

## **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**

NOTES TO THE TEXT OF A DRAFT INTERNATIONAL LEGAL INSTRUMENT RELATING  
TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL  
KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

*prepared by the Secretariat*

1. The Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“IGC”), which took place from September 4 to 8, 2023, decided that the notes on each article as contained in document WIPO/GRTKF/IC/SS/GE/23/2 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.
2. Pursuant to this decision, the notes on each article are annexed to this document.

[Annex follows]

Notes on Article 1

The objectives have been drafted in a short and concise manner. Specific measures to implement the objectives of the instrument are contained in the subsequent provisions of the instrument. Moreover, the instrument does not contain any provisions that are already addressed by other international instruments, or that are not relevant to the patent system. For instance, there is no reference to issues related to access and benefit-sharing or to misappropriation, as these issues are already dealt with in other international instruments, such as the Convention on Biological Diversity (CBD), 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 (Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization of the United Nations and the World Health Organization's *Pandemic Influenza Preparedness Framework*, 2011. Yet, it is important to note that, in my view, enhanced efficacy, transparency and quality of the patent system will ultimately result in facilitating benefit-sharing and avoiding misappropriation. The term "efficacy" also makes it clear that a disclosure requirement implemented at the national level should be effective, practical, easily implementable and not result in overly burdensome transaction costs.

## Notes on Article 2

1. The definitions of *genetic resources*, *genetic material*, *country of origin* and *in situ conditions* detailed in the list of terms have been taken directly from existing multilateral agreements relating to the GRs, notably the CBD.
2. The following definitions have not previously been defined at the multilateral level: *materially/directly based on*, *source of genetic resources*, and *source of traditional knowledge associated with genetic resources*.
3. The term “*materially/directly based on*” specifies the relationship between the claimed invention and the GRs and Associated TK which activates the obligation to disclose (referred to in the IGC discussions as the “trigger”).
4. Currently there is a significant divergence in triggers at the national and regional levels e.g. *directly based on*, *based on*, *based on or derived from*, *is the basis of*, *used in an invention*, *invention concerns*, *relates to or makes use*, ***an invention-creation accomplished by relying on genetic resources***. There is also significant ambiguity regarding the meaning of these terms. In order to maximise legal certainty, two amplifying adverbs (*materially/directly*) have been proposed, in addition to the trigger concept “*based on*”, for consideration by Member States, reflecting discussions held during IGC 36 in June 2018. The alternate term “*materially*” has been included as the term “*directly*” has been contentious within the IGC’s deliberations. However, by defining the term in the list of terms it is hoped that this concern has been addressed. An alternative to the inclusion of amplifying adverbs (“*materially/directly*”) in the trigger language is to simply retain the trigger concept “*based on*” and use a definition of “*based on*” to clarify the scope of the trigger.
5. A contentious issue related to the concept of “*directly based on*”, which is included in the proposal of the EU first tabled in 2005<sup>1</sup>, is the requirement for the inventor to have physically accessed the GRs. This touches on different views within the IGC as to whether or not physical access to a GR is still required by an inventor noting technological advances in this area. To address this difference of view, the definition is now silent on this issue. In addition, it was also proposed by the EU that the definition includes the phrase “*must make immediate use*”. In my view, respectfully, there is a lack of clarity in relation to the meaning of this term. To address this issue, the terms “*necessary*” and “*material to*” have been included to reduce ambiguity. In addition, the phrase “*the claimed invention must depend on the specific properties of the GRs and Associated TK*” is included in the definition.
6. “*Source*” should be understood from its common meaning “*from which something originates or can be obtained*”<sup>2</sup>. The two definitions relating to GRs and Associated TK simply provide a non-exhaustive list of from where GRs or Associated TK may have been sourced.
7. The definition for *traditional knowledge* is still under discussion within the IGC, as part of the traditional knowledge track of the negotiations and is yet to be agreed, though, in my view, there has been some convergence of views reflected in recent discussions. Nor have any definitions been agreed at the international level in other processes, leaving it to national interpretation. Pending agreement on this matter in the IGC, it is proposed not to define the term at this time and leave it to national interpretation.

---

<sup>1</sup> Document WIPO/GRTKF/IC/8/11.

