

Information Note¹

for IGC 35

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

Introduction

The first consolidated document on genetic resources (GRs) was produced at IGC 20 in February 2012. This document attempted to summarize proposals and positions within IGC working documents and Member States' proposals. This initial document was then significantly refined at IGCs 22, 23, 29 and 30.

In preparation for IGC 35, this short information note summarizes some key issues that Member States may wish to give focused attention to. Member States are also 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.

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.

In preparing this note, I have used WIPO/GRTKF/IC/35/4 (Consolidated Document Relating to Intellectual Property and Genetic Resources) as the framework document, noting this document details in textual form the key positions of Member States. I have also considered the following documents:

- WIPO/GRTKF/IC/35/5 (Report on the Compilation of Materials on Databases Relating to Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/35/6 (Report on the Compilation of Materials on Disclosure Regimes Relating to Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/35/7 (Joint Recommendation on Genetic Resources and Associated Traditional Knowledge);
- WIPO/GRTKF/IC/35/8 (Joint Recommendation on the use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources);
- WIPO/GRTKF/IC/35/9 (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)

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 35.

- 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).

Overview of the Consolidated Document

The consolidated document (WIPO/GRTKF/IC/35/4) addresses the policy objectives of the instrument, noting that there are three alternatives and these are not yet agreed. Key policy elements included within these alternate positions comprise:

- *Enhance the transparency of the [IP] [patent] system relating to GRs and TK associated with GRs.*
- *Facilitate mutual supportiveness with international agreements relating to GRs and TK associated with GRs.*
- *Facilitate the possibility of ABS through the disclosure of country of origin or source of GRs in separate systems such as the CBD.*
- *Ensure that IP/patent offices have access to the appropriate information on GRs and TK associated with GRs to prevent the granting of erroneous IP/patent rights.*

The two broad approaches incorporated within the consolidated document are:

- **Disclosure Requirement.** Inclusion of a 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. Within this approach, defensive measures are considered complementary measures and not an alternative approach to addressing policy objectives.
- **Defensive 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 35

The very first issue that needs to be considered is a determination of, and agreement on, the **objective(s)** of the instrument. Objective(s), whilst still not agreed, have been revised to focus on the IP/patent system. Recognition that the focus of GRs work at WIPO is on how the IP/patent system, through a disclosure requirement and/or defensive measures, can improve the implementation of the IP/patent system (by, for example, enhancing the quality of granted patents). Where possible within this focus, it might also mutually support international agreements relating to GRs and TK associated with GRs, such as the Convention on Biological Diversity (CBD) and its Nagoya Protocol. Bearing this in mind, Member States may wish to consider merging the three alternatives of objective(s) in the consolidated document.

In relation to **disclosure requirements**, 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. The key issues Member States may wish to focus on at IGC 35 are:

- Should disclosure requirements be **mandatory or voluntary**?
- In addition to GRs, should the instrument also apply to **derivatives and TK associated with GRs**?

- What should **trigger** disclosure, “utilization of” subject matter, “directly based on” subject matter, or “directly based on the utilization of” subject matter?
- What should be the **content** of disclosure? For example, should it be the origin and/or source of the GR, and information regarding compliance with access and benefit-sharing requirements including prior informed consent?
- Should there be **exceptions and limitations** to a disclosure requirement, and if so, which ones?
- Should issues concerning IP/patent **subject matter eligibility** for GRs and/or derivatives as found in nature and/or isolated therefrom be addressed in this instrument, and, if so, where would this be better addressed, in the preamble or in the main body of the instrument?
- What should be the **consequence of non-compliance**? Should non-compliance affect the validity of a granted patent and, if so, what would the permissible condition for revocation be?

In relation to **defensive approaches** 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 objectives, while other Member States believe that disclosure requirements could be complemented by defensive measures. Against this backdrop, Member States may wish to consider the need for additional **due diligence measures** under this international instrument. There seems to be a broad view among Member States that **databases**, whatever the approach (a disclosure requirement or not), have a key role to play in relation to the IP/patent system and GRs. Member States may consider whether databases could be conceived as stand-alone defensive measures to achieve the policy objectives or only as supplementary measures to a disclosure requirement.

While the above is a brief and informal summary of the main policy/substantive issues, the IGC may also wish to consider which mechanisms and other processes within the IGC would best enable productive discussion of the issues and the reaching of agreement on them. The IGC has, for example, in the past used a mix of plenary and informal sessions, and the new mandate for the 2018-2019 biennium refers to the possible establishment of an *ad hoc* expert group(s) to “address a specific legal, policy or technical issue”.

Other useful resources

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 35, such as:

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