

Information Note¹
for IGC 42 - Genetic Resources

Prepared by Mr. Ian Goss, the IGC Chair-designate

Introduction

1. In preparation for IGC 42, noting the significant gap in formal negotiations on this subject matter (IGC 36 - March 2018), this information note summarizes the status of the current negotiations relating to genetic resources (GRs) and key issues that Member States may wish to consider. Examples of relevant provisions from national and regional laws are included to assist understanding and analysis of the different approaches in the text before the IGC. The selection of the examples is without prejudice to any Member States' positions.

2. I emphasize that the views in this note are mine alone and are without prejudice to any Member States' positions on the issues discussed. As an information note, it has no status, nor is it a working document for the session. It is a paper for reflection only.

Status of GR Negotiations

3. The consolidated document on GRs was first produced at IGC 20 in February 2012. This document summarized proposals and positions within IGC working documents and Member States' proposals. This initial document was then significantly refined at IGCs 22, 23, 29, 30 and 35. During IGC 36, Member States were unable to agree to transmit the revised document issued by the facilitators to IGC 40, and as such the consolidated working document reverted to the initial revision produced by IGC 35. This Document WIPO/GRTKF/IC/42/4 (*Consolidated Document Relating to Intellectual Property and Genetic Resources*) is the latest version of the text before the IGC. This document incorporates a number of proposals/options, including defensive measures and disclosure proposals.

4. In addition to the consolidated working document, a number of Member States' proposals/joint recommendations remain on the table for consideration by the IGC.

5. From my perspective, the GR negotiations are at a point at which the Member States need to decide on the final form of the instrument taking account of the different approaches reflected in the consolidated working document and joint recommendations presented by a number of Member States. In order to facilitate this decision-making, on my own authority, I prepared a Chair's text on GRs and associated traditional knowledge (TK).

6. This text was presented at IGC 40 in 2019, and subsequently the WIPO General Assembly in 2019 and 2021 agreed to include this text as a working document (WIPO/GRTKF/IC/42/5). This text is an attempt 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. It also attempts to incorporate the two primary mechanisms proposed by Member States to achieve the IGC's mandate relating to GRs: a mandatory disclosure regime and initiatives relating to information systems to support prior art searching.

¹ Note from the WIPO Secretariat: The Chair-designate of the IGC, Mr. Ian Goss, has prepared this information note to assist Member States in their preparations for IGC 42.

7. I also believe 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.**

8. In addition, Member States need to have a clearer understanding of technical and practical issues relating to the establishment and functioning of information systems and various kinds of due diligence mechanisms.

9. In developing this text, I:

- considered the existing documentation of the IGC² and the WIPO Secretariat's publication *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge*;
- attempted to address the key risks identified by users, in particular legal certainty, accessibility to GRs and Associated TK, and transactional costs/burdens; and
- was mindful of the desire for a degree of policy space for Member States which have already established disclosure regimes, as long as that policy space does not compromise the benefits of a standardised set of international standards in this area.

10. The primary policy focus of the text is to 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, which, in my view, will facilitate benefit-sharing and the prevention of the granting of erroneous patents and the misappropriation of GRs and associated TK. In order to achieve these outcomes, the text establishes at the international level a framework of minimum and maximum standards.

11. Whilst formal negotiations on GR have not been conducted since 2018, several informal activities were conducted to maintain the momentum of the work of the Committee. These included a WIPO Seminar on GRs, WIPO briefings on the status of negotiations and informal consultations I held in 2021 with all Groups on the Chair's Text. In addition, I received feedback on the Chair's text from Member States and observers. A summary of the outcomes of my consultations are detailed below:

- There is a broad cross regional support for the draft text as a foundation document, accepting that there remain differences of views on the scope of the instrument.
- Notwithstanding broad support for the text, several Member States remain opposed to a mandatory disclosure mechanism, preferring non-mandatory defensive mechanisms.
- Key policy/technical issues raised which require further consideration include:
 - Objectives of the instrument;
 - Relationship with related international instruments including the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising

² Such as WIPO/GRTKF/IC/42/4 Consolidated Document Relating to Intellectual Property and Genetic Resources; WIPO/GRTKF/IC/42/9 Joint Recommendation on Genetic Resources and Associated Traditional Knowledge; WIPO/GRTKF/IC/42/10 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/42/8 The Economic Impact of Patent Delays and Uncertainty: U.S. Concerns about Proposals for New Patent Disclosure Requirements.

