

NON-PAPER*

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

Prepared by Mr. Ian Goss, Former Chair of the IGC, for IGC 43

May 14, 2022

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*

* Note from the IGC Chair, Ms. Lilyclaire Bellamy: The former Chair of the IGC, Mr. Ian Goss, has requested me to make this paper available as a non-paper for IGC 43 for the Committee's use as it deems fit. This paper contains an amended version of the Chair's Text that he put forward in April 2019, and, as he advises me, is based on the consultations on that text that he undertook and the written comments he received. While I have not seen those comments, I am of the view that his amendment of the text should be shared with the Committee as Mr. Goss has requested. The non-paper includes an Addendum that Mr. Goss has also requested be made available to the Committee. It represents his views and perspectives. In light of the above, I have requested the Secretariat to make this non-paper available for IGC 43 as requested by Mr. Goss. Aside from this note, the rest of this non-paper is as received from Mr. Goss on May 14, 2022. References to "Chair" or "I" are references to Mr. Goss, and aside from his amendments, the Text is current as at when it was first drafted, namely April 2019.

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

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. 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.

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.

DRAFT

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

Amended in track-changes by Mr. Goss on May 14, 2022

The Parties to this instrument,

Recognizing and reaffirming obligations set forth in the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) and Member States' commitment to achieving the ends of the UNDRIP⁵:

Acknowledging the UN Sustainable Development Goals and Indigenous Peoples' commitment to sustainability and ethical use in relation to GRs and traditional knowledge associated with genetic resources:

Reaffirming respect for the rights of sovereign holders, and indigenous people[s] and local communities, and entities provided under their national laws over their genetic resources, and traditional knowledge associated with genetic resources:

Desiring the promotion of the efficacy, transparency and quality of 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 IP 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 IP patent system in contributing to the protection of GRs and Associated TK, including preventing misappropriation.

Recognizing that an international disclosure requirement related to GRs and Associated TK in IP patent applications contributes to legal certainty and consistency and, therefore, has benefits for the 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,

Recognising and reaffirming that whilst the operative articles are focused initially on the patent system that it incorporates a mandatory review clause to consider extension of the instrument to other areas of IP, and consider issues arising from new and emerging technologies and developments in related international forums, that are relevant to the application of the instrument.

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

Have agreed as follows:

⁵Outcome Document of the World Conference on Indigenous Peoples approved unanimously in 2014 by all 193 Member States of the UN General Assembly (G.A. Resolution A/RES/69/2)

ARTICLE 1 OBJECTIVES

The objectives of this instrument are to contribute to the protection of GR and associated TK within the IP system by:

- (a) enhancinge 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.

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.

“Confidential information” includes traditional knowledge that is considered secret, sacred or culturally sensitive. This information has strict rules of sharing and disclosure that are maintained through customary laws and protocols of Indigenous Peoples and local communities.

“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 resources⁶” (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 the country of origin, indigenous peoples and local communities, 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 indigenous peoples or local communities, scientific literature, publicly accessible databases, patent applications and patent publications.

⁶ 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 2005⁷, 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*”⁸. 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.

7-8. The term confidential information has been included to clarify that such information includes traditional knowledge that is sacred, secret or culturally sensitive.

⁷ Document WIPO/GRTKF/IC/8/11.

⁸ 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 from which ~~of~~ the GRs, were obtained 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, another ~~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 community⁹, from which ~~that provided~~ the Associated TK was obtained, 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, another ~~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.~~

~~3.34 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.~~

~~3.45~~ Contracting Parties shall not place an obligation on Offices to verify the authenticity of the disclosure.

~~3.56~~ Each Contracting Party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information.

⁹ This includes an individual custodian within an individual or local community, or an entity outside the indigenous or local community authorized by the indigenous or local community to act as a custodian.

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 3.4~~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 disclosure requirements relating to GRs and associated TK~~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 ~~disclose~~provide the information ~~specified~~required in Article 3 of this instrument. Contracting parties should endeavor to develop these measures in conjunction with indigenous and local communities, subject to relevant national laws.

6.2 Each Contracting Party shall provide an applicant an opportunity to rectify a an unintentional failure to ~~disclose~~include the ~~minimum~~-information ~~specified~~detailed in Article 3 before implementing pre grant 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 ~~shall~~may provide for post grant sanctions or remedies where an applicant, either willfully or with fraudulent intent, failed to ~~there has been fraudulent intent in regard to the disclosure~~ the information specified 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, including indigenous and local communities, ~~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. Additionally, this paragraph attempts to recognize the interests and rights of indigenous peoples and local communities to be consulted on such measures.

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 indigenous and local communities and 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 instrument¹⁰.

