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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Sixteenth Session
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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL
PROPERTY AND GENETIC RESOURCES: SUBMISSION BY BRAZIL

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

“invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee.” [...]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of Brazil submitted a document entitled “Brazilian Policy regarding Intellectual Property and Genetic Resources” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

BRAZILIAN POLICY REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES

This paper describes the current state of the Brazilian system for the protection of biodiversity as far as intellectual property rights are concerned, in particular access to and disclosure of the origin of genetic resources and associated traditional knowledge.

The Brazilian legal framework enshrining the principles of prior informed consent – PIC, mutually agreed terms – MAT, and access and benefit sharing – ABS includes the following pieces of legislation: a) Law 9.279/96 “Industrial Property Law”; b) Provisional Measure 2.186-16, of 2001; c) decisions by the Industrial Property National Institute (INPI) and by the Managing Council of the Genetic Patrimony (CGEN). The executive bodies of the system are the INPI itself - which is the Brazilian patent office - as well as the CGEN.

The CGEN in turn is a collective inter-ministerial body that holds monthly meetings. It is chaired by the Ministry of Environment. Its membership includes representatives of other 19 bodies or entities of the Federal Administration, all of them holding the right to vote: Ministry of Environment; Ministry of Science and Technology; Ministry of Health; Ministry of Justice; Ministry of Agriculture, Livestock and Supply; Ministry of Defense; Ministry of Culture; Ministry of External Relations; Ministry of Development, Industry and Foreign Trade; Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA); Research Institute Botanical Garden of Rio de Janeiro; National Council for Scientific and Technological Development (CNPq); National Institute for Amazon Research; Emílio Goeldi Museum of Pará; Brazilian Agricultural Research Corporation (Embrapa); Oswaldo Cruz Foundation; National Foundation for Indigenous People (Funai); INPI and Palmares Cultural Foundation. INPI, therefore, takes part in all CGEN deliberations.

Other than these regular members, some representatives of civil society hold a standing invitation to CGEN meetings with the right to speak, such as the Brazilian Association of Biotechnology Companies (ABRABI) and the Brazilian Society for the Advancement of Science (SBPC).

Researchers wishing to have access to the national genetic patrimony or associated traditional knowledge with a view to conducting scientific research, technology development or bio-prospection must request prior authorization to CGEN or to a certified agent. Whenever access to the national genetic patrimony results in the filing of a patent request, applicant must notify to the INPI the number of the corresponding authorization as well as the origin of the genetic patrimony or associated traditional knowledge. In the cases where either a) access occurred prior to the coming into force of Provisional Measure 2116-16 (June, 30th 2000) or b) access to the national genetic patrimony did not occur; applicants must simply declare to INPI that access did not take place.

(a) Procedure before CGEN

According to the applicable national legislation, researchers wishing to be granted access to genetic resources and/or associated traditional knowledge must present to the CGEN

a list of documents among which are (i) a research project; (ii) proof of experience in research projects; (iii) proof of technical qualification; (iv) information regarding the destination of the samples; as well as (v) “a contract on the utilization of the genetic patrimony and sharing of benefits”.

Contracts referred to under item (v) must contain an explicit provision regarding a proposed scheme for sharing of benefits. This may take different forms, such as profit sharing; payment of royalties; access to and transfer of technology; licensing of products or processes; and human resources training.

Applications are analyzed in accordance with the provisions of decisions n° 34 (associated traditional knowledge) and 96 (access to genetic patrimony) of the CGEN. The evaluation process is divided into two phases: (i) a preliminary analysis; and (ii) final evaluation. In both cases, after the applicant has filed the request, the Executive-Secretariat of CGEB shall conduct a preliminary evaluation in 30 days to ascertain that all requisites mentioned under MP 2.286-16/2001 and Decree 3945/2001 are met. When applicants have failed to fulfill any legal requisites, a delay is granted (120 days to applications under traditional knowledge provisions; and 180 to access to genetic resources provisions) to allow them to comply with the relevant provisions before the application is dismissed.

If the application fulfills all legal requisites for presentation it will be subjected to the preliminary analysis (phase “i”) to be undertaken by the Evaluation Committee of Applications (CAP). That Committee is made up by two or more “rapporteurs” “ad hoc” (anthropologists, biologists, chemists, etc.) who are experts in the subject. Experts’ reports serve as a basis for the final evaluation of the Council. No more than 70 days must elapse between the preliminary analysis and the issuance of the reports. The presentation of the reports is the last step in the “preliminary analysis” phase.

The preliminary phase may take up to 4 months approximately if the applicant does not present additional information or recourse during the process. If that happens, the preliminary phase may take up to 11 months approximately (applicants have a maximum of seven months available for presenting additional pieces of information or recourse).

The final evaluation phase initiates with the appointment of one counselor as “rapporteur” of the process in the plenary meeting. The other counselors receive a summary of the application process prepared by the Executive Secretariat. After the report is read, all counselors deliberate on the matter and may request to withhold the relevant documentation for further analysis. In case a positive decision is taken, the Executive Secretariat will issue an access authorization.

To sum up: the “preliminary phase” and the final “evaluation phase” altogether can be concluded in less than three months when applicants provide all relevant documents required by law. The procedure before the GCEN protects moreover non-disclosed information as it provides for secrecy in analysis proceedings.

(b) Procedure before the INPI

According to Resolutions 207 and 208 of INPI and 34 of CGEN, all of them enacted in April 2009, whenever a patent request is the result of an authorization of access to the national genetic patrimony such request must contain the number of the correspondent authorization.

This information may be provided anytime before the beginning of the patent examination procedure.

If evidence is found that the research leading to the patent request may have accessed genetic patrimony, and the applicant did not provide information on access authorization, the competent authority will request the applicant to provide such information within 60 days. The applicant shall provide a written form with the number of the authorization or declare that there was no access to the genetic patrimony. If the applicant fails to meet this deadline the request will be dismissed (Art. 34, II, Law 9.279/96).

If authorities verify that applicants have provided false information regarding access to the genetic patrimony, other than the penal responsibility they may incur in, the sharing of benefits will necessarily be governed by Articles 26 and 30 of Provisional Measure 2.186-16. According to Article 26, violators are subject to compensations amounting to 20% of the gross income obtained in the commercialization of the product or of the royalties obtained by violators from third parties as a result of the licensing of products, processes or of the use of technology. According to Article 30, as regulated by Decree 5.459/2005, violators are subjected to fines.

(c) Evolution of the Brazilian system

To improve the current system, the Brazilian Government is currently discussing a draft Presidential Decree that will establish a specific procedure to regularize accesses which occurred without prior authorization by the CGEN. Presently, administrative fines are due when access occurs without authorization. In the project under discussion, such fines would not apply or would be reduced when applicants filled voluntarily a request to regularize the research. Patents request pending the regularization of access are suspended until the publication of the Decree establishing the specific procedure before CGEN.

In 15 September 2009, the Ministry of Environment and the Ministry of Science and Technology signed a Technical Cooperation Agreement which grants the National Council for Scientific and Technological Development (CNPq) the competence to authorize access to the genetic patrimony for research purposes. The partnership between the two Ministries aims at accelerating the administrative procedures in those requests that do not involve access to associated traditional knowledge.

[End of Annex and of document]