

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Forty-Seventh Session
Geneva, June 5 to 9, 2023

CHAIR'S TEXT OF A DRAFT INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Document prepared by the Secretariat

1. With references to the Decisions of the Forty-Third Session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee"), and the Decisions of the Fifty-Fifth Session of the WIPO General Assembly, document WIPO/GRTKF/IC/43/5 ("Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources") is included in this document.

2. *The Committee is invited to review the document, in accordance with its 2022/2023 mandate and its work program for 2023.*

[Document WIPO/GRTKF/IC/43/5 follows]

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Forty-Third Session
Geneva, May 30 to June 3, 2022

CHAIR'S TEXT OF A DRAFT INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Tabled by the Chair of the IGC

1. The enclosed document is the document as referred to in the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the IGC") for the 2022/2023 biennium.
2. It was initially prepared by Mr. Ian Goss when he was the Chair of the IGC.
3. As the new Chair, Ms. Lilyclaire Bellamy will take note of any comments made on the text, and consider next steps in relation to it.
4. *The Committee is invited to review and comment on the document contained in the Annex.*

[Annex follows]

Draft
**International Legal Instrument Relating to Intellectual Property, Genetic Resources and
Traditional Knowledge Associated with Genetic Resources**

Prepared by Mr. Ian Goss
**Chair, WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources,
Traditional Knowledge and Folklore**

April 30, 2019

Introductory remarks¹

1. To date, the negotiations being conducted by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) relating to intellectual property and the effective and balanced protection of genetic resources (GRs) and traditional knowledge associated with genetic resources (Associated TK)² have been unable to reach a conclusion.
2. The IGC's inability so far to find a consensus position is reflected in the different policy interests contained in the alternate objectives within the IGC's current draft text on GRs and Associated TK³. There is, in my view, scope for bridging these different perspectives and room for balancing the rights and interests of users and the rights and interests of providers and knowledge holders. In addition, a **clearer understanding of the modalities of an international disclosure requirement would enable policymakers to make informed decisions regarding the costs, risks and benefits of a disclosure requirement.**
3. From this perspective, I have prepared this draft text of an international legal instrument on intellectual property and GRs and Associated TK for consideration by the IGC.
4. I have prepared this draft text solely under my own authority as a contribution to the negotiations being conducted by the IGC.
5. This draft is without prejudice to any Member States' positions and reflects my views alone. My draft text attempts to take account of the policy interests of all Member States and other stakeholders expressed over the past nine years of text-based negotiations in the IGC. In particular, it attempts to balance the interests and rights of the providers and users of GRs and Associated TK, without which, in my view, a mutually beneficial agreement will not be achieved.
6. In developing this text, I have given careful consideration to the existing documentation of the IGC⁴ and the WIPO Secretariat's publication *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge*. I have also conducted a detailed review of existing national and regional disclosure regimes. There has been a significant cross regional growth in GRs and Associated TK disclosure regimes at regional and national levels. Currently around 30 regimes are in place and a number of Member States are currently considering the introduction of such regimes. These regimes vary significantly in terms of scope, content, relationship with access and benefit-sharing regimes, and sanctions.

¹ Note from the Chair: These introductory remarks do not form part of the draft instrument.

² These negotiations are currently being conducted pursuant to the IGC's mandate for 2018/19.

³ WIPO/GRTKF/IC/40/6 Consolidated Document Relating to Intellectual Property and Genetic Resources.

⁴ Such as WIPO/GRTKF/IC/40/6 Consolidated Document Relating to Intellectual Property and Genetic Resources; WIPO/GRTKF/IC/38/10 Joint Recommendation on Genetic Resources and Associated Traditional Knowledge; WIPO/GRTKF/IC/38/11 Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources; WIPO/GRTKF/IC/11/10 Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications; Proposals by Switzerland; WIPO/GRTKF/IC/8/11 EU Proposal: Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications; WIPO/GRTKF/IC/17/10 Proposal of the African Group on Genetic Resources and Future Work; and, WIPO/GRTKF/IC/38/15 The Economic Impact of Patent Delays and Uncertainty: U.S. Concerns about Proposals for New Patent Disclosure Requirements.

In my view, these differences create inherent risks to users in terms of legal certainty, accessibility to GRs and Associated TK, and transactional costs/burdens with potential negative impacts on innovation. In addition, a global and mandatory disclosure regime would enhance transparency in relation to the use of GRs and Associated TK within the patent system, improving the efficacy and quality of the patent system. This would, in my view, also facilitate benefit-sharing and the prevention of the granting of erroneous patents and the misappropriation of GRs and Associated TK.