¹⁰ 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 10¹¹
GENERAL PRINCIPLES ON IMPLEMENTATION

10.1 Contracting Parties shall 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.]

¹¹ 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.
- ~~(c)~~
- ~~(d)~~
- (d) The Assembly shall support participation of Indigenous Peoples and local communities and relevant stakeholders. A fund shall be established to support participation of Indigenous Peoples and local communities. Each meeting of the Assembly shall include on the agenda presentations by Indigenous Peoples' and Local community representatives. An Indigenous fellow shall be appointed on a rotating basis to serve as a focal point for Indigenous Peoples' and local communities' participation.
- (e) 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.
- (f) 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

ADDENDUM CHAIRS GR TEXT (WIPO/GRTK/IC/43/5) FORMER IGC CHAIR – MR IAN GOSS

Introduction

1. As requested by several Groups and Member States at IGC 42, as the former Chair, I have produced an amendment to IGC Working Document WIPO/GRTK/IC/42/5 – Chairs GR Text. I would ask members when reviewing these changes to consider them in conjunction with the comments I have made in this addendum.
2. I would emphasise that this amendment is produced as an independent contribution to the work of the Committee and has no status. My sole interest in completing this work is to recognise the significant contribution of those members and stakeholders who provided substantive feedback, whatever their position on the draft text, and to hopefully in a small way contribute to a successful conclusion to the negotiations on this subject matter after over a decade of text-based negotiations.
3. In developing the text, I have considered and reflected on the informal and formal feedback provided to me since the development of the original text in 2019, a text which was subsequently accepted as a working document at the WIPO 2019 General Assembly.
3. As advised to members previously, the intent of this work was to produce a final draft for consideration by members as a consensus text, or as a minimum be accepted as the primary working document on this subject matter. This reflects my belief that the current consolidated working document has limited utility as a negotiating text. It essentially includes two incompatible proposals which are a barrier to progress. In addition, the significant number of competing options and proposals, and bracketed text within the consolidated text prejudices members ability to make informed policy decisions.
4. In developing this amendment, I would highlight the following points:
 - (a) The positions reflected in the text are mine alone based on an attempt to balance the policy interests of all members, the users, and the holders of GR and associated TK.
 - (b) In balancing the above interests there are inherent policy compromises which member states will need to consider if a consensus text is to be achieved.
 - (c) I have also been mindful that any instrument implemented at the national level needs to be:
 - i. effective and practical in terms of implementation (does not result in overly burdensome transaction costs);
 - ii. adds to legal certainty;
 - iii. protects the interests and rights of the holders whilst facilitating users access to the subject matter, based on free and prior informed consent, were relevant; and
 - iv. within the constraints of the instruments agreed objectives, provides policy space for extant regimes.
 - (d) In considering this work I would emphasise that the text is still a work in progress and there remain several key issues which are yet to be resolved. These are identified and discussed in the body of this addendum.

- (e) I would underscore that the scope of the instrument, in accord with the Mandate provided by the WIPO General Assembly, is focused on what role the IP system should play in the protection of GRs and associated TK. I would note that the multi-lateral international instruments which deal specifically with the protection of GRs and associated TK include the CBD and its Nagoya Protocol relating to ABS, and the International Treaty on Plant Genetic Resources for Food and Agriculture. In addition, the UNDRIP addresses indigenous rights relating to this subject matter. From my perspective, the instrument attempts to address the intersection between these instruments and the IP system.
- (f) The development of any new international instrument needs to consider the impact on existing national/regional regimes already in place. As such the text establishes minimum and maximum standards to inform implementation at a national/regional level.
- (g) The instrument, reflecting divergent views in relation to its scope, is developed as a building block or framework instrument. This reflects the inclusion of a review clause within the instrument and recognises that any new instrument will require review and amendment over time, taking account of outcomes in related forums such as the CBD.

Scope

- 5. The scope of the addendum is:
 - (a) Key issues raised during consultation.
 - (b) Discussion of outstanding issues requiring resolution.
 - (c) Concluding Remarks.

Consultation

6. During 2018-2022 informal consultations on the text were conducted with interested members, Groups, and stakeholders. To support a frank exchange of views the consultations were conducted in confidence with no attribution, or prejudice to future positions. Key feedback/issues raised during the consultations are detailed below.

7. **General.** Apart from a small number of member states and some industry representatives, who do not support disclosure, there was broad support for the text. This reflected an emerging consensus at IGC 36 in relation to a mandatory disclosure regime. In addition, there was a view amongst some supporters of the text that it could provide a better basis for negotiation than the consolidated working text. However, it was also recognised that there were several key issues requiring further discussion/debate. The majority of these relate to the scope of the instrument. These are discussed below.

