

## **WIPO General Assembly**

### **Fifty-Fifth (30<sup>th</sup> Extraordinary) Session** **Geneva, July 14 to 22, 2022**

#### **REPORT ON THE INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE (IGC)**

*prepared by the Secretariat*

#### **I. INTRODUCTION**

1. The WIPO General Assembly, at its Fifty-Fourth (25<sup>th</sup> Ordinary) Session in October 2021, agreed on the mandate for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for the 2022/2023 biennium.

2. The IGC's mandate for the 2022/2023 biennium, which was set out in document WO/GA/54/10, provides as follows:

“Bearing in mind the Development Agenda recommendations, reaffirming the importance of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Committee), noting the different nature of these issues and acknowledging the progress made, the WIPO General Assembly agrees that the mandate of the Committee be renewed, without prejudice to the work pursued in other fora, as follows:

“(a) The Committee will, during the next budgetary biennium 2022/2023, continue to expedite its work, with the objective of finalizing an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property, which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).

“(b) The Committee’s work in the 2022/2023 biennium will build on the existing work carried out by the Committee, including text-based negotiations, with a primary focus on narrowing existing gaps and reaching a common understanding on core issues<sup>1</sup>.

“(c) The Committee will follow, as set out in the table below, a work program based on open and inclusive working methods for the 2022/2023 biennium, including an evidence-based approach as set out in paragraph (d). This work program will make provision for 6 sessions of the Committee in 2022/2023, including thematic, cross-cutting, and stocktaking sessions. The Committee may establish *ad hoc* expert group(s) to address a specific legal, policy, or technical issue<sup>2</sup>. The results of the work of such group(s) will be submitted to the Committee for consideration.

“(d) The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/40/6, WIPO/GRTKF/IC/40/18, WIPO/GRTKF/IC/40/19 and the Chair’s Text on a *Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, as well as any other contributions of Member States, such as conducting/updating studies covering, inter alia, examples of national experiences, including domestic legislation, impact assessments, databases, and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert group(s) established by the Committee and related activities conducted under Program 4. The Secretariat is requested to continue to update studies and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GRs and associated TK, with a view to identifying any gaps and continuing to collect, compile and make available online information on national and regional *sui generis* regimes for the intellectual property protection of TK and TCEs. Studies or additional activities are not to delay progress or establish any preconditions for the negotiations.

“(e) In 2022, the Committee is requested to provide to the General Assembly a factual report along with the most recent texts available of its work up to that time with recommendations, and in 2023, submit to the General Assembly the results of its work in accordance with the objective reflected in paragraph (a). The General Assembly in 2023 will take stock of progress made, and based on the maturity of the texts, including levels of agreement on objectives, scope, and nature of the instrument(s), decide on whether to convene a diplomatic conference and/or continue negotiations.

“(f) The General Assembly requests the Secretariat to continue to assist the Committee by providing Member States with necessary expertise and funding, in the most efficient manner, of the participation of experts from developing countries and LDCs, taking into account the usual formula for the IGC.

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<sup>1</sup> Core issues include, as applicable, inter alia, definitions, beneficiaries, subject matter, objectives, scope of protection, and what TK/TCEs are entitled to protection at an international level, including consideration of exceptions and limitations and the relationship with the public domain.

<sup>2</sup> The expert group(s) will have a balanced regional representation and use an efficient working methodology. The expert group(s) will work during the weeks of the sessions of the IGC.

**WORK PROGRAM – 6 SESSIONS**

<b>Indicative Dates</b>	<b>Activity</b>
February/March 2022	(IGC 42) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days.
May/June 2022	(IGC 43) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument. Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
September 2022	(IGC 44) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Possible recommendations as mentioned in paragraph (e) Duration 5 days.
October 2022	WIPO General Assembly Factual report and consider recommendations
November/December 2022	(IGC 45) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s). Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
March/April 2023	(IGC 46) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
June/July 2023	(IGC 47) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s). Stocktaking on GRs/TK/TCEs and making a recommendation Duration 5 days.
October 2023	WIPO General Assembly will take stock of the progress made, consider the text(s) and make the necessary decision(s)."

