

## **Genetic Resources – Informal Issues Paper\***

**Non-paper prepared by the Chair of the IGC for the 2012-2013 biennium, His Excellency Ambassador Wayne McCook**

At IGC 23 (February 2013), which addressed the subject of genetic resources (GRs), the Committee further developed the “Consolidated document relating to intellectual property and genetic resources” (“the Consolidated Document”).

In preparation for IGC 26 (February 2014), this short and informal paper summarizes some key issues that members may wish to give focused attention to in preparation for broader solution-seeking negotiations in the IGC.

In doing so, members may wish to consider what options require international agreement at WIPO and whether there are options that are more practical in nature and may be implemented within the existing international legal framework, noting that some already have been implemented.

### **BROADER CONTEXT**

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.

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. However, it should be noted that TK is often (but not always) associated with a genetic resource and linked as “associated TK” (for example, traditional medical knowledge concerning the healing properties of a plant genetic resource).

### **WHAT ARE THE INTELLECTUAL PROPERTY ISSUES ASSOCIATED WITH GRS?**

Inventions based on or developed using GRs may be patentable. Some members are concerned about patents being granted over inventions based on or developed using GRs (and associated TK) without fulfilling the existing patentability requirements of novelty and inventiveness. Some Member States of WIPO consider that defensive protection of GRs should also address applications for IP rights that do not evidence compliance with access and benefit-sharing (ABS) obligations, specifically those related to prior and informed consent (PIC), mutually agreed terms, fair and equitable benefit-sharing, and disclosure of origin.

A number of countries have enacted domestic legislation putting into effect the CBD’s ABS obligations that access to a country’s GRs should depend on securing that country’s PIC and agreeing to fair and equitable benefit-sharing through mutually-agreed terms. Many delegations feel that the patent system in particular should support and assist in the implementation of these ABS obligations, such as through enabling the tracking of compliance with the obligations.

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\* This non-paper serves to provide an informal guide to the significant issues to be discussed at the upcoming Twenty-Sixth session of the IGC. It is a paper for reflection only and is not a working document for the session.

Some delegations believe that all IP ought to be covered, including plant varieties, although in this respect UPOV, not WIPO, is the competent organization for international policy discussions and the development of international norms.

#### WHAT ARE THE OBJECTIVES THAT THE IGC WISHES TO ACHIEVE?

The IGC (in the part headed “Policy Objectives” in the Consolidated Document) currently identifies two possible main objectives in its search for appropriate ways in which to regulate the interface between IP and access to and benefit-sharing in GRs:

- To comply with International/National laws relating to ABS,
- To ensuring that IP offices have appropriate information on GRs and associated TK to make proper and informed decisions in granting IP rights.

#### WHAT SOLUTIONS ARE PROPOSED TO DEAL WITH THE ISSUES? A MENU OF OPTIONS

**Databases** and other information systems: it has been proposed to create and further develop databases and information systems related to GRs to help patent examiners find relevant prior art and avoid the granting of erroneous patents;

**Disclosure requirements:** one of the options is to develop disclosure requirements, in other words, provisions which require patent (and perhaps also other IP) applications to show the source or origin of GRs, as well as evidence of PIC and benefit-sharing;

**Contract:** some believe that the issues can be dealt with through suitably drafted contracts, and guidelines for IP-related clauses for such contracts are proposed;

**Guidelines** or recommendations on defensive protection: for example, guidelines to help guide patent authorities when examining TK or GR-related applications, so as to decrease the likelihood of the grant of patents in respect of inventions that do not fulfill patentability requirements;

**Improved classification, search and examination:** 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 TK-related applications. Furthermore, certain TK journals were accepted as part of non-patent literature for patent examination purposes. These practical steps, taken early on in the life of the IGC, could be revisited and expanded upon.

#### WHAT HAS ALREADY BEEN DONE?

Databases, patent examination guidelines, improved classification, search and examination tools and contractual guidelines are not truly normative although they can be of help in addressing, complementing and/or implementing normative standards. They can, and in some cases already have been, established and implemented as practical steps, within existing international legal frameworks.<sup>1</sup>

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<sup>1</sup> Some examples of what has already been done are noted in the main body of this paper. In addition, under the auspices of the IGC, WIPO has been engaged in the development of model IP clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation (see document WIPO/GRTKF/IC/17/INF/12). A database of existing ABS agreements has been created as a capacity-building tool (see WIPO/GRTKF/IC/17/INF/11). As the IGC has itself recognized, these are non-normative, practical tools which were developed some time ago and are already being updated and improved upon. As tasked by the IGC, the Secretariat has developed draft patent examination guidelines (see WIPO/GRTKF/IC/13/7). Further, regarding improved search tools and patent classification systems, until 2005, only one subgroup in the IPC – A61K 35/78 – existed for medicinal plants, which made it very difficult for patent examiners to identify relevant prior art when examining traditional medicine-based patent applications. To improve the IPC, more than 200 new subgroups relating to medicinal plants have been included (see generally WIPO/GRTKF/IC/13/7).

## THE PROPOSED DISCLOSURE REQUIREMENT

**It seems that the key normative issue is the proposal for a disclosure requirement. This is not to suggest that the other steps are not valuable or necessary: in fact, they may be necessary to complement and implement a disclosure requirement. However, they are practical initiatives that can be undertaken by States and others within existing international legal frameworks.**

### PROPOSAL FOR A DISCLOSURE REQUIREMENT: WHAT ARE SOME OF THE ISSUES?

Regarding a proposed disclosure requirement, the following could be considered as the key issues that need to be discussed:

- Subject matter (GRs and associated TK?);
- Nature of the obligation to disclose (mandatory or voluntary? is the obligation ‘substantive’ or ‘formal’?);
- Information to be disclosed (origin/source, proof of legal access, PIC and benefit-sharing?);
- Trigger for disclosure (what relationship or ‘link’ between the GRs (and associated TK) and the claimed invention would trigger a required disclosure);
- Consequence of non-compliance (dismissal or no further processing of a pending application prior to the grant of the right, nullity or unenforceability of a granted patent, or administrative or criminal sanctions outside of the patent system without effect on any granted patent?);
- How would the requirement be implemented, verified and monitored? (for example, through the PCT/PLT?);
- How would a claim to a right over a GR be attested? - Who would have standing to assert a claim or to initiate an action for non-compliance with a disclosure requirement?;
- How would overlapping claims by several claimants be addressed?;
- What burden would these requirements place on stakeholders and what harm might the requirement pose to stakeholders, if any?;
- Would any forms of compensation for any harm be required?

### CONCLUSIONS

In summary, the immediate issues for the IGC to consider are:

- Which issues and options may need to be addressed through international norms in an international legal instrument to be developed at WIPO?
  - At what level of detail should these issues and options be regulated, in other words, how much room (policy space) should be left for implementing Member States?
  - What working methodology(ies) should the IGC utilize to facilitate the achievement of agreement on these issues and options?
  - Which of the proposed solutions that are more practical in nature should be developed and implemented further? How and by whom?
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