7. I invite Member States to consider this draft text in the context of the IGC's work on GRs and Associated TK. I look forward to receiving feedback on the draft from Member States and stakeholders.

8. The text of the draft legal instrument follows below. Several but not all of the articles are accompanied by explanatory notes. These notes do not form part of the text, and are simply meant to provide further background and explanation. In the event of any inconsistency between the text of an article and the note accompanying it, the text of the article takes precedence.

IGC CHAIR'S DRAFT

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

April 30, 2019

The Parties to this instrument,

Desiring the promotion of the efficacy, transparency and quality of the 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 patent system in contributing to the protection of GRs and Associated TK,

Recognizing that an international disclosure requirement related to GRs and Associated TK 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 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:

ARTICLE 1 OBJECTIVES

The objectives of this instrument are to:

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

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.

ARTICLE 2 LIST OF TERMS

The terms defined below shall apply to this instrument, unless expressly stated otherwise:

“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 GRs and/or Associated TK 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 GRs and/or Associated TK*.

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

“Genetic resources⁵” (GRs) are genetic material of actual or potential value.

“In situ conditions” means conditions where GRs 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 GRs, such as 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.

“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.

⁵ 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”.

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 2005⁶, 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*”⁷. 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.

⁶ Document WIPO/GRTKF/IC/8/11.

⁷ Oxford Dictionary of English (3rd Edition), (2010), OUP Oxford.

ARTICLE 3 DISCLOSURE REQUIREMENT

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

- (a) the country of origin of the GRs, 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 GRs.

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

- (a) the indigenous peoples or local community that provided the Associated TK, 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 Associated TK.

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.

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.

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.

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.

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.

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.

ARTICLE 7 INFORMATION SYSTEMS

7.1 Contracting Parties may establish information systems (such as databases) of GRs and Associated TK, in consultation with relevant stakeholders, taking into account their national circumstances.

7.2 The information systems, with appropriate safeguards, should be accessible to Offices for the purposes of search and examination of patent applications.

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 GRs and Associated TK, especially periodicals, digital libraries and databases of information related to GRs and Associated TK, 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 instrument⁸.

⁸ 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 IP 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.

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.

[ARTICLE 10⁹
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.]

⁹ Note from the Chair: I have adapted the final and administrative clauses (Articles 10 to 20) from other existing WIPO treaties. I recognize that they have not yet been discussed before by the IGC and that they would still need to be formally considered and reviewed by Member States and the WIPO Secretariat. Therefore, each of these articles is bracketed.

**[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 WIPO to grant financial assistance to facilitate the participation of delegations of Contracting Parties that are regarded as developing countries in conformity with the established practice of the General Assembly of the United Nations or that are countries in transition to a market economy.
- (c) The Assembly shall deal with matters concerning the maintenance and development of this instrument and the application and operation of this instrument. The Assembly shall conduct the review referred to in Article 9 above, and may agree on amendments, protocols and/or annexes to this instrument pursuant to the review. The Assembly may establish one or more technical working groups to advise it on the matters referred to in Articles 7 and 9 above, and on any other matter.
- (d) The Assembly shall perform the function allocated to it under Article 13 in respect of the admission of certain intergovernmental organizations to become party to this instrument.
- (e) Each Contracting Party that is a State shall have one vote and shall vote only in its own name. 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 which 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*.

11.2 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.

11.3 The Assembly shall endeavour to take its decisions by consensus and 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**

The Secretariat of WIPO shall perform the administrative tasks concerning this instrument.]

**[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
REVISIONS**

This instrument may only be revised by a diplomatic conference. The convocation of any diplomatic conference shall be decided by the Assembly of Contracting Parties to this instrument.]

**[ARTICLE 15
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 16
ENTRY INTO FORCE**

This instrument shall enter into force three months after 20 eligible parties referred to in Article 13 have deposited their instruments of ratification or accession.]

**[ARTICLE 17
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.]

**[ARTICLE 18
RESERVATIONS**

No reservations to this instrument shall be permitted.]

**[ARTICLE 19
AUTHORITATIVE TEXT**

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

19.2 An official text in any language other than those referred to in paragraph 19.1 shall be established by the Director General of WIPO on the request of an interested party, after consultation with all the interested parties. For the purposes of this paragraph, “interested party” means any Member State of WIPO whose official language, or one of whose official languages, is involved and the European Union, and any other intergovernmental organization that may become party to this instrument, if one of its official languages is involved.]

**[ARTICLE 20
DEPOSITARY**

The Director General of WIPO is the depositary of this instrument.]

Done at

[End of Annex and of document]