

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

Geneva, September 4 to 8, 2023

DRAFT TEXT PROPOSAL FROM INDIA TO WIPO IGC FOR MODIFICATIONS IN THE DRAFT NEGOTIATING TEXT FOR INTERNATIONAL INSTRUMENT FOR PROTECTION OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

Document submitted by the Delegation of India

1. On July 3, 2023, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry of India to submit the document entitled “Draft Text Proposal from India to WIPO IGC for Modifications in the Draft Negotiating Text for International Instrument for Protection of Genetic Resources and Associated Traditional Knowledge” for discussion by the Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

2. Pursuant to the request above, the Annex to this document contains the submission referred to.

3. *The Committee is invited to take note of this document.*

[Annex follows]

**DRAFT TEXT PROPOSAL FROM INDIA TO WIPO IGC FOR MODIFICATIONS IN THE
DRAFT NEGOTIATING TEXT FOR INTERNATIONAL INSTRUMENT FOR PROTECTION OF
GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE**

India proposes following changes in the articles of the draft text to be discussed at the special session of the IGC from September 4 to 8, 2023.

DISCLAIMER: *This text proposal is without prejudice to India's position on these and other substantive matters at the IGC. India reserves the right to make subsequent modifications to this text proposal and to complement its proposals at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time*

PREAMBLE

The Parties to this instrument,

Desiring the promotion of the efficacy, transparency and quality of **[IN: the Intellectual Property (IP) patent]** system in relation to genetic resources (GRs) and traditional knowledge associated with genetic resources (Associated TK),

Emphasizing the importance of patent offices having access to appropriate information on GRs and Associated TK to prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to GRs and Associated TK,

Recognizing the potential role of the **[IN: IP patent]** system in contributing to the protection of GRs and Associated TK, **[IN: including preventing misappropriation]**,

Recognizing that an international disclosure requirement related to GRs and Associated TK in **[IN: IP patent]** applications contributes to legal certainty and consistency and, therefore, has benefits for the **[IN: IP patent]** system and for providers and users of such resources and knowledge,

Recognizing that this instrument and other international instruments related to GRs and Associated TK should be mutually supportive,

Recognizing and reaffirming the role that the intellectual property (IP) system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of providers and users of GRs and Associated TK,

Acknowledging the UN Declaration on the Rights of Indigenous Peoples (UNDRIP)

Have agreed as follows:

Explanation Note: The preamble sets the tone and defines the metes and bounds of the subsequent text. The Preamble is widely accepted as the spirit and soul of the instrument and there is a limited scope of amendment.

Since further work is required to determine the applicability of this instrument to other IP rights, the Preamble of the instrument must be broader to encompass IP rights and not be restrictive to just patents. The recitals in the Preamble are used as an interpretative tool for understanding the context, rationale, and intent of the instrument. Therefore, a broad reference to IP protection in the preamble would allow for the possibility to review the instrument later and facilitate provisions of Article 9.

ARTICLE 1

OBJECTIVES

The objectives of this instrument are to **[IN: contribute to the protection of GRs and associated TK within the IP system by:**

- (a) **enhancing** the efficacy, transparency and quality of the patent system with regard to GRs and Associated TK, and
- (b) **preventing** patents from being granted erroneously for inventions that are not novel or inventive with regard to GRs and Associated TK.]

Explanation Note: The essential mandate of the IGC relating to GRs has been to examine the role that the IP system should play in facilitating *the effective and balanced protection of genetic resources and traditional knowledge associated with genetic resources.* Therefore the objectives of the legal instrument proposed must necessarily draw a linkage to the contribution of the IP system in protection of GRs and associated TK. There are presently several international instruments which would otherwise establish the given objectives in the event if there is no connect established to the larger objective of contributing towards protection of GRs and Associated TK. The current limited scope of the Objectives could possibly defeating the purpose of this instrument in terms of defining and interpreting its more substantive provisions.

The proposed inclusion of “contribute to protection of GR and associated TK within the IP system” leaves no room for ambiguity in interpreting and defining the objective of the instrument.

