Assembly:

- (a) Shall deal with all matters concerning the maintenance and development of this Instrument as well as its application and operation;
- (b) Shall perform the function allocated to it under Article [13.2] in respect of the admission of certain intergovernmental organizations to become party to this Instrument;
- (c) Shall conduct the review referred to in Article [9];
- (d) Shall decide the convocation of a Diplomatic Conference for the revision of this Instrument as referred to in Article [15], including as a result of the review referred to in Article [9], and shall give the necessary instructions to the Director General of WIPO for the preparation of any such Diplomatic Conference;
- (e) May establish technical working groups as it deems appropriate;
- (f) May adopt amendments to the present Article and Article [12]; and
- (g) Shall perform such other functions as are appropriate to implementing the provisions of this Instrument.

11.3 The Assembly shall endeavor to take its decisions by consensus. Where a decision cannot be reached by consensus, the matter at issue shall be decided by vote. In such a case:

- (a) Each Contracting Party that is a State shall have one vote and shall vote only in its own name; and
- (b) Any Contracting Party that is an intergovernmental organization may participate in the vote, in place of its Member States, with a number of votes equal to the number of its Member States that are party to this Instrument. No such intergovernmental

organization shall participate in the vote if any one of its Member States exercises its right to vote and *vice versa*.

11.4 The Assembly shall meet upon convocation by the Director General of WIPO and, in the absence of exceptional circumstances, during the same period and at the same place as the General Assembly of WIPO.

11.5 The Assembly shall establish its own rules of procedure, including the convocation of extraordinary sessions, the requirements of a quorum and, subject to the provisions of this Instrument, the required majority for various kinds of decisions.

ARTICLE 12 INTERNATIONAL BUREAU

12.1 The International Bureau of WIPO shall perform the administrative tasks concerning this Instrument. In particular, the International Bureau shall prepare the meetings and provide the secretariat for the Assembly and for such technical working groups as may be established by the Assembly.

12.2 The Director General of WIPO and any staff member designated by the Director General shall participate, without the right to vote, in all meetings of the Assembly and any such technical working groups established by the Assembly. The Director General, or a staff member designated by the Director General, shall be *ex officio* Secretary of such a body.

12.3 The International Bureau shall, in accordance with the directions of the Assembly, make the preparations for any Diplomatic Conferences. The Director General of WIPO and persons designated by the Director General shall take part, without the right to vote, in the discussions at such Conferences.

ARTICLE 13 ELIGIBILITY TO BECOME A PARTY

13.1 Any Member State of WIPO may become party to this Instrument.

13.2 The Assembly may decide to admit any intergovernmental organization to become party to this Instrument which declares that it is competent in respect of, and has its own legislation binding on all its Member States on, matters covered by this Instrument and that it has been duly authorized, in accordance with its internal procedures, to become party to this Instrument.

ARTICLE 14 RATIFICATION AND ACCESSION

14.1 Any State or intergovernmental organization referred to in Article [13] may deposit with the Director General of WIPO:

- (a) an instrument of ratification if it has signed this Instrument; or
- (b) an instrument of accession, if it has not signed this Instrument.

14.2 The effective date of the deposit of an instrument of ratification or accession shall be the date on which that instrument is deposited.

ARTICLE 15 REVISION

This Instrument may only be revised by a Diplomatic Conference. The convocation of any Diplomatic Conference shall be decided by the Assembly.

ARTICLE 16 AMENDMENT OF ARTICLES [11] AND [12]

16.1 Articles [11] and [12] of this Instrument may be amended by the Assembly.

16.2 Proposals for the amendment of the Articles referred to in Article [16.1] may be initiated by any of the Contracting Parties or by the Director General of WIPO. Such proposals shall be communicated by the Director General of WIPO to the Contracting Parties at least six months in advance of their consideration by the Assembly.

16.3 Adoption of any amendment to the Articles referred to in Article [16.1] shall require three-fourths of the votes cast.

16.4 Any such amendment shall enter into force one month after written notifications of acceptance by the Contracting Parties, effected in accordance with their respective constitutional processes, have been received by the Director General from three-fourths of the Contracting Parties at the time the Assembly adopted the amendment. Any amendment thus accepted shall bind all of the Contracting Parties at the time the amendment enters into force, or which become Contracting Parties thereof at a subsequent date.

ARTICLE 17 SIGNATURE

This Instrument shall be open for signature at the Diplomatic Conference in..... and thereafter at the headquarters of WIPO by any eligible party for one year after its adoption.

ARTICLE 18 ENTRY INTO FORCE

This Instrument shall enter into force three months after 15 eligible parties referred to in Article [13] have deposited their instruments of ratification or accession.

ARTICLE 19 EFFECTIVE DATE TO BECOME A PARTY

This Instrument shall bind:

- (a) The 15 eligible parties referred to in Article [18], from the date on which this Instrument entered into force; and
- (b) Each other eligible party referred to in Article [13], from the expiration of three months from the date on which it has deposited its instrument of ratification or accession with the Director General of WIPO.

ARTICLE 20 DENUNCIATION

This Instrument may be denounced by any Contracting Party by notification addressed to the Director General of WIPO. Any denunciation shall take effect one year from the date on which the Director General of WIPO received the notification. It shall not affect the application of this Instrument to any patent application pending and any international registration in force in respect of the denouncing Contracting Party at the time of the coming into effect of the denunciation.

ARTICLE 21 RESERVATIONS

No reservations to this Instrument shall be permitted.

ARTICLE 22 LANGUAGES

22.1 This Instrument shall be signed in a single original in the Arabic, Chinese, English, French, Russian and Spanish languages, all texts being equally authentic.

22.2 An official text in any language other than those referred to in Article [22.1] shall be established by the Director General of WIPO, after consultation with all the interested parties, in such other languages as the Assembly may designate. For the purposes of this paragraph, "interested party" means any Contracting Party whose official language, or one of whose official languages, is concerned.

**ARTICLE 23
DEPOSITARY**

The Director General of WIPO is the depositary of this Instrument.

Done at

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