

Information Note¹

for IGC 36

Prepared by Mr. Ian Goss, the IGC Chair

Introduction

1. The first consolidated document on genetic resources (GRs) was 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. Document WIPO/GRTKF/IC/36/4 (Consolidated Document Relating to Intellectual Property and Genetic Resources) is the latest version of the text before the IGC.

2. In preparation for IGC 36, this short information note summarizes some key issues that Member States may wish to give focused attention to. 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.

3. 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.

4. As I indicated in the Information Note prepared for IGC 35, Member States are strongly encouraged to consider what options require international agreement at the IGC and whether there are options that are more practical in nature and may be implemented within the existing international legal framework noting that some have already been implemented. For example, to help patent examiners find relevant prior art and avoid the granting of erroneous patents, new subclasses were introduced several years ago into the International Patent Classification (the IPC) to facilitate the identification of relevant prior art when dealing with traditional knowledge-related applications. Furthermore, certain traditional knowledge journals were accepted as part of non-patent literature for patent examination purposes.

5. In preparing this note, I have used WIPO/GRTKF/IC/36/4 (Consolidated Document Relating to Intellectual Property and Genetic Resources) as the framework document. I have also considered the following documents:

- WIPO/GRTKF/IC/36/5 (Report on the Compilation of Materials on Databases Relating to Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/36/6 (Report on the Compilation of Materials on Disclosure Regimes Relating to Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/36/7 (Joint Recommendation on Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/36/8 (Joint Recommendation on the use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources);

¹ Note from the WIPO Secretariat: The Chair of the IGC, Mr. Ian Goss, has prepared this information note to assist Member States in their preparations for IGC 36.

- WIPO/GRTKF/IC/36/9 (Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems)
- WIPO/GRTKF/IC/8/11 (Disclosure Of Origin Or Source Of Genetic Resources And Associated Traditional Knowledge In Patent Applications (EU Proposal))
- WIPO/GRTKF/IC/11/10 (Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland)
- WIPO/GRTKF/IC/19/11 (Like-Minded Countries Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resources).

6. I have also used two very useful materials prepared by the WIPO Secretariat, which are:

- Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, <http://www.wipo.int/publications/en/details.jsp?id=4194>; and
- Disclosure Requirement Table, http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf.

Broader context

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

8. GRs can be differentiated from the two other subjects being dealt with by the IGC: traditional knowledge (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 intellectual property (IP) instrument. By contrast, GRs as such are not produced by the human mind and the IP issues that they raise are distinct. 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. The questions before the IGC, therefore, are (1) are one or both of these objectives legitimate for the IGC to pursue, and (2) having determined the objective(s) to be pursued, which mechanisms, if any, are needed to achieve them.

Overview of the Consolidated Document

9. The consolidated document (WIPO/GRTKF/IC/36/4) includes two broad approaches or “mechanisms” for addressing intellectual property (IP) issues related to GRs. Two sets of policy objectives have been identified respectively for the two approaches.

10. The two broad approaches or mechanisms incorporated within the consolidated document are:

- **Disclosure Requirement.** Inclusion of a new 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 TK associated with GRs) in applications, where the subject matter/claimed invention includes utilization of/is directly based on GRs and TK associated with GRs. Some Member States consider there should be no new disclosure requirement.
- **Defensive/Complementary Measures.** This approach incorporates 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.

Key Issues for Consideration by IGC 36

11. In relation to **disclosure requirements**, it seems that Member States who support some form of a disclosure, generally agree that the objectives are to:

- ensure mutual supportiveness with international agreements;
- enhance transparency in the IP/Patent system; and
- ensure IP Offices have access to the appropriate information so as to prevent misappropriation through the granting of erroneous IP/patent rights.

12. In addition to the above objectives, I would also observe that there is significant diversity in disclosure regimes established nationally and regionally, reflected in the examples described below. In part, this is due to differences in how disclosure regimes are regulated nationally and regionally, through environmental/biodiversity laws, patent laws, or a combination of both. Differences might potentially increase legal uncertainty and regulatory burdens/costs for business operating across multiple jurisdictions. Member States may wish 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.

13. Member States may wish to focus on the following key issues relating to disclosure requirements at IGC 36:

(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.

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 State 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, 19804 (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.”

(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 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. It appears to be possibly the narrowest trigger.

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

(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.”

In addition to 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.”

14. In relation to **defensive/complementary measures** identified in the consolidated document, it is noted that some Member States are of the view that defensive 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 defensive measures. Against this backdrop, Member States may wish to consider, under this international instrument, the need for additional:

- **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.

15. There seems to be a broad view among Member States that **databases**, whatever the approach (a new disclosure requirement or not), have a key role to play in relation to the IP/patent system and GRs. Member States may wish to consider whether databases could be considered as stand-alone defensive measures to achieve the objectives or only as complementary measures to disclosure requirements. Member States may also wish to consider whether or not, and, if so, which, 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?

Other useful resources

16. 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 36, such as:

- Brief 10: Intellectual Property and Genetic Resources, <http://www.wipo.int/publications/en/details.jsp?id=4011>;
- Regional, National, Local and Community Experiences, http://www.wipo.int/tk/en/resources/tk_experiences.html;
- Lectures and presentations on the selected topics,

http://www.wipo.int/tk/en/resources/tk_experiences.html#4

- Presentations on disclosure requirements; and
- Presentations on databases.