3. Paragraph (e) of the mandate for this biennium (quoted above) requests the IGC, in 2022, to "provide to the General Assembly a factual report along with the most recent texts available of its work up to that time with recommendations". This document is prepared pursuant to this decision.

## II. IGC SESSIONS IN 2022

4. Pursuant to the mandate for the 2022/2023 biennium and the work program for 2022, the IGC has, thus far, held two sessions in 2022, as follows:

- (a) IGC 42, from February 28 to March 4, 2022, on the subject of GRs; and
- (b) IGC 43, from May 30 to June 3, 2022, on the subject of GRs.

5. IGC 42 developed the “Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 2”, and decided that this text, as at the close of the session on March 4, 2022, be transmitted to IGC 43. The text was included in document WIPO/GRTKF/IC/43/4 and made available for IGC 43. The full decisions of IGC 42 are available [online](#).

6. IGC 43 continued to work on the text, but the Member States were unable to reach consensus on transmitting Rev. 2 to IGC 47. It was decided to transmit the text in the annex to document WIPO/GRTKF/IC/43/4 to IGC 47, in accordance with the Committee’s mandate for 2022-2023. It was also decided that document WIPO/GRTKF/IC/43/4, as well as document WIPO/GRTKF/IC/43/5, be included in this factual report.

7. IGC 43 decided that the Secretariat should organize further *ad hoc* virtual meetings of experts on possible disclosure requirements, and a virtual Seminar and/or other virtual technical meetings on information systems, registers and databases of GRs, TK and TCEs before IGC 47, and provide written reports on such meetings to the Committee. These meetings should include experts reflecting different interests and balanced geographical representation, and should not replace nor delay the text-based negotiations underway in the Committee.

8. IGC 43 noted divergent views on the way forward, including on whether the Consolidated Document (WIPO/GRTKF/IC/43/4, as amended over time) and/or the Chair’s Text (WIPO/GRTKF/IC/43/5, as amended over time), should be the basis for negotiations on GRs. The Committee took note that some members consider that the Chair’s Text (WIPO/GRTKF/IC/43/5) should be the basis for the Committee’s negotiations on GRs and the basis upon which a Diplomatic Conference should be convened, while others disagree.

9. The Committee invited the Chair, taking into account comments, to revise the Chair’s Text as contained in document WIPO/GRTKF/IC/43/5, while maintaining its integrity as the Chair’s Text, for IGC 47.

10. On information systems, registers and databases of GRs, TK and TCEs, the Secretariat is invited to issue an online survey which Member States and accredited observers could respond to, if they so wish. Responses to the survey would be published by the Secretariat online and in an updated version of document WIPO/GRTKF/IC/43/6. The full decisions of IGC 43 are available [online](#).

11. Pursuant to the decisions taken at IGC 43 as described immediately above and for information purposes only, documents WIPO/GRTKF/IC/43/4 and WIPO/GRTKF/IC/43/5 are enclosed in the present document.

## III. AD HOC EXPERT GROUP ON GENETIC RESOURCES

12. Paragraph (c) of the mandate provides that the IGC “may establish *ad hoc* expert group(s) to address a specific legal, policy or technical issue”.

13. Pursuant to this decision and the decisions of IGC 42, an *ad hoc* expert group on genetic resources met on May 29, 2022, prior to IGC 43. The documents prepared for the *ad hoc* expert group on genetic resources are available [online](#).

#### IV. RECOMMENDATIONS TO THE GENERAL ASSEMBLY IN 2022

14. As noted above, paragraph (e) of the mandate provides that, in 2022, the IGC is requested to provide to the WIPO General Assembly a factual report along with the most recent texts available of its work up to that time with recommendations.

15. Pursuant to this element of the mandate, IGC 43 referred to above agreed on the following recommendations to the 2022 WIPO General Assembly:

“The 2022 WIPO General Assembly is invited to consider the ‘Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)’ (document WO/GA/55/6), and to note that the Secretariat will conduct virtual activities to expedite the work of the IGC on genetic resources. The General Assembly welcomes the Chair of the Committee conducting consultations with Member States and indigenous caucus on the methodology of the Committee with a view to Member States agreeing on the methodology to be used in the future sessions.”

