

## **Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore**

**Twenty-Fourth Session  
Geneva, April 22 to 26, 2013**

### **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**

*Document submitted by the Delegations of Canada, Japan, the Republic of Korea, the Russian Federation and the United States of America*

1. On March 25, 2013, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Mission of the United States of America to the United Nations Office and other International Organizations, on behalf of the Delegations of Canada, Japan, the Republic of Korea and the United States of America, to resubmit a "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", contained in document WIPO/GRTKF/IC/23/6, for discussion by the Twenty-Fourth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), as a working document under Agenda Item 5. The proposal was issued as document WIPO/GRTKF/IC/24/6, dated March 26, 2013.
2. On April 22, 2013, the International Bureau of WIPO received a request from the Mission of the United States of America to the United Nations Office and other International Organizations, to issue a revised version of the proposal. This revised version includes a new co-sponsor, the Delegation of the Russian Federation, and also some additional questions.

3. Pursuant to the request above, the Annex to this document contains the revised proposal referred to.

4. *The Committee is invited to take note of and consider the proposal in the Annex to this document.*

*[Annex follows]*

## 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

In the context of the IGC's work on mechanisms to address erroneous patents, and misappropriation of genetic resources (GR) and/or traditional knowledge associated with genetic resources (TKa) and in recognition of the commitment of WIPO Members to the Development Agenda Recommendations, the IGC requests the Secretariat with the involvement of the Chief Economist to undertake additional work as follows:

To update the WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge (Study No. 3, 2004), with information regarding disclosure requirements and related Access and Benefit Sharing (ABS) systems that have been implemented by WIPO Members. Having regard to the need for a fact based analysis of whether disclosure requirements and related ABS systems address concerns regarding erroneous patents and address misappropriation, without reducing the incentive to innovate or benefit sharing, the study should analyze:

1. Benefits received by provider countries due to disclosure requirements and related ABS systems;
2. Costs to national offices / jurisdictions resulting from a disclosure requirement; and
3. Costs associated with a disclosure requirement and related requirements (proof of prior informed consent (PIC) and mutually agreed terms (MAT)) to patent applicants.
4. Costs incurred by those applicants who have actually used a GR and/or TKa, and those who may not have used a GR and /or TKa but need to determine what is required of them in respect to the disclosure requirement.

In particular, the study should, at a minimum, analyze those national and regional intellectual property laws, regulations and procedures that require the disclosure of source or origin of a genetic resource and/or TKa and, for each country or region (as the case may be) with such a requirement:

- Determine how many disclosures of source/origin have been made by patent applicants.
- What documents are required to be presented to the PO when filing an application for patent?
- What guidelines is available to applicants so that they can understand the requirements placed upon them?
- How does the patent office verify this information (if it does)? At which stage of application is consideration of the decision on the appropriateness of disclosure of origin of GR is taken? At the stage of formal examination? Are the substantive examiners also involved in this process? If substantive examiners are involved, are there special instructions for the examiners ? What provision should they contain?
- Determine what additional requirements are imposed beyond disclosure of the source/origin. This may include for example, determining which authorities require proof of PIC and MAT.

- Where proof of PIC/MAT is required, the study should collect information on the procedures to be followed to obtain PIC/MAT. For example, is a copy of the contract of transfer of GR required or is any other document required? How would the Office handle a thick contract? How does the Office handle confidential commercial information that is in the contract?
- If the application presume using several GRs (or a genus of GRs)- is a disclosure required (or documents required) for each type? How does the office consider the situation where a genus of GRs is involved, is the applicant require to only disclose a representative GR within the class of the genus?
- If the GR is a wild plant, growing in a forest, in the field, in a city park or in on inventor's uncultivated land- What kind of document is needed for such a GR? Are there exclusions for wild growing flora?
- Is there any difference regarding disclosure requirements between national and foreign inventors?
- If a GR is obtained from a botanic garden, (ex situ origin country of origin of which is identified), but the features of the GR (the plant) have possibly already changed during the process of cultivation in the botanic garden, what should be indicated by applicant: the botanic garden or the country provided the botanic garden with this GR? If a contract (PIC or MAT) is required, who are the participants of the contract? Should it be concluded with the botanic garden or the country of origin?
- Where an applicant makes an error with respect to the disclosure requirement, how can an applicant correct the error? For example, can the applicant change the source, if without deceptive intent the applicant discloses the source as one country when it was another? Does the Office consider the name of the source new matter, and thus require the patent application to be re-filed?
- For each Office with a disclosure requirement, determine the average processing time of a patent application, in which disclosure of origin was required, as well as the average processing time of all applications.
- Where disclosure of the source/origin was required and was made, was the genetic resource: directly accessed (*in situ*); accessed from a seed bank or other depository; or purchased as a commodity?
- Since the imposition of a disclosure requirement, has the number of patent applications filed in this area of technology increased or decreased? If it has decreased, have applicants who may have previously filed a patent application decided to maintain their inventions as trade secrets rather than filing a patent application?
- If your system requires the payment of monetary benefits, please explain the value of those monetary benefits.
- What quantity of non-monetary benefits have been received since the imposition of a disclosure requirement and related ABS system? How many ABS agreements have been signed since then?
- What information on the origin of a GR presented by the applicant is published during the publication of the application and/or patent?
- How will the information on the origin of a GR be used in the future?

- Will information received as a result of a disclosure requirement be added to a database for search purposes?
- For WIPO Member States with a disclosure requirement, how many ABS agreements have been signed since imposition of the disclosure requirement?
- If there have been ABS agreements, do the agreements remind the recipients of GRs and/or TKa of the need to disclose the source/origin of the same when seeking intellectual property protection?
- Are criminal or civil sanctions and/or fines imposed for failure to disclose the source or origin of a GR and/or TKa in a patent application? If so, describe the situations in which these sanctions were imposed and what the sanctions were, and describe any appeals and decisions of the relevant appellate body.
- If there was a disclosure requirement, did the Office also require disclosure of prior art that is material to the patentability of the invention? If not, what was the basis for having a disclosure requirement of the source of GR and/or TKa, but not on prior art that is material to patentability? How did disclosure improve examination?
- How often was the source or origin material to patentability? For countries with an IP law that required disclosure, was there also a national law related to misappropriation or misuse of GR and/or TKa?
- Does the Office provide a mechanism for third parties to submit information material to patentability to a patent application?
- Are there any other than mechanism for third parties to submit information material to patentability? Does the Office provide a mechanism to oppose a patent (pre or post grant)? If yes, would it be reason for opposition in case of lack of compliance with the disclosure requirement?
- How does the WIPO Member State ensure that PIC or MAT were satisfied where the disclosure requirement does not apply?
- Does the IP Office have any other relevant experience to share?

This study should aim to be completed as soon as possible so that delegations are able to make an informed decision on our work on GRs and/or TKa.

[End of Annex and of document]