- from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) and the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP);
- More emphasis on the rights of indigenous peoples in the objective/preamble;
- Amendments to improve Articles 3 and 6 to reduce ambiguity in the interest of legal certainty;
- Concerns from some Members States regarding divergence from their existing regional/national regimes or policy positions, in particular, on the scope of rights, sanctions, and relationship with their access and benefit-sharing (ABS) regimes; and
- consideration of a reciprocity clause and an international information system relating to GRs and associated TK.

Discussion of Key Issues

International Context

11. The relevant international frameworks for regulating access to and benefit-sharing in GRs are the CBD, the Nagoya Protocol, as well as the International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA) of the United Nations Food and Agriculture Organization.

12. The key relevance of these instruments is that they are the primary multi-lateral instruments dealing with the protection of GRs and associated TK, including access and benefit-sharing. A key debate within the Nagoya Protocol negotiations related to national check points, and whether the patent office should be specifically identified as a check point. Ultimately this was not agreed noting that there were ongoing discussions underway in WIPO relating to disclosure of GRs and associated TK within the intellectual property (IP) system.

13. From my perspective, noting the international context, I believe the IGC negotiations relating to GRs relate specifically to the IP system and what role, if any, it should play in facilitating *“the effective and balanced protection of genetic resources and traditional knowledge associated with genetic resources.”*

14. The key questions before the IGC are **(1) does the IP system have a role at the international level in supporting the protection of GRs and associated TK, (2) what are the objectives of such a role, and (3) what are the appropriate mechanisms.**

14. In relation to these questions we appear to have a clear consensus, reflected in the IGC working documents, that the IP system does have a role to play.

Subject Matter

15. In considering these questions it is important to consider the nature of the subject matter. GRs can be differentiated from the two other subjects being dealt with by the IGC: TK and traditional cultural expressions (TCEs). TK and TCEs, which are developed by the human mind, can be considered “intellectual property” suitable for direct protection by an IP instrument. By contrast, GRs as such are not produced by the human mind and the IP issues that they raise are distinct.

16. Inventions based on or developed using GRs may be patentable, and, therefore, some members are concerned about patents being granted in error over inventions based

on or developed using GRs. Their interest is in improving the quality of patent examination and the efficiency and transparency of the patent system. One option would be to ensure patent offices have access to the appropriate information. Some members consider that the patent system/IP system should also facilitate compliance with the access and benefit-sharing obligations, specifically those related to prior and informed consent, mutually agreed terms, fair and equitable benefit-sharing, deriving from the international frameworks referred to above.

Objectives

17. Reflecting the various Member States' perspectives discussed above three objectives have been identified in the working documents:

1. enhancing efficacy, transparency and the quality of the IP/patent system relating to GRs and associated TK,
2. facilitating mutual supportiveness with agreements relating to GRs and associated TK; and
3. ensuring patent offices have the appropriate information to prevent the granting of erroneous IP/patent rights.

18. In reviewing these objectives, I would reflect that the objectives would appear to provide a balanced approach to the interests of all Member States. Also, objective 3 could be considered to be supporting or underpinning objectives 1 and 2. In addition, from my perspective, objective 1 clearly articulates an intent in regard to the role of the IP system in supporting the protection of the subject matter at the international level; *through enhancing the efficacy, transparency and quality of the IP patent system relating to GRs and associated TK*. An objective which would also facilitate mutual supportiveness with international agreements relating to the protection of GRs and associated TK, and prevent the granting of erroneous IP/patent rights.

19. *The key questions for Member States to consider are:*

1. *Does objective 3 provide sufficient specificity noting an implied relationship with objectives 1 and 2.*
2. *If not, would members accept the three objectives as a balanced formulation which protects the interests of all Member States.*
3. *If the answer to questions 1 and 2 is no, what formulation would achieve consensus, and could the preamble be used to address Member States concerns.*

Policy Mechanisms

20. The consolidated document (WIPO/GRTKF/IC/42/4) includes two broad approaches or "mechanisms" for addressing IP issues related to GRs:

- **Defensive Measures.** This approach incorporates defensive measures such as databases, voluntary codes and guidelines for IP/patent offices, third party dispute mechanisms and due diligence regimes within patent offices under national laws to ensure compliance with relevant ABS regimes.
- **Disclosure Requirement.** Inclusion of a mandatory disclosure requirement within IP/patent legislation relating to the disclosure of information (for example, information about the country of origin or source of GRs and associated TK) in applications, where the subject matter/claimed invention is materially or directly based on GRs and associated TK. Within this approach, defensive measures (below) are

considered complementary to a disclosure requirement not as an alternative approach to addressing the policy objectives.