ARTICLE 2

LIST OF TERMS

“**[Materially ~~[IN: /Directly]~~ based on**” means that the GRs and/or Associated TK ~~[IN: must]~~ have been ~~[IN: necessary or]~~ material to the development of the claimed invention, ~~[IN: and or]~~ that the claimed invention ~~[IN: must]~~ depends on the specific properties of the GRs and/or Associated TK”

Explanation Note: The current definition proposes a very narrow trigger, thereby, requiring disclosure only in such instances where there is a very strong causal link between the GR and/or ATK used and the claim of invention in the patent application. This could possibly be interpreted very differently to the obligations under other international legal instruments such as CBD and the Nagoya Protocol and could lead to inconsistency in interpretation and implementation. Therefore, substantive changes have been proposed in the definition to make the scope broader and clearer in terms of requiring disclosure where either of the conditions have been fulfilled.

[IN: “Traditional Knowledge associated with Genetic Resources” means any knowledge which is evolving, generated in a traditional context, whether documented or not, collectively preserved, and transmitted from generation to generation and including but not limited to know-how, skills, innovations, practices, and learning, that are associated with GRs.]

Explanation Note: The objective of this instrument is to contribute to the effective and balanced protection of genetic resources and traditional knowledge associated with genetic resources and it would run contrary without a proper definition. For applicants who are required to disclose traditional knowledge associated with genetic resources, it is important to have a clear and precise definition for them to perform due diligence and subsequently disclose. The definition is an attempt to balance the interests of the providers and users of GRs and associated TK and without a definition, a beneficial agreement would not be achieved.

“**Source of Genetic Resources**” refers to any source from which the applicant has obtained the GRs, ~~[IN: such as including]~~ a research centre, gene bank, 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 GRs.

Explanation Note: The phrase ‘such as’ may be replaced with ‘including’ to ensure that the scope of the definition is interpreted inclusively and not restrictively.

“**Source of Traditional Knowledge Associated with Genetic Resources**” means any source from which the applicant has obtained the traditional knowledge associated with genetic resources, ~~[IN: such as including]~~ scientific literature, ~~[IN: publicly accessible]~~ databases, patent applications and patent publications.

Explanation Note: The phrase 'such as' may be replaced with 'including' to ensure that the scope of the definition is interpreted inclusively and not restrictively. Further, it is not essential that TK related databases are always publicly accessible but may have restricted accessibility and yet the applicant may have relied on the same.

ARTICLE 3

DISCLOSURE REQUIREMENT

3.1 Where the claimed invention in a patent application is [materially ~~IN: /directly~~] based on GRs, each Contracting Party shall require applicants to disclose:

- (a) ~~IN: the country of origin of the GRs, or, the source of the GRs, and,~~
- (b) ~~in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, country of origin of the GRs, except in cases where it is not known to the applicant, or where it does not apply.]~~

3.2 Where the claimed invention in a patent application is [materially ~~IN: /directly~~] based on Associated TK, each Contracting Party shall require applicants to disclose:

- (a) ~~IN: the indigenous peoples or local community that provided the Associated TK, or, the source of the Associated TK, and,~~
- (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 indigenous peoples or local community or holders and practitioners of TK that provided the Associated TK, except in cases where this information is not known to the applicant, or where it does not apply.]~~

Explanation Note to formulations proposed in Article 3.1 and 3.2: In terms of the content of disclosure, the current formulation gives precedence to the country of origin in case of GRs, and the indigenous people or local community for associated TK, which may or may not be known, while the inventor and/or the applicant would always be aware of the source of the GRs and/or ATK on which the research is carried out or from where the knowledge of the properties has been obtained. Further the interpretation of the country of origin leads to ambiguity on the scope whether it means the country from which GR is obtained or the geographical origin of the GRs. Therefore, a revised formulation has been proposed to provide precedence to source which is clearer and easier to determine and almost always known or ought to be known. Additionally, the same has been supplemented in case of GRs with country of origin where it is known and applicable and with indigenous people or local community or holders and practitioners of TK which are also important constituents and often the source of providing traditional knowledge.

This when read with the changes made in the definition of source of GR and ATK make easier and clearer for the applicants to make the disclosure as part of their application.

3.3 In cases where none of the information in paragraph ~~IN: s 3.1 and/or~~ 3.2 is known to the applicant, ~~IN: each a~~ Contracting Party ~~IN: shall may~~ require the applicant to make a declaration to that effect.

