

## ***Ad Hoc* Expert Group on Genetic Resources**

**Geneva, May 29, 2022**

SUBSTANTIVE BACKGROUND NOTE

*Prepared by the International Bureau of WIPO*

1. The overall objective of the *ad hoc* expert group on genetic resources is, as indicated in the mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“IGC”) and the Decisions of the Forty-Third Session of the IGC (“IGC 43”), to address specific legal, policy or technical issues. The results of the work will be reported to and further addressed by the IGC.

2. The IGC Chair and Vice-Chairs identified the list of issues, taking into account the suggestions made by Member States. The *ad hoc* expert group will, therefore, address the following issues:

- Information systems;
- Disclosure requirements:
  - Subject matter
  - Trigger
  - Content
  - Sanctions/remedies;
- Interlinkages between information systems and disclosure requirements.

3. This Substantive Background Note provides some background information on the list of issues, and proposes some questions for the *ad hoc* expert group to consider.

### **Information systems**

4. Information systems related to genetic resources (GRs) are considered by many to have a key role to play to help patent examiners find relevant prior art and avoid the granting of erroneous patents.

5. The *ad hoc* expert group is invited to provide advice and analysis on the following policy questions relating to the establishment and functioning of an information system:

- minimum interoperability standards and structures of information systems content, such as especially periodicals, digital libraries, databases, repositories and distributed ledgers of information related to GRs and associated traditional knowledge (TK);
- the different types of information systems that already exist or are technologically feasible for maintaining legal certainty on IP and GRs;
- principles and modalities related to the sharing of relevant information related to GRs and associated TK, such as determination of the category of people authorized to access various categories of content of the information systems;
- the relationship between such information systems and the PCT Minimum Documentation or existing international database collaboration frameworks; and
- the type of legal or technical protection, if any, afforded to the information included in the system.

6. The *ad hoc* expert group is also invited to consider practical questions that would need to be addressed when considering the establishment and functioning of such information systems, such as in particular:

- the responsibility for establishing and maintaining such information systems;
- the involvement of various stakeholders in the establishment and maintenance of GRs information systems, such as:
  - centralized or distributed systems?
  - who leads the process?
  - who will document GRs?

- to whom will the IP rights that may arise belong?
- should indigenous peoples and local communities be consulted?
- the structure and content of the information systems;
- the form and formats in which that content would be expressed, stored and exchanged;
- its interoperability with other information systems both nationally and internationally; and
- the management of rights pertaining to the information systems.

### **Disclosure requirements**

6. Disclosure requirements are provisions which require intellectual property (IP)/patent applicants to include as part of the application several additional categories of information, such as the source or origin of GRs, as well as evidence of prior informed consent and a benefit-sharing agreement. While the IGC has been tasked to determine, as a policy matter, whether or not a disclosure requirement is needed at the international level, the *ad hoc* expert group is invited to discuss certain sub-issues relating to disclosure requirements.

#### Subject matter

7. A determination of the scope of subject matter covered by the instrument negotiated by the IGC is one important issue. Two questions the *ad hoc* expert group is invited to discuss are:

- While there is consensus that the instrument should apply to GRs, should it also apply to TK associated with GRs, noting that TK is not always associated with a GR. Furthermore, TK is addressed in a separate draft IGC text, which includes *inter alia* a proposed disclosure requirement.
- Should the instrument apply to any IP right or to patent rights only?

8. In relation to this issue, the *ad hoc* expert group needs to consider the use of terms, such as “genetic resources” (including the issue of whether “derivatives” should be included in the definition of GRs).

#### Trigger

9. The *ad hoc* expert group is invited to consider what should be the relationship or “link” between the subject matter of disclosure (e.g. GRs) and the claimed invention in order to trigger the application of an IP/patent disclosure requirement, such as “utilization of”, “directly based on” or any other terms.

10. The definitions of terms used to define the trigger, such as “utilization of”, “directly based on” or any other terms, are an additional issue to be considered.

#### Content

11. With respect to content, the *ad hoc* expert group is invited to consider what would need to be disclosed in the IP/patent application. For example, should it be the source of the GRs, their providing country, evidence of PIC, and/or evidence of benefit-sharing through mutually agreed terms?

12. In relation to this issue, the *ad hoc* expert group is invited to provide advice and analysis on the use of terms, such as “source”, “providing country”, and “country of origin”.

### Sanctions and Remedies

13. A legal and administrative question relating to disclosure requirements is to determine how situations of non-compliance should be addressed. Two questions the *ad hoc* expert group is invited to discuss are:

- What legal and administrative measures should be taken to address situations of non-compliance?
- Should such measures be able to affect the validity of a granted patent? If so, what would the permissible condition(s) for revocation be? Aside from revocation, what other options are there?

### **Interlinkages between information systems and disclosure requirements**

14. Some IGC participants are of the view that information systems only, without any additional disclosure requirements, would be the best way to achieve the desired objectives, while other IGC participants believe that information systems would only supplement disclosure requirements. Other participants are of the view that information systems and disclosure requirements would function in tandem and are complementary mechanisms to provide legal certainty for IP and GRs.

15. The *ad hoc* expert group is invited to discuss what are the interlinkages between information systems and disclosure requirements.

### **Other matters**

16. The *ad hoc* expert group is invited to identify any other legal, policy or technical issues that the IGC may need to address, as well as provide to the IGC any other analysis or advice or recommendations that it might wish.

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