8. Scope.

(a) **Subject Matter.** The question of the inclusion of TK associated with GR has been raised, noting the Committee has not reached a consensus on the definition of TK. Additionally, the issue of inclusion of derivatives and digital sequencing information (DSI) was raised. An issue that also relates directly to the trigger. On this latter issue, it was clear during consultations, that there was no consensus. Also, it was noted that discussions on derivatives and DSI are ongoing in other forums, notably the CBD.

(b) **IP Rights Covered.** The issue of which IP Rights should the instrument cover was raised. However, there was no consensus with some members wishing to include all IP Rights, including designs and Plant Breeders Rights, whilst others sought to limit it to patents. All members recognised that patents were a key area of commercial use of GRs within the IP system. Additionally, the issues of petty or utility model patents was raised. Also, several members whilst recognising the intent to focus initially on the patent system, believed that the preamble and objective should address the broader IP system. This would reflect that the instrument is a first step in this area.

(c) **Trigger.** At the heart of any disclosure mechanism is the trigger, which prompts the disclosure. In particular, the scope of the trigger. Not surprisingly this engendered significant comment. However, there was also recognition that there was significant divergence in triggers at the national level, many of which are not defined. In essence the consultations identified two perspectives. Those members looking for a broad trigger in which any GRs and/or associated TK **utilised** in the innovation would need to be disclosed, including derivatives, and those members supporting a narrow trigger in which the innovation **must depend** on the specific properties of the GRs and/or associated TK.

9. **Linkage with ABS Regimes.** As with the trigger there were different perspectives on the linkage of the instrument with ABS, in particular the CBD and its Nagoya Protocol. Some members preference is to incorporate a specific linkage within the text, whilst others preference is to specifically exclude the requirement.

10. **Rights of Indigenous Peoples and Local Communities.** There was considerable support for strengthening language and provisions within the text relating to the aspirations and rights of indigenous peoples reflected in the UNDRIP. In particular, full participation of indigenous peoples and local communities and ensuring safeguards relating to information systems. The issue of ensuring free, prior, and informed consent when users access the subject matter from indigenous and local communities was also raised.

11. **Misappropriation.** Several members and groups raised the issue that their significant concerns relating to the misappropriation of GR and associated TK are not reflected in the text. It was also noted that the revised preamble in the consolidated text now includes misappropriation.

12. **Beneficiaries.** A group identified that in some circumstances holders of TK associated with GRs may be an individual custodian within an indigenous or local community, or an entity outside the community authorised by the community as a custodian. They suggested Article 3.2 (a) should be revised to reflect this situation.

13. **Obligations of IP Offices to verify the authenticity of the Disclosure.** A stakeholder group recommended that Article 3.5 be deleted as it established a maximum standard which could potentially result in avoidance of the disclosure requirement.

14. **Sanctions and Remedies (Revocation).** The key issue raised during consultations on sanctions and remedies was the issue of post grant sanctions, in particular revocation. There was general recognition that revocation was not a desirable outcome from the perspective of the holder and the user, in terms of access and benefit sharing. In addition, there was a strong view from several members that in the interests of legal certainty, that an IP Right should not be revoked solely based on an applicant's failure to provide the information detailed in Article 3. However, it was also recognised that in circumstances of wilful or fraudulent intent that revocation was an appropriate sanction, and that the policy space for such actions are inherent within the IP system. In recognising that such action was a last resort there was also broad support for a dispute resolution mechanism at the national level.

14. **Article 3.3 (If Source unknown).** There was a broad view amongst members consulted that this provision was not required and created a significant opportunity for applicants to avoid the disclosure requirements. They noted that it would be highly unusual for an applicant to not, at a minimum, know the source of the GR and /or associated TK. In essence, such a situation would be an exception which could be dealt with at a national level on an individual basis rather than establishing a specific provision at the international level.

15. **Information Systems.** A member state has suggested that this article should specifically include provision for the establishment of an international information system administered by WIPO. This reflects proposals detailed in a Joint Recommendation and an information paper presented at IGC 42. Additionally, a stakeholder group has proposed provisions relating to safeguards to protect confidential, sacred and secret information, and to ensure compliance with free prior and informed consent.

16. **Reciprocity Clause.** A member state has proposed the introduction of a reciprocity clause in the text. This is a relatively new proposal and I do not believe there is sufficient maturity in discussions in this area to warrant consideration in the text, at this time.