Defensive Measures

21. In relation to **defensive measures** identified in the consolidated document and within the Joint Recommendations, it is noted that some Member States are of the view that these measures only, without any additional disclosure requirements, would be the best way to achieve the desired objectives, while other Member States believe that disclosure requirements could be complemented by these measures. Against this backdrop, Member States may wish to discuss and consider further, the nature and need for the establishment of international norms relating to:

- **due diligence measures** to ascertain the access to GRs in accordance with applicable access and benefit-sharing legislations;
- **administrative measures** to prevent patents from being granted erroneously with regard to claimed inventions based on or developed using GRs;
- **administrative measures** to allow third parties to dispute the validity of a patent relating to GRs; and
- **voluntary codes of conduct and guidelines** for users regarding the use of GRs.

22. There seems to be a broad view among Member States that **databases**, whatever the approach or combination of approaches, have a key role to play in relation to the IP/patent system and the protection of GRs. As such, Member States may wish to consider what international standards and safeguards are needed relating to databases of information related to GRs. If the instrument also applies to TK associated with GRs, what kind of additional safeguards might be needed for TK that is widely held and/or publicly available?

23. Notwithstanding a current lack of agreement on a disclosure requirement, from my perspective it would be useful to identify which of these measures the IGC believes there is merit in establishing international standards/norms for e.g. databases. This perhaps would enable further consideration of these measures to be undertaken by the secretariat or a separate working group with recommendations brought forward to the committee.

Disclosure Requirement

24. In relation to a disclosure requirement, the approach has been significantly refined over the period of the negotiations with the inclusion of an administrative mechanism option focused on ensuring transparency within the IP/patent system rather than a regime based around a substantive patentability requirement. However, amongst Members States supporting some form of disclosure regime, there remain variances with regards to the scope of the regime. In particular:

- the scope of IP Rights covered,
- the nature of the trigger, which would prompt the disclosure requirement,
- nature of sanctions, in particular revocation, and;
- relationship with access and benefit sharing regimes e.g. Nagoya Protocol.

25. These variances reflect how disclosure regimes are regulated nationally and regionally, through environmental/biodiversity laws, patent laws, or a combination of both. Variances which could potentially increase legal uncertainty and regulatory burdens/costs for business operating across multiple jurisdictions. Members States need to consider whether

the establishment of a set of international disclosure standards relating to GRs and/or TK associated with GRs, within the IP system, could assist in alleviating those potential risks.

26. Member States may wish to focus on the following key issues relating to disclosure requirements at IGC 42. In considering these issues members may also find the explanatory notes within the Chair's Text, related to these key issues, a useful reference.

(1). Scope/Subject matter

One important issue Member States are invited to consider is whether the instrument should apply only to patent rights (and patent applications) or also to other IP rights. Disclosure requirements have been incorporated into IP legislation in many countries. In several of them, these requirements apply specifically to patent law, for example, in Sweden and China. In some countries, these requirements apply to all relevant IP rights, for example, in Ethiopia and Brazil.

It seems that this depends on the types of laws which disclosure requirements are introduced, i.e., disclosure requirements in patent laws apply to patent rights/applications, while disclosure requirements introduced in biodiversity or access and benefit-sharing legislation often apply to all relevant IP rights.

I believe, considering the primary commercialisation of GRs is within the Patent system, that the instrument should initially apply only to patent systems and Member States could further review other IP areas at a later time.

Member States are also invited to consider, in addition to GRs, whether the instrument should also apply to TK associated with GRs. It should be noted that TK is not always associated with a GR. It should also be noted that a disclosure requirement provision is currently included in the TK text before the IGC. Therefore, Member States may wish to consider discussing whether disclosure requirements in the GRs text should also apply to TK associated with GRs.

In relation to this question, Member States should also define those terms, such as GRs (including the issue of whether derivatives should be included in the definition of GRs) and TK associated with GRs. Another question would be what exclusions from the material scope of application of disclosure requirements might be envisaged.