Explanation Note: India's proposed modification of Article 3.3 is in line with the other changes in Article 3, indicating that it is highly unlikely to research into genetic resources and not be aware about the source where the invention in a patent claim is materially based on the GRs. The revised formulation makes it a mandatory requirement for the applicant to ensure due diligence and disclose the source. In the event such a requirement is not made obligatory and diluted through the existing formulation in para 3.3., the purpose of the instrument would be defeated as the applicant may escape disclosure citing lack of available information.

However such a possibility has been retained for ATK given the possibility that this information may not be available with the applicant/ inventor or the applicant/ inventor is not aware of the actual source and mandatory disclosure may lead to additional burden or transactional costs.

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, **[IN: within a prescribed period, in accordance with its national law]**.

Explanation Note: Changes have been proposed to provide a degree of certainty in terms of a defined time period in which the modifications could be made to the patent application and to ensure it does not remain an open ended process. This would provide necessary certainty to the applicant and the patent office in terms of the time period for a subsequent disclose in case the information is not available with the applicant at the time of filing.

ARTICLE 6

SANCTIONS AND REMEDIES

6.1 Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures, **[IN: prior to and post grant of patent,]** to address an applicant's failure to provide the information required in Article 3 of this instrument.

Explanation Note: The proposed change requires member states to provide measures both at the pre and post grant stage to ensure the disclosure requirements are effectively implemented.

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^{**[IN: 1]**}.

Explanation Note: The foot note has been inserted to clarify that the scope of this provision is only mandatory till such time a patent has been granted. Where a patent is already enforced and the remedies or sanctions are provided post-grant, there should be no obligation on part of either the patent office or other competent judicial or administrative authority imposing sanctions or providing remedies to provide an opportunity to rectify the failure to disclose or include such information in the application which is already completed and no further modifications would be possible.

6.3 "Subject to Article 6.4, **[IN: ~~no a~~]** Contracting Party **[IN: ~~shall may not be required to~~]** 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."

Explanation Note: This modification would allow a party to maintain the policy space for ensuring that this is a minimum standard in line with other provisions of this instrument.

6.4 Each Contracting Party **[IN: ~~may shall~~]** provide for post grant sanctions or remedies, **[IN: including revocation,]** where there has been fraudulent intent in regard to the disclosure requirement in Article 3 of this instrument, in accordance with its national law.

Explanation Note: Provisions relating to mandatory disclosure requirements would be more effective if there are possible sanctions and remedies in place which dissuade applicants from making an intentional wrongful or non-disclosure. Where it has been proven that there was a fraudulent intent in making a non or a wrongful disclosure, maintenance of a patent right may run contrary to principles of equity and due process of law.

6.5 Without prejudice to non-compliance as a result of a fraudulent intention as addressed under Article 6.4, Contracting Parties **[IN: ~~shall may~~]** put in place adequate dispute **[IN:**

¹ **Provided that this obligation shall only arise before the grant of patent.**

resolution] mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions, in accordance with national law.”

Explanation Note: This modification would allow a party to maintain the policy space for ensuring that this is a minimum standard in line with other provisions of this instrument.

ARTICLE 8

RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument shall be implemented in a mutually supportive manner with other international agreements^[IN: 2] relevant to this instrument³.

² [IN: Such instruments include inter alia the Convention on Biological Diversity, the Nagoya Protocol and International Treaty on Plant Genetic Resources for Food and Agriculture]

³ **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

India proposes an inclusion of 10.2 to be read as:

[IN: 10.2 The contracting parties may, but shall not be obliged to, provide more extensive obligations than is required under this instrument, either prior to or subsequent to entry into force of the instrument.]

[IN: ~~10.2-10.3~~ Nothing shall prevent Contracting Parties from determining the appropriate method of implementing the provisions of this instrument within their own legal systems and practices.

Explanation Note: This provision has been inserted mindful that international IP instruments usually provide minimum standards with flexibilities for Member States to implement those standards. This would also allow member states to retain a degree of policy space, especially for those Member States which have already established disclosure regimes, while ensuring that such policy space does not compromise the benefits of a standardised set of international standards in this area.

[End of Annex and of document]