

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

Geneva, June 24, 2018

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 Thirty-Fifth Session of the IGC (“IGC 35”), which took place from March 19 to 23, 2018, to address specific legal, policy or technical issues. The results of the work will be reported to and further addressed by the IGC.

2. In accordance with the Decisions taken at IGC 35, Member States, through the Regional Coordinators, were invited to suggest the specific issues to be considered by the *ad hoc* expert group. The IGC Chair and Vice-Chairs identified the list of issues from the suggestions made by Member States and provided them to the Regional Coordinators for comments. The *ad hoc* expert group will, therefore, address the following issues:

- Subject Matter, including scope (intellectual property or patents) and use of terms – genetic resources, traditional knowledge associated with genetic resources, derivatives;
- Disclosure:
 - Trigger and use of terms – directly based on, utilization.
 - Content and use of terms – source, providing country, country of origin.
 - Consequences of non-compliance – sanctions/remedies;
- Databases: technical issues such as safeguards and practical issues relating to the establishment and functioning of databases;
- Due Diligence Mechanisms: technical issues relating to the establishment and functioning of various kinds of such mechanisms.

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.

Subject matter

4. A determination of the subject matter of 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 genetic resources (GRs), should it also apply to traditional knowledge (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 intellectual property (IP) right or to patent rights only?

5. 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) and TK associated with GRs.

Disclosure

6. Disclosure requirements are provisions which require 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 needs 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.

Trigger

7. 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.
8. The definitions of “utilization of”, “directly based on” or any other terms for trigger are the other issues to be considered.

Content

9. 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 origin, evidence of PIC, and/or evidence of benefit-sharing through mutually agreed terms?
10. 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”.

Consequence of non-compliance

11. An important 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?

Databases

12. Databases and other information systems related to 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.
13. The *ad hoc* expert group is invited to provide advice and analysis on 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?
14. 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 databases, such as in particular:
 - the responsibility for compiling and maintaining such a database;
 - the structure and content of the database;
 - the form in which that content would be expressed;
 - its interoperability with other databases both nationally and internationally;
 - a determination of the category of people authorized to access the content of the database; and
 - the type of protection afforded to the information included in the database and the management of the rights pertaining to the database.

Due diligence mechanisms

15. Some IGC participants consider that due diligence mechanisms, such as databases, voluntary codes of conduct and guidelines are needed as defensive/complementary measures to assess and verify the access to GRs in accordance with applicable national and regional access and benefit-sharing systems.

16. The *ad hoc* expert group is invited to discuss what kinds of mechanisms might be needed, and technical issues relating to the establishment and functioning of such mechanisms.

Other matters

17. 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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