(2). Nature of disclosure

Many countries have adopted some forms of disclosure requirements relating to GRs and/or TK in their national laws, with different levels of obligations for the applicants:

- Mandatory disclosure requirements in relation to formalities, which refer to the need to submit certain types of documents or a required physical format.

For example, **Switzerland**: Article 49(a) of the *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* states: "The patent application must contain information on the source: a) of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b) of [TK] of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource."

Article 81(a) of *the Federal Act* further states:

“Any person who willfully provides false information under Article 49(a) is liable to a fine of up to 100,000 francs. The court may order the publication of the judgment.”

Norway: Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:

“If an invention concerns or uses biological material or [TK], the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of [TK] shall be subject to prior consent, the application shall state whether such consent has been obtained. [...] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

- Mandatory disclosure requirements of substantive nature, which refer to the nature of the invention or to the underlying standards of patentability. In other words, such disclosure requirements are considered as having consequences for patentability.

For example, **South Africa:** Section 30 of the *Patents Amendment Act (Act No. 20 of 2005)* provides:

“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use.

“(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, [GR], or of the [TK] or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use.”

India: Article 10(4)(d)(ii) of the *Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005*, provides:

“If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b),^[7] and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely: [...] (d) disclose the source and geographical origin of the biological material in the specification, when used in an invention.”

- Voluntary disclosure requirements, as part of the patent procedure without any consequences for patent prosecution or patent validity.

For example, **Germany**: Section 34(a) of the *Patent Act as published on December 16, 1980 (as last amended by Article 1 of the Act of October 19, 2013)* provides:

“Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.”

In my view, the instrument should introduce a mandatory requirement. To support legal certainty, such disclosure requirement should clearly state what would activate the obligation to disclose (“*trigger*”) and which information would need to be disclosed (“*content*”).

(3). Trigger of disclosure

Two options have been proposed in relation to the issue of the trigger: “utilization of” and “directly based on”.

- “Utilization” is a term used in the Nagoya Protocol, and is focused on research and development (R&D). In some countries, the term “use” is used instead of “utilization”.

For example, **People’s Republic of China (PRC)**: Article 26 of the *Patent Law of the PRC (as amended by the Decision of December 27, 2008, regarding the Revision of the Patent Law of the PRC)* provides:

“With regard to an invention-creation accomplished by relying on [GRs], the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.”

Relevant implementing rules also explain that the expression “the invention/creation accomplished by relying on GRs” refers to “[...] those invention/creation of which the accomplishment uses the genetic function of [GRs]”.

India: Section 10 of the *Patents (Amendments) Act 2002* states:

“Every complete specification shall [...] disclose the source and geographical origin of the biological material in the specification, when used in an invention.”

Norway: Section 8b of *Patent Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:

“If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.”

- “Directly based on” means that the invention must make immediate use of the GR.

For example, **Switzerland:** Article 49 of the *Amendment of Patent Law of June 2, 2007, RO 2008 2551* provides:

“For inventions based on [GRs] or [TK] the patent application must contain information concerning the source:
(a) of the [GRs] to which the inventor or the applicant had access, when the invention is based directly on that resource;
(b) of [TK] of indigenous or local communities related to the [GRs] to which the inventor or applicant had access, when the invention is based directly on that knowledge.”

The definitions of “utilization of” and “directly based on” are other issues to be considered.

“Derived from” is another term that has been used in some national laws. This could possibly be the broadest trigger. In the absence of a specific definition, the term could be interpreted to encompass different things, ranging from direct physical derivation from a GR to any synthetic biology product that is created using gene sequence data simply obtained from an online repository or database, and anything in between these two.

For example, **Andean Community:** Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states:

“Applications for patents shall be filed with the competent national office and shall contain: [...] (h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from [GRs] or byproducts originating in one of the Member Countries; (i) if applicable, a copy of the document that certifies the license or authorization to use the [TK] of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations [...]”

Other terms used to express the triggers are “produced or developed on the basis of”, “based on”, “relying on” and “concerning”.