*16. The WIPO General Assembly is invited to consider the “Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)” (document WO/GA/55/6), and to note that the Secretariat will conduct virtual activities to expedite the work of the IGC on genetic resources. The General Assembly welcomes the Chair of the Committee conducting consultations with Member States and indigenous caucus on the methodology of the Committee with a view to Member States agreeing on the methodology to be used in the future sessions.*

[Documents WIPO/GRTKF/IC/43/4 and WIPO/GRTKF/IC/43/5 follow]

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

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

CONSOLIDATED DOCUMENT RELATING TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Document Prepared by the Secretariat

1. At its Forty-Second Session, which took place from February 28 to March 4, 2022, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) developed, on the basis of document WIPO/GRTKF/IC/42/4, a further text, “The Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 2”. The Committee decided that this text, as at the close of Agenda Item on “Genetic Resources” on March 4, 2022, be transmitted to the Forty-Third Session of the Committee, in accordance with the Committee’s mandate for the 2022-2023 biennium and the work program for 2022.
2. Pursuant to the decision above, “The Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 2” is annexed to the present document.
3. The Committee is invited to review and comment on the document contained in the Annex towards developing a revised version thereof.

[Annex follows]

**The Consolidated Document Relating to Intellectual Property  
and Genetic Resources Rev. 2**

**(Dated March 4, 2022)**

## [PREAMBLE

1. *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 UNDRIP<sup>1</sup>;
2. *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;
3. *[Ensuring][Desiring to ensure]* 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;
4. *Recognizing* the principles of free and prior informed consent and mutually agreed terms in relation to access and utilization of genetic resources and traditional knowledge associated with genetic resources;
5. *Recognizing* the role of the [IP]/[patent] system in contributing to the protection of genetic resources, and traditional knowledge associated with genetic resources, including preventing misappropriation [contributing to the traceability of access to GRs / contributing to the traceability of utilization of GRs];
6. *Acknowledging* the important contribution of the patent system to scientific research and development, innovation and economic development;
7. *Stressing* the need for Members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and traditional knowledge associated with genetic resources;
8. *[Ensuring mutual supportiveness] [Desiring to ensure coherence]* with international agreements relating to the protection of genetic resources and/or traditional knowledge associated with genetic resources and those relating to [IP]/[patents];
9. *Emphasizing* the importance of [IP]/[Patent] Offices having access to the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of [IP]/[patent] rights;
10. *Recognizing* the role of databases for storing information related to genetic resources and non secret traditional knowledge associated with genetic resources, in preventing the erroneous granting of patents, pre and post grant;
11. *Reaffirming* the important economic, scientific, cultural, and commercial value of genetic resources and traditional knowledge associated with genetic resources;
12. *[Reaffirming* the [stability] need for reliability and predictability of granted [IP]/[patents] [IP]/[patent] rights, and recognizing the need for legal certainty with respect to disclosure requirements related to GRs and TK associated with GRs in [IP]/[patent] applications;]
13. *Recognizing and reaffirming* the role the [IP]/[patent] system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual

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<sup>1</sup> Outcome 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)

advantage of stakeholders, providers, holders and users of genetic resources, and traditional knowledge associated with genetic resources;

[14. *Emphasizing* that no [patents] [intellectual property] on life forms, including human beings, are to be granted;]

15. *Reaffirming*, the sovereign rights of States over their natural resources, where applicable, and that the authority to determine access to genetic resources, in such cases, rests with the national governments and is subject to national legislation.]

## **[ARTICLE 1] DEFINITIONS**

### **TERMS USED IN THE OPERATIVE ARTICLES**

#### **[Traditional Knowledge Associated with Genetic Resources**

Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning, and is:

- (a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];
- (b) linked with, and is an integral part of, the cultural and social identity and traditional heritage of indigenous peoples, local communities and/or [other beneficiaries]; and
- (c) transmitted between or from generation to generation, whether consecutively or not.]

#### **[Country of Origin**

“Country of origin” is the [first] country which possesses genetic resources in in-situ conditions.

ALT

“Country of origin” is the country which first possessed genetic resources in in-situ conditions and still possesses those genetic resources.]

#### **[[Country Providing]][Providing Country]**

“Country providing/Providing country” means, [[in accordance] [consistent] with Article 5 of 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], a [providing country][country providing] that is the country of origin [or that has acquired the genetic resources and/or that has accessed the traditional knowledge [in accordance] [consistent] with the [Convention on Biological Diversity].]