Outstanding Issues Requiring Resolution

17. Whilst several issues have been raised in consultations, some of which I have addressed in the amended text, I view the following issues as central to reaching a consensus text. I would also highlight that to progress the instrument to a diplomatic conference that every issue does not have to be resolved at a working level. Ultimately some of these will require decision at the political level. In addition, the final text will be further refined during the diplomatic conference process to improve the clarity of the text including addressing legal ambiguities (legal scrub) and unresolved issues. Committees will normally be established to address these, including working, drafting, and steering committees. In essence, the Committee does not need to agree all issues or language, rather the members need to agree that the text is sufficiently mature that an agreement at the diplomatic level can be achieved.

18. **Balancing Holder/User (Industry) Policy Interests.** The core issue preventing progress in relation to this subject matter remains the position of a small number of member states who oppose any form of mandatory disclosure. A position which has not changed since text-based negotiations commenced. From my perspective this reflects a policy position focused primarily on addressing the concerns of some industry stakeholders rather than a considered and balanced analysis of the issues from a holder and user perspective. Clearly, industry have legitimate concerns in terms of legal certainty, accessibility to the subject matter, transactional costs and burdens, and potential delays in the innovation process. These have been recognised throughout the negotiations and significant efforts have been made to address these, whilst ensuring the interests and rights of the holders are maintained. These efforts reflect significant compromises on the part of member states who support some form of mandatory disclosure. I would also note that these efforts are supported by members across all groups including member states with strong industry interests.

19. **Scope.** As identified during consultations the main area of contention amongst disclosure proponents is the scope of the instrument in terms of the subject matter, IP Rights covered and the trigger.

(a) **Subject Matter.**

- i. The points raised in the consultation process regarding the lack of an agreed definition of TK is noted. On this issue members should reflect that no definitions have been agreed at the international level in other processes, including within the CBD and UNDRIP, leaving it to national interpretation. Members could consider removing it from the subject matter until the issue is resolved in the TK negotiation, noting we are near consensus in this area. However, on balance and reflecting compromises in other areas I believe its removal at this time would seriously prejudice achievement of a consensus text, nor address concerns of indigenous stakeholders.
- ii. In relation to inclusion of derivatives and digital sequencing information this remains a contentious issue amongst disclosure proponents with some members opposed to their inclusion. It is noted that these issues are still under discussion within the CBD. Rather than prejudice these ongoing discussions the instrument proposes that this issue be addressed in the proposed review of the instrument.

(b) **IP Rights Covered.**

- i. In relation to the rights covered, I believe the approach taken in the draft instrument provides the best opportunity to reach agreement on this issue after 11 years of text-based negotiations. Whilst this represents a compromise it enables the primary area for commercialisation of the subject matter to be addressed initially whilst a review is conducted into the relevance of other forms of IP. This was a compromise position which had significant buy-in at IGC 36.
- ii. With respect to Plant Breeders Rights I would note they are currently not included within the remit of this Committee or its Mandate, as reflected in the WIPO Convention 1979. This is an issue the Committee may wish to consider further. In particular, should an agreement be reached how to pursue the matter with UPOV.
- iii. In relation to petty or utility model patents it is noted that they are not universally used by all member states. Additionally, there are differences in how these models operate across national jurisdictions, including the technologies included. However, they are covered by the PCT. Currently the text does not preclude utility model patents noting that it simply refers to a patent application. There is no delineation between a utility model or standard patent. From my perspective this provides for flexibility at the national level.

(c) **Trigger.** Whilst there is a clear desire amongst disclosure proponents to find a compromise position in relation to the trigger language, a solution remains allusive. In part, this reflects different policy perspective and interpretations of the meaning of related terms in other fora, in particular the CBD where they are still under discussion. This is also an area of significant divergence in extant national regimes. Ultimately any trigger will need to be implemented and interpreted at the national level. However, maximising legal certainty should be a key driver. In an attempt to achieve this, two amplifying adverb options (materially/directly) have been proposed in the instrument, in addition to the most common term used in national

regimes, “*based on*”. Options to address this issue include holding a final agreement over until a diplomatic conference where a technical working group could develop a solution for agreement of the parties. Alternatively, the Committee could establish their own technical working group. The challenge of the latter option is that it will further delay agreement with any work unlikely to be delivered until 2024. The former approach would be preferable in my view.