In my opinion, the term “directly based on” clearly indicates a causal link and is possibly the narrowest trigger. In practice, this would mean that only those GRs without which the invention could not be made, should be disclosed. Clearly whatever the words used the definition of the trigger is fundamental to the scope of the instrument and the impact on legal certainty and requires careful consideration

(4). Content of disclosure

Three categories of information have been proposed related to the content of disclosure:

(1) the country of origin;

For example, **Norway**: Section 8(b) of *the Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* adopts a very detailed rule:

“If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material, the application shall also state the country of origin. The country of origin means the country from which the material was collected from its natural environment. If the national law in the country of origin requires that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.”

(2) the source of the GRs and/or TK; and

For example, **People’s Republic of China**: *Article 26(5) of Patent Law Amendment, December 27, 2008*, which entered into force in October 2009 states: “

[...] for an invention-creation, the completion of which depends on genetic resources, the applicant shall indicate the direct source and original source of said genetic resources in the application documents; the applicant shall state reasons if the original source of said genetic resources cannot be indicated.”

(3) information regarding compliance with access and benefit-sharing requirements, including prior informed consent.

For example, **Andean Community**: *Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states that a patent application shall contain:

“[a] copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries; [...] if applicable, a copy of the document that certifies the license or authorization to use the

traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested [were] obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations.”

South Africa: *Section 30 of the Patent Law (as amended in 2005)* provides:

“Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.”

I think that, depending on the specific circumstances, different information could be requested to be disclosed. In this line, if known by the patent applicant, the country of origin of the GRs should be disclosed. When it is not possible for the patent applicant to disclose this information, the source of the GRs should be disclosed. Finally, if none of the previous information is available, the applicant should make a declaration to that effect. In addition, we need to consider if we need to differentiate between the information required to be disclosed relating to associated TK and GRs.

Also, when considering which categories of information should be disclosed, the definitions of “country of origin” and “sources” should also be considered.

(5). Consequence of non-compliance

As I indicated before, the consolidated document has been significantly refined with inclusion of an administrative mechanism option focused on ensuring transparency within the IP/patent system rather than solely a regime based around a substantive patentability requirement. One issue to be addressed is whether pre-grant and post-grant measures need to be described in detail in the instrument, noting that international IP instruments usually provide minimum standards with flexibilities for Member States to implement those international IP instruments.

A key question relating to consequence of non-compliance is whether non-compliance should affect the validity of a granted patent and, if so, what would the permissible condition(s) for revocation be, especially taking into account that an administrative mechanism is included? Aside from revocation, what other options are there?

For example, **Switzerland:** Article 81(a) of *the Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* provides a fine for wrongful provision of false information but not patent invalidation:

“Any person who willfully provides false information under Article 49(a) [on disclosure of source] is liable to a fine of up to 100,000 francs. The court may order the publication of the judgment.”

Andean Community: Article 75 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:

“The competent national authority shall decree the absolute invalidity of a patent at any time, either *ex officio* or at the request of any person, where:

“[...]

“(g) a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin;

“(h) a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the member countries is the country of origin.”

South Africa: Section 61 of the *Patents Amendment Act 2005 (Act No. 20 of 2005)* states:

“Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely [...] that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) [concerning the disclosure requirement] contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made.”

India: Article 10(4)(d)(ii) of the *Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005*, provides:

“If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b),[7] and if such material is not available to the public, the application shall be completed by depositing the material to an international depository

authority under the Budapest Treaty and by fulfilling the following conditions, namely: [...] (d) disclose the source and geographical origin of the biological material in the specification, when used in an invention.”

It is my opinion that it should be left to the Parties to decide which measures to put in place to address non-compliance with a disclosure requirement. This flexibility would apply to both the regulation of pre-grant and post-grant sanctions. However, in order to ensure legal certainty and facilitate the sharing of benefits, Parties should not be able to revoke a patent or render it unenforceable based solely on an applicant's failure to provide the information required by the disclosure requirement.

Other useful resources

3. I note that there are some very useful resources available on the WIPO website which Member States may wish to use as reference materials in their preparations for IGC 42, such as:

- Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, <https://www.wipo.int/publications/en/details.jsp?id=4194>;
- Disclosure Requirement Table, https://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf.
- Brief 10: Intellectual Property and Genetic Resources, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_10.pdf;
- Regional, National, Local and Community Experiences, https://www.wipo.int/tk/en/resources/tk_experiences.html;
- Lectures and presentations on the selected topics, https://www.wipo.int/tk/en/resources/tk_experiences.html#4
 - Presentations on disclosure requirements; and
 - Presentations on databases.