### **[Erroneous Grant/Granting of Patents**

Erroneous grant/granting of patents means the granting of patent rights on inventions that are not novel, that are obvious, or that are not industrially applicable.]

### **[[Invention] Directly Based On**

“[[Invention] Directly based on” means that the [subject matter][invention] [must] make [immediate] use of the genetic resource, and depend on the specific properties of the resource of which the inventor [must] have had [physical] access.]

ALT

“[Invention] Directly based on” means that the [invention] [must] make [immediate] use of the genetic resource, and the inventive concept must depend on the specific properties of the resource of which the inventor must have had physical access.]

### **Genetic Material**

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

ALT

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

### **Genetic Resources**

“Genetic resources” are genetic material of actual or potential value.

ALT

“Genetic resources” means any material of plant, animal, or microbial origin containing functional units of heredity of actual or potential value, and includes derivatives and genetic information thereof.

### **[Source**

ALT 1

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or botanical garden.]

ALT 2

“Source” should be understood in its broadest sense possible:

- (i) Primary sources, including in particular [Contracting Parties] [Countries] providing genetic resources, the Multilateral System of ITPGRFA, [patent owners, universities, farmers, and plant breeders,] indigenous and local communities; and
- (ii) Secondary sources, including in particular ex-situ collections and [scientific literature].]

ALT 3

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or [botanical garden] or any other depository of genetic resources.]

### **[Utilization**

“Utilization” of genetic resources means to conduct research and development, [conservation, collection, characterization, among others,] [including commercialization] on the genetic and/or biochemical composition of genetic resources, and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

ALT

[“Utilization” of genetic resources means to conduct research and development [outside of the traditional uses by the knowledge holders] [including commercialization] on the genetic and/or biochemical composition of genetic resources and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity] [and to make a new product, or a new method of use or manufacturing of a product.]]]

### **OTHER TERMS**

#### **[Biotechnology**

“Biotechnology” [as defined in Article 2 of the Convention on Biological Diversity] means any technological application that uses biological systems, living organisms [or derivatives thereof], to make or modify products or processes for specific use.]

#### **[Country Providing Genetic Resources**

[“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, [or taken from ex-situ sources,] which may or may not have originated in that country.]

ALT

[“Country providing genetic resources” is the country that possesses the genetic resource and/or traditional knowledge in in situ conditions and that provides the genetic resource and/or traditional knowledge.]]

### **[Derivative**

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources[, even if it does not contain functional units of heredity].]

### **In-Situ Conditions**

“In-situ conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties [Article 2, CBD].

### **Ex-Situ Conservation**

“Ex-situ conservation” means the conservation of components of biological diversity outside their natural habitats.

### **[Misappropriation**

“Misappropriation” is the [acquisition] [utilization] of genetic resources [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with national legislation] [of the country of origin or providing country].]

ALT

“Misappropriation” is the use of genetic resources and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

### **[[Physical] Access**

“[[Physical]/[Direct] access” to the genetic resource is its physical possession [or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property]].]

### **[Protected Genetic Resources**

“Protected genetic resources” means, genetic resources that are protected either pursuant to an intellectual property right or other legal right. Once intellectual property rights in a genetic resource expire, the genetic resource should be in the public domain and not treated as a protected genetic resource.]

**[Source of Traditional Knowledge Associated with Genetic Resources**

“Source of Traditional Knowledge Associated with Genetic Resources” means any source from which the applicant has acquired the traditional knowledge associated with genetic resources, including indigenous and local communities, scientific literature, publicly accessible databases, and patent applications, and patent publications. <sup>2]</sup>

**[Unauthorized Use**

“Unauthorized use” is the acquisition of genetic resources, [traditional knowledge associated with genetic resources] without the consent of the competent authority in accordance with national legislation of the providing country.]

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<sup>2</sup> This phrase does not appear verbatim in the document, but was introduced contemporaneously with the global deletion of “associated traditional knowledge” from the text. Upon reflection, it was felt that the Member State which introduced the phrase should have the opportunity to clarify its continuing relevance to the text.

