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

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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, Norway, the Republic of Korea, the Russian Federation and the United States of America

INTRODUCTION

1. On February 23, 2018, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Permanent Mission of the United States of America to the World Trade Organization (WTO), on behalf of the Delegations of Canada, Japan, Norway, the Republic of Korea, the Russian Federation 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", as contained in document WIPO/GRTKF/IC/34/11, for discussion by the Thirty-Fifth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).
2. Pursuant to the request above, the Annex to this document contains the proposal referred to.

3. *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 address concerns regarding erroneous patents and misappropriation, and whether disclosure requirements affect the incentive to innovate, the study should analyze:

1. What impact disclosure requirements have with regard to secure compliance with ABS-system?
2. Costs and burdens to national offices/jurisdictions resulting from a disclosure requirement; and
3. Costs and burdens associated with a disclosure requirement to patent applicants, both for 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;
4. What impact disclosure requirements have with regard to the credibility of the patent system among different stake holders and the society at large?

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 is the trigger(s) for the duty to disclose information of the source/origin?
- What information and documents are required to be presented to the PO when filing an application for patent?
- What is the situation where the applicant does not know the source/origin? Can the applicant in such cases fulfill the disclosure obligation by providing information of the immediate source where the applicant/inventor have received GR and/or Tka from, state that he or she not know the source/origin or must he or she conduct further investigations to provide the required information?
- What guidelines are available to applicants so that they can understand the requirements placed upon them?

- Does the patent office verify this information, and, if it does, in what way? At which stage of application is consideration of the decision on the appropriateness of disclosure of origin of GR 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 are those instructions?
- Determine what additional requirements are imposed beyond disclosure of the source/origin. This may include for example, determining which authorities require information or 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 required 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 an 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 the 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 required, as well as the average processing time of all applications in the relevant field of technology.
- 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?
- If your system requires the payment of monetary benefits, please explain the value of those monetary benefits.
- To the extent that such information is available within your territory, 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?

- Has there been an increase in the number of ABS agreements signed since the imposition of a disclosure requirement?
- Are there any examples where misappropriation has been revealed due to disclosure of source/origin etc. of GR and/or TKa in patent applications?
- 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?
- 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.
- Can failure to disclose lead to refusal of the application or that the handling of the application is stopped?
- Can failure to disclose lead to a granted patent being invalidated or rendered unenforceable?
- How do disclosure systems affect (including, but not limited to, with regard to any ABS requirements) entities acquiring patent rights from the original applicant, wherein the patent contains GRs/TKa disclosed by this original applicant, prior to the invention being marketed?
- What are the economic (i.e., as opposed to, e.g., administrative) costs to applicants in cases where their refusal or failure to disclose GRs/TKa leads to the rejection of an application or the invalidation of a patent (or claims thereof)?”
- 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? Does 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]