<sup>2</sup> Oxford Dictionary of English (3<sup>rd</sup> Edition), (2010), OUP Oxford.

### Notes on Article 3

1. Article 3 establishes a mandatory disclosure requirement. To support legal certainty, it is crucial, in my view, that the provisions on a disclosure requirement clarify the following:

- (a) the relationship between the claimed invention and the GRs and Associated TK which activates the obligation to disclose, referred to in the IGC discussions as the “*trigger*”; and,
- (b) the information which needs to be disclosed, referred to in the IGC discussions as the “*content*”.

2. The trigger and the content should be workable in practice and reflect the various circumstances where GRs and Associated TK can be sourced. This means that any disclosure requirement should not lead to obligations for patent applicants which cannot be fulfilled or which can only be fulfilled with unreasonable time and effort and which would, therefore, hinder innovation based on GRs and Associated TK.

#### *Trigger*

3. Articles 3.1 and 3.2 clarify the relationship between the claimed invention and the GRs and Associated TK, which activates the obligation to disclose. Accordingly, Articles 3.1 and 3.2 require the invention to be “*materially/directly based on*” one or more GRs and Associated TK.

4. In the context of GRs, the term “*materially/directly based on*” clarifies that the subject matter which is triggering a disclosure are GRs which were necessary or material to the development of the claimed invention. “Based on” includes any GRs that were involved in the development of the invention. The term “*materially/directly*” indicates that there must be a causal link between the invention and the GRs. In practical terms, this means that only those GRs without which the invention could not be made, should be disclosed. Those GRs, which may be involved in the development of the invention but which are not material to the claimed invention, shall not trigger the disclosure requirement. This includes in particular research tools such as experimental animals and plants, yeasts, bacteria, plasmids, and viral vectors, which, while technically GRs, are often standard consumables that may be acquired from commercial suppliers and that do not form part of the claimed invention, and thus need not be disclosed.

5. In the context of Associated TK, “*materially/directly based on*” means that the inventor must have used the TK in developing the claimed invention and the claimed invention must have depended on the TK.

#### *Content of Disclosure*

6. Depending on the specific circumstances, Article 3 requires different information to be disclosed in patent applications:

- (a) Paragraphs 3.1 and 3.2 detail the information which should be disclosed, if applicable and if known to the patent applicant.

*In the context of GRs (paragraph 3.1), a Contracting Party shall require the patent applicant to disclose the country of origin of the GRs. In order to ensure mutual supportiveness with other international instruments, in accord with the principles of this instrument, the country of origin should be understood as defined in the CBD, i.e., the country which possesses the GRs in*

*in situ* conditions. However, many GRs are found *in situ* in more than one country. Therefore, there often exists more than one country of origin for a specific GR. However, according to Article 3.1 (a), what should be disclosed is the specific “country of origin of the GR” (underlining added), i.e. the same GR on which the claimed invention is [*materially/directly*] based, which is the country from which that GR was actually obtained (of which there can only be one in respect of each GR).

*In the context of Associated TK*, a Contracting Party shall require the patent applicant to disclose the indigenous people or local community that provided this knowledge, i.e., the holder of that knowledge from which it was accessed or learned.

- (b) Sub paragraphs 3.1(b) and/or 3.2(b) apply in those cases where the information in sub paragraph 3.1(a) and/or 3.2(a) is not available or these sub-paragraphs do not apply, and thus it is not possible for the patent applicant to disclose this information. For example, GRs in areas beyond national jurisdiction such as the high seas.

*In the context of GRs*, this may be the case, for instance, if the invention is based on a GR taken from the Multilateral System of the ITPGRFA. It may also provide national flexibility to those Parties that, in accordance with Article 6 paragraph 3 (f) of the Nagoya Protocol, require applicants to disclose the specific indigenous people or local community from which a GR has been sourced. In these cases, which are just examples, the applicable sources will therefore be the Multilateral System of the ITPGRFA or the specific community, respectively.

*In the context of Associated TK*, sub paragraph 3.2(b) provides flexibility, for instance, if the TK cannot be attributed to a single indigenous people or local community, or if the indigenous people or local community does not wish to be mentioned in the patent application. It would also cover those situations where the TK has been taken from a specific publication, which does not indicate the indigenous people that held the knowledge.

