QUESTIONNAIRE ON VARIOUS REQUIREMENTS FOR DISCLOSURE RELATING TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

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

JULY 2002

1. At its third session, held in Geneva from June 13 to 21 2002, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the "Committee"), approved the invitation issued to WIPO in paragraph 4 of Section C of Decision VI/24 of the Conference of the Parties to the Convention on Biological Diversity (CBD) and transmitted by the Executive Secretariat of the CBD.[1] The invitation, as accepted by the Committee, was phrased as follows:

> "[The COP] [i]nvites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:
>
> (a) Genetic resources utilized in the development of the claimed inventions;
>
> (b) The country of origin of genetic resources utilized in the claimed inventions;
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> (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
>
> (d) The source of associated traditional knowledge, innovations and practices; and
>
> (e) Evidence of prior informed consent."

2. The Committee agreed upon a work schedule (proposed in document WIPO/GRTKF/IC/3/12) that would permit a technical study to be prepared and consulted upon in time for it to be transmitted as a technical information document to the seventh COP. The work schedule comprises the following steps:

> "1. *Intersessional Period between the third and fourth sessions of the Committee* (June to December 2002): A questionnaire could be sent to Committee members regarding the issues identified for study in the invitation contained in paragraph 4, Section C, of Decision VI/24.

[1] See paragraph … of the Report …The decisions made at the sixth Conference of the Parties to the CBD that are of relevance to WIPO were described in document WIPO/GRTKF/IC/3/12 ("Certain Decisions of the Sixth Conference of the Parties to the Convention on Biological Diversity").

"2. *Fourth session of the Committee* (December 2002): A draft technical study, including a compilation of responses received from Committee members and a draft analysis of those responses, could be presented to the Committee for its consideration and comments.

"3. *Intersessional Period between the fourth and fifth sessions of the Committee* (December 2002 to June 2003): Subject to the decisions of the Committee upon consideration of the draft technical study, the comments received from the Committee members could be incorporated into the draft study in order to produce the revised technical study.

"4. *Fifth session of the Committee* (June 2003): The revised technical study could be presented to the Committee for consideration and for transmission, if agreed, to the Twenty-Ninth Session of the WIPO General Assembly.

"5. *Twenty-Ninth Session of the WIPO General Assembly* (September 2003): The revised technical study, if so agreed by the Committee, could be presented to the General Assembly for its consideration. If so decided by the WIPO General Assembly, the final technical study could be transmitted as a technical information document to the seventh COP of the CBD, which will take place in Kuala Lumpur, Malaysia, in the first quarter of 2004."[2]

3. The Committee also accepted the suggestion made by the delegations of the Dominican Republic, Venezuela, Peru, Bolivia and Sri Lanka that the questionnaire referred to in step one of the schedule be submitted to Members for comments prior to its general distribution. The Secretariat accordingly engaged in informal consultations with Members on a draft list of questions in July 2002.

4. Following these consultations, the Annex of the present document contains a list of questions aimed at eliciting aspects of national laws and experience that have bearing on the requested technical study. The initial draft of the study will be greatly facilitated by responses to this questionnaire from a wide range of Members. Members are therefore invited to provide their responses to the questionnaire by September 30, 2002. This timeframe is proposed in order to allow for the Secretariat to take account of Members' responses in the preparation of the initial draft study which is required to be ready by early October 2002 in order to be circulated in advance of the IGC meeting on December 2002.

[Annex follows]

[2] Document WIPO/GRTKF/IC/3/12, paragraph 3.

ANNEX

QUESTIONNAIRE CONCERNING REQUIREMENTS ON PATENT APPLICANTS TO DISCLOSE THE ORIGIN OF GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND PRIOR INFORMED CONSENT

Background to the Questionnaire

1. This questionnaire touches on a range of issues concerning genetic