## **[I. [MANDATORY] DISCLOSURE]**

### **[ARTICLE 2] [OBJECTIVE]**

[The objective of this instrument is to contribute to the protection of genetic resources and traditional knowledge associated with genetic resources within the [IP] [patent] system by:

- (a) [Enhancing] [transparency], [efficacy] and quality in the [IP][patent] system in relation to genetic resources and/or traditional knowledge associated with genetic resources;] and
- (b) [Ensuring] [Desiring to ensure] that [IP] [patent] offices have access to the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of [IP] [patent] rights.]

### **[ARTICLE 3] [SUBJECT MATTER OF INSTRUMENT]**

This instrument applies to genetic resources, and [traditional knowledge associated with genetic resources].

ALT

This instrument [shall]/[should] apply to patent applications for inventions directly based on genetic resources and traditional knowledge associated with genetic resources.]

### **[ARTICLE 4] [DISCLOSURE REQUIREMENT]**

4.1 Where the [subject matter] [claimed invention] within a [IP] [patent] application [includes utilization of] [is directly based on] genetic resources and/or [traditional knowledge associated with genetic resources], each [Member State]/[Party] [shall]/[should] require applicants to;

- (a) disclose the [providing country [that is the country of origin]] [country of origin [and]] [or [if unknown],] source of the genetic resources, [and, where applicable, the indigenous peoples or local communities from which the genetic resources] and/or [traditional knowledge associated with genetic resources] [were]/[was] obtained.
- (b) [If the source and/or [providing country [that is the country of origin]] [country of origin] is not known to the applicant, make a declaration to that effect.]

4.2 In accordance with national law, a [Member State]/[Party] may require applicants to provide relevant information regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]

ALT 1

4.2 The disclosure requirement of Paragraph 1 shall not include a requirement to provide relevant information regarding compliance with ABS requirements, including PIC.

ALT 2

4.2 In accordance with national law, a [Member State]/[Party] may require applicants to provide relevant information regarding their entitlement to use the genetic resource.

4.3 The disclosure requirement [shall/should/may] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices [shall]/[should/may] provide guidance to [IP] [patent] applicants on how to meet the disclosure requirement.

4.4 Each [Member State]/[Party] [shall]/[should] make the information disclosed, that supports the disclosure requirement, publicly available [, except for information considered confidential.<sup>3</sup>]

**[ARTICLE 5]  
[EXCEPTIONS AND LIMITATIONS**

[In complying with the obligation set forth in Article 4, members may, in special cases, and in conjunction with Indigenous peoples and local communities, adopt justifiable exceptions and limitations necessary to protect the public interest [and public health], provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument, or mutual supportiveness with other instruments.]

[ALT

5.1 A [IP] [patent] disclosure requirement related to genetic resources and [traditional knowledge associated with genetic resources] [shall]/[should] not apply to the following:

- (a) [All [human genetic resources] [genetic resources taken from humans] [including human pathogens];]
- (b) [Derivatives];
- (c) [Commodities];[/genetic resources when they are used as commodities];
- (d) [Traditional knowledge [and other information] in the public domain];
- (e) [Genetic resources from areas beyond national jurisdictions [and economic zones]];
- (f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29<sup>th</sup> 1993]] [entry into force of the Nagoya Protocol on October 12, 2014]; and
- (g) [Genetic resources and traditional knowledge associated with genetic resources necessary to protect human, animal or plant life or health [including public health] or to avoid serious prejudice to the environment].

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<sup>3</sup> An alternative formulation from the Nagoya Protocol Art. 14(2) is “without prejudice to the protection of confidential information”.

**[ARTICLE 6]  
[NON-RETROACTIVITY]**

[Member States]/[Parties] [shall]/[should] not impose the disclosure requirement in this instrument on [IP] [patent] applications filed [or having a priority date] prior to that [Member State's]/[Party's] ratification of or accession to this instrument[, subject to [national laws] [national disclosure requirements relating to GRs and associated TK] that existed prior to such ratification or accession.]

**[ARTICLE 7]  
[RECIPROCITY]**

Contracting Parties may choose to apply the disclosure requirement specified in Article 4 only to the genetic resources and traditional knowledge associated with genetic resources of Parties to this Instrument.]