- (c) Paragraph 3.3 applies where none of the information referred to in paragraph 3.1 and/or 3.2 is known to the patent applicant. In these cases, the applicant shall make a declaration that the relevant information is not known. This paragraph is not an alternative to paragraph 3.1 or 3.2, but only applies if the information according to paragraphs 3.1 and/or 3.2 is not known to the patent applicant. That allows patent applicants to still apply for a patent if for justified and very exceptional reasons the relevant information is not known to them e.g., because the provenance of a GR cannot be identified anymore due to the relevant documents having been destroyed by *force majeure*.

7. Paragraph 3.5 specifically states that the Contracting Parties shall place no obligations on patent offices to verify the authenticity of the disclosure. This article is directed at minimising the disclosure regime’s transactional cost/burden on patent offices and ensuring it does not create unreasonable processing delays for patent applicants. It also recognises that patent offices do not have the inherent expertise to carry out such actions.

8. A specific scope issue in relation to the disclosure regime is the requirement for an applicant to declare the source of Associated TK if they are aware that the invention was materially/directly based on such TK. I am aware that some members believe that a further in-depth discussion of the concept of TK is needed before including references to TK in a disclosure regime. However, taking into account that other international instruments refer to but do not necessarily define TK, and noting the objectives of this instrument and ongoing developments in this area, this subject matter has been retained.

Notes on Article 5

This article recognises that in order to maintain legal certainty within the patent system a non-retroactivity clause is required. However, it also recognises that a number of mandatory disclosure regimes already exist at the national and regional level.

## Notes on Article 6

1. Paragraph 6.1 requires each Party to put in place appropriate and effective legal, administrative and/or policy measures to address non-compliance with the disclosure requirement of Article 3. This provision leaves it up to the Parties to decide which measures are appropriate, effective and proportionate. The measures could include pre-grant sanctions, such as suspending the further processing of a patent application until the disclosure requirement is met, or withdrawing/lapsing the application if the applicant fails or refuses to provide the minimum information required in Article 3 within a time period as determined at the national level. These measures could also include post-grant sanctions, such as fines for wilfully failing to disclose the required information or intentionally providing incorrect information as well as the publication of judicial rulings.
2. Paragraph 6.2 provides for an initial opportunity for an applicant who unintentionally failed to provide the minimum information detailed in Article 3 to address the disclosure requirement. The time period to correct the failure would be determined based on national patent laws. See also Article 3, Paragraph 4.
3. Paragraph 6.3 proposes a ceiling for non-compliance with the disclosure obligations detailed in Article 3. This provision aims to ensure that no patents will be revoked or rendered unenforceable based **solely** on an applicant's failure to provide the information required by Article 3 of this instrument. This is important for ensuring legal certainty for patent applicants. It also facilitates the sharing of benefits, as revoking a patent based on non-compliance with the disclosure requirement would destroy the very basis for benefit-sharing – namely, the patent. This is because the invention protected by the revoked patent would fall into the public domain, and no monetary benefits would be generated through the patent system. Therefore, revoking patents or rendering patents unenforceable would run counter to the stated objective of the instrument for the effective and balanced protection of GRs and Associated TK.
4. Paragraph 6.4 recognises the policy space already inherent in international, regional and national patent regimes for a patent to be revoked or the scope narrowed post grant in extreme cases such as provision of false or fraudulent information, either by the patent office or through legal challenge by a third party. Paragraph 6.5 recognises the serious consequences of revocation of a patent to a provider and user and incorporates a requirement for a dispute resolution mechanism at the national level to allow all parties to reach a mutually agreed solution, such as a negotiated royalty agreement.

Notes on Article 9

1. This article is a compromise text developed to address the view of some members that the scope of the instrument should include other IP rights and issues. Notwithstanding this view, members also recognised that the primary commercial use of GRs within the IP system is within the patent system and that further work is required to determine the applicability to other IP rights. In addition, this article attempts to reconcile differences of view regarding the inclusion of derivatives within the scope of the instrument. This would appear to be prudent noting ongoing discussions in other international forums.
2. This approach enables the instrument to be progressed as a foundation instrument with an in-built mechanism to address additional issues within a predetermined time-frame.

[End of Annex and of document]