20. **Revocation.** The ability to revoke an IP right post grant for failing to provide the information relating to disclosure remains a key area of contention amongst all members, notwithstanding their current position on a disclosure regime. This issue is further complicated by some national disclosure regimes which incorporate such provisions. At IGC 36 considerable efforts were made by disclosure proponents to reach a compromise position on this issue, which is currently reflected in the text as a maximum ceiling. A position which as discussed above recognises that revocation is a last resort and should only be applied in situations where an applicant provides false or fraudulent information. It also recognises that such action is already inherent within national IP regimes. In the interests of balance, the proposal also includes a dispute resolution mechanism at the national level to allow parties to reach a mutually agreed solution. I believe that this approach remains the best opportunity to reach an agreement on this issue. However, I recognise that there is a need to tighten the language in this space and have attempted to do so in my proposed amendment. I would expect that this language would be further refined as part of a legal scrub during a diplomatic conference.

21. **Linkage with ABS Regimes.** In relation to this issue, I recognise the strong interest of a significant body of the membership in ensuring that any IP instrument in this area is mutually supportive of related international instruments which deal specifically with protection of GRs and associated TK such as the CBD and its Nagoya Protocol relating to ABS, and the International Treaty on Plant Genetic Resources for Food and Agriculture. This desire has manifested itself into an interest from some members to establish a clear linkage with their national ABS Regimes. The challenge in this area is that not all members are parties to the CBD, its Nagoya Protocol, or have established national ABS regimes. Additionally, many of these regimes are established outside the IP system focusing on environmental systems/laws. To address this challenge two broad approaches have been taken in the instrument. Firstly, the establishment of a mandatory disclosure mechanism which from my perspective establishes a transparency mechanism or checkpoint which will facilitate benefit sharing and aid in the prevention of misappropriation. Secondly, by remaining silent on a linkage to national ABS Regimes, the instrument sets a minimum standard in this area. This approach allows members to consider the issue at the national level without establishing obligations in other jurisdictions.

22. **Information Systems.**

(a) Several proposals in relation to information systems have been proposed during the negotiations, including within a joint proposal and information papers submitted by members. Broadly, members see merit in such proposals. However, the majority view remains that such systems are complimentary to a mandatory disclosure regime. In addition, a key concern of some member states and indigenous observers, remains ensuring safeguards are established to protect confidential information, including secret, sacred and culturally sensitive knowledge, and ensuring free prior and informed consent. Additionally, there remain issues relating to; funding of such systems, standards, and if they should be optional at the national level. Currently the text proposes such systems should be optional and that the Assembly of Parties consider the establishment of a technical working group to address the issues raised during the negotiations.

(b) From my perspective I see the establishment of databases as a key complimentary measure to any mandatory disclosure regime. However, I believe that this issue should not prevent members recommending the instrument be progressed to a diplomatic conference,

noting broad agreement to the concept of information systems. Additionally, as I have said previously, I believe the Committee should establish a technical working group to address issues raised during the negotiations and within the varied proposals. The working group should include balanced representation across all groups and stakeholders, including indigenous representatives.

Participation Indigenous Peoples and Local Community Representatives.

23. The last issue I would like to bring to the attention of members is participation of Indigenous Peoples in any final negotiations. They remain a key stakeholder in the negotiations as the primary holder of knowledge relating to GRs and associated TK. A stakeholder group which has a unique perspective on the negotiations and who have clear interests reflected in the UNDRIP, which all members of WIPO are party to. I would encourage members to continue to find solutions to enhance their participation during the negotiations, including ensuring at a minimum they continue to participate in working groups and informals. Additionally, members need to consider what role they should play in any subsequent diplomatic conference process.

Concluding Remarks

24. This addendum identifies the key issues discussed during consultations on WIPO/GRTKF/IC/43/5, post IGC 40 and prior to IGC 43. I would emphasise that the addendum does not attempt to cover every issue raised, rather it focuses on the substantive issue raised by members, clearly from my individual perspective. It reflects my views alone, without prejudice to any member or stakeholder position. My sole interest in completing this work is to recognise the significant contribution of those members and stakeholders who provided substantive feedback, whatever their position on the draft text, and to hopefully in a small way contribute to a successful conclusion to the negotiations on this subject matter after over a decade of text-based negotiations.

25. As I have previously publicly stated I believe it is time for a decision on this subject matter, reflecting that the vast majority of members are supportive of some form of a mandatory disclosure regime. Whilst there are issues still to be resolved in particular; trigger language, rights covered, post grant sanctions and linkage with ABS regimes; I believe that if you recapture the spirit of IGC 36 these can be overcome. However, I accept that this will require compromise and an incremental approach to any agreement and most important of all political will.

26. Lastly, I would like to recognise the interests of indigenous peoples and local communities in these negotiations. Interests reflected in the UNDRIP which all WIPO members are party to. Whatever the outcome in terms of these negotiations I believe it is incumbent on the member states to ensure they are consulted and have a say in the negotiations.

Mr Ian Goss
WIPO IGC Chair from IGC 29 to 42

14 May 2022