**[ARTICLE 8]  
[SANCTIONS AND REMEDIES]**

8.1 [Each [Member State]/[Party] [shall]/[should] put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with the disclosure requirement of Article 4. [Member States]/[Parties] shall develop these measures in conjunction with the Indigenous peoples and local communities concerned, where applicable.

8.2 Such measures [should/shall/may] include pre and/or post grant measures.

ALT

[8.2 Subject to national legislation, such measures [shall/should] [may] [include, inter alia] consist of:

- (a) Pre-Grant.
  - (i) Suspending the grant of [IP] [patent] applications until the disclosure requirements are met.
  - (ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].
  - (iii) Preventing or refusing to grant an [IP right] [patent].
  - (iv) Providing an opportunity for [IP] [patent] applicants to supplement the [IP] [patent] application with additional information to disclose the source or origin of any genetic resource or traditional knowledge used. Since such information is irrelevant to how to make and use the invention, there would be no impact upon the filing date of the application and no fee required for its submission after the filing date of the application.
  
- (b) [Post-Grant].
  - (i) Publication of judicial rulings regarding failure to disclose.
  - (ii) [Fines or adequate compensation for damages, including payment of royalties.]
  - (iii) Other measures [including revocation, restorative justice, and economic compensation for holders of genetic resources, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]]

8.3 Revocation of [an IP right] [a patent] as a sanction for non-compliance with Article 4 may be provided under national law for willful or deliberate instances of refusal to comply, but only after the [IP right] [patent] holder has been offered the opportunity to reach a mutually satisfactory resolution with relevant parties, as defined under national law, and such negotiations have failed.

ALT

8.3 Failure to fulfill the disclosure requirement [shall]/[should] not affect the validity or enforceability of granted [IP] [patent] rights.

8.4 [IP] [patent] offices [shall]/[should/may] provide an opportunity, within a reasonable time, for applicants to correct any disclosures that are erroneous or incorrect.

8.5 [Member States]/[Parties] [shall]/[should] put in place adequate dispute resolution mechanisms.]

**[II. ALTERNATIVES TO ARTICLES 2-8  
NO NEW DISCLOSURE REQUIREMENT]**

**ALT  
[ARTICLE 2]  
[OBJECTIVE]**

The objective of this instrument is to prevent the grant of patent rights on inventions that are not novel, non-obvious, and industrially applicable.

ALT

The objectives of this instrument are to:

- (a) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources, which could protect Indigenous peoples and local communities from the limitations of the traditional use of genetic resources and their traditional knowledge associated with genetic resources that might result from the erroneous patenting thereof;
- (b) ensure that patent offices have the appropriate available information on genetic resources and traditional knowledge associated resources needed to make informed decisions on granting patents; and
- (c) preserve a rich and accessible public domain in order to foster creativity and innovation.]

**ALT  
[ARTICLE 3]  
[SUBJECT MATTER OF INSTRUMENT]**

This instrument [shall]/[should] apply to patent applications for inventions directly based on genetic resources and traditional knowledge associated with genetic resources.]

**ALT  
[ARTICLE 4]  
[DISCLOSURE]**

4.1 Patent applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources and [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

4.2 [Where the subject matter of an invention is made using genetic resources obtained from an entity having a legal right over the genetic resource [(including a patent owner)], that entity may in the permit agreement or license granting the applicant access to the genetic resource or the right to use the genetic resource, require a patent applicant to:

(a) include within a specification of any patent application and any patent issuing thereon a statement specifying that the invention was made using the genetic resource and other relevant information, and

[(b) obtain consent for uses not encompassed within the permit agreement or license.]]

4.3 [Patent offices [shall]/[should] publish the entire disclosure of the patent on the Internet, on the date of the patent grant and [shall]/[should] also strive to make the contents of the patent application publicly accessible over the Internet.]

4.4 [Where access to a genetic resource or [traditional knowledge associated with genetic resources] is not necessary to make or use the invention, information regarding the source or origin of genetic resource or the [traditional knowledge associated with the genetic resource] can be provided at any time after the filing date of the application and without payment of a fee.]

4.5 The disclosure of the [geographic location] where the genetic material was obtained [shall]/[should]/[may][does] not place an obligation on the patent office to verify the contents of the disclosure. But patent offices [shall]/[should] provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect.

4.6 Failure to examine a patent application in a timely manner due to disclosure requirements shall result in an adjustment of the term of the patent to compensate the patentee for administrative delays, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays.]

### **[III. [DEFENSIVE]/[COMPLEMENTARY] MEASURES]**

#### **[ARTICLE 9] [DUE DILIGENCE]**

[Member States]/[Parties] [shall]/[should] encourage or establish a fair and reasonable due diligence system to ascertain that [protected] genetic resources have been accessed in accordance with [applicable] legislation or regulatory requirements.

- (a) A database may be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law.
- (b) Such databases *can be accessed* in accordance with national law and with appropriate safeguards, by stakeholders to confirm lawful chain of title of [protected] genetic resources upon which a [patent][IP right] is based.]]
- (c) Where databases are to be utilized as part of a due diligence mechanism, the creation of said databases and the rules governing access, uses, and the application of safeguards, should be developed and implemented in conjunction with indigenous peoples and local communities and in accordance with their laws, customs, and protocols.

#### **[ARTICLE 10] [[PREVENTION OF THE [ERRONEOUS]<sup>4</sup> GRANT OF [IP RIGHTS]/[PATENTS] AND VOLUNTARY CODES OF CONDUCT**

10.1 [Member States]/[Parties] [shall]/[should]:

- (a) Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted [erroneously] with regard to claimed inventions that include genetic resources and [traditional knowledge associated with genetic resources] where, under national law, those genetic resources and [traditional knowledge associated with genetic resources]:
  - (i) anticipate a claimed invention (no novelty); or
  - (ii) obviate a claimed invention (obvious or no inventive step).
- (b) Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include genetic resources and [traditional knowledge associated with genetic resources].
- (c) [Encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines for users regarding the protection of genetic resources and [traditional knowledge associated with genetic resources].]
- (d) Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases containing [information associated with] genetic resources and [traditional knowledge associated with genetic resources] for use by patent offices] [with appropriate safeguards].

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<sup>4</sup> A Member State requested to change this title to "Protection of the Demand of the Patents". However, the facilitators do not understand the meaning of this proposal and request clarification before such a change is made.

[10.2 As a complement to the disclosure obligation provided for in Article 4, and in the implementation of this instrument, the [Member State]/[Party] may consider the use of databases on traditional knowledge and genetic resources in accordance with its needs, priorities, and safeguards as may be required under national laws and special circumstances.]

ALT

10.1 Databases on genetic resources may be established in accordance with national law, in consultation with the relevant stakeholders, and with appropriate safeguards, for the purposes of search and examination of [IP]/[patent] applications.

10.2 The databases should be accessible to [IP]/[patent] offices and other approved users to aid in the prevention of the erroneous grant of [IP]/[patents].

#### Database Search Systems

10.3 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources and [traditional knowledge associated with genetic resources] for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:

- (a) With a view towards interoperability, databases [shall]/[should] comply with minimum standards and structure of content.
- (b) Appropriate safeguards [such as filters] [shall]/[should] be developed in accordance with national law.
- (c) These databases will be accessible to patent offices [and other approved users].

#### WIPO Portal Site

10.4 [Member States]/[Parties] [shall]/[should] establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources and non-secret [traditional knowledge associated with genetic resources] within their territory. The WIPO portal site will enable an examiner [and the public] to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards [such as filters].]

10.5 [Member States]/[Parties] should provide effective, legal, policy or administrative measures, as appropriate and in accordance with national law, to implement and administer the WIPO portal.]

#### **[IV. FINAL PROVISIONS]**

##### **[ARTICLE 11] [PREVENTIVE MEASURES FOR PROTECTION]**

[Genetic resources as found in nature or isolated therefrom [shall]/[should] not be considered as [inventions] [IP] and therefore no [IP] [patent] rights [shall]/[should] be granted.]]

##### **[ARTICLE 12] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS**

12.1 This instrument [shall]/[should] establish a mutually supportive relationship [between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources and [traditional knowledge associated with genetic resources] and] [with] relevant [existing] international agreements and treaties.

ALT

12.1 [This instrument should be consistent with international IP agreements. Members recognize the coherent relationships between policies that promote the granting of patents involving the utilization of genetic resources and/or [traditional knowledge associated with genetic resources] and policies that promote the conservation of biological diversity, promote access to genetic resources, and the sharing of the benefits of such genetic resources.]

12.2 [This instrument [shall]/[should] complement and is not intended to modify other agreements on related subject matter, and [shall]/[should] support in particular, [the Universal Declaration on Human Rights, and] Article 31 of the UN Declaration on the Rights of Indigenous Peoples.]

12.3 [No provision in this instrument shall be interpreted as harming, or being to the detriment of the rights of indigenous people enshrined in the United Nations declaration on the rights of indigenous people. In the case of a conflict of laws, the rights of indigenous people enshrined in such declaration shall prevail and any interpretation shall be guided by the provisions of such declaration.]]

[12.4 The [PCT] and [PLT] [shall]/[should] be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources and [traditional knowledge associated with genetic resources]. [The amendments [shall]/[should] also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]]

##### **[ARTICLE 13] INTERNATIONAL COOPERATION**

[[Relevant WIPO bodies [shall]/[should] encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group [shall]/[should] develop a set of guidelines for [the search and examination of applications related to genetic resources and [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

ALT

[Patent examination authorities should share information related to sources of information related to genetic resources and/or traditional knowledge, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge. WIPO Members should cooperate in the sharing of information related to genetic resources and knowledge, including traditional knowledge, regarding the use of genetic resources.]

**[ARTICLE 14]  
TRANSBOUNDARY COOPERATION**

[In instances where the same genetic resources and [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties [shall]/[should] endeavor to cooperate, as appropriate, with the involvement of indigenous [people[s]] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

**[ARTICLE 15]  
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING**

[Relevant WIPO bodies [shall/should]] [WIPO shall/should] develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO [shall/should] provide technical assistance, cooperation, capacity building and financial support, subject to budgetary resources, for developing countries in particular the least developed countries to implement the obligations under this instrument.]

[End of Annex and of Document]

## **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 remarks***<sup>7</sup>

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)<sup>8</sup> 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 TK<sup>9</sup>. 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 IGC<sup>10</sup> 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

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<sup>7</sup> Note from the Chair: These introductory remarks do not form part of the draft instrument.

<sup>8</sup> These negotiations are currently being conducted pursuant to the IGC's mandate for 2018/19.

<sup>9</sup> WIPO/GRTKF/IC/40/6 Consolidated Document Relating to Intellectual Property and Genetic Resources.

<sup>10</sup> 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.

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. 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 resources”<sup>11</sup>** (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.

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<sup>11</sup> 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 2005<sup>12</sup>, is the requirement for the inventor to have physically accessed the GRs. This touches on different views within the IGC as to whether or not physical access to a GR is still required by an inventor noting technological advances in this area. To address this difference of view, the definition is now silent on this issue. In addition, it was also proposed by the EU that the definition includes the phrase “*must make immediate use*”. In my view, respectfully, there is a lack of clarity in relation to the meaning of this term. To address this issue, the terms “*necessary*” and “*material to*” have been included to reduce ambiguity. In addition, the phrase “*the claimed invention must depend on the specific properties of the GRs and Associated TK*” is included in the definition.
6. “*Source*” should be understood from its common meaning “*from which something originates or can be obtained*”<sup>13</sup>. The two definitions relating to GRs and Associated TK simply provide a non-exhaustive list of from where GRs or Associated TK may have been sourced.
7. The definition for *traditional knowledge* is still under discussion within the IGC, as part of the traditional knowledge track of the negotiations and is yet to be agreed, though, in my view, there has been some convergence of views reflected in recent discussions. Nor have any definitions been agreed at the international level in other processes, leaving it to national interpretation. Pending agreement on this matter in the IGC, it is proposed not to define the term at this time and leave it to national interpretation.

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<sup>12</sup> Document WIPO/GRTKF/IC/8/11.

<sup>13</sup> Oxford Dictionary of English (3<sup>rd</sup> 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 instrument<sup>14</sup>.

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<sup>14</sup> 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 10<sup>15</sup>**  
**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.]

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<sup>15</sup> 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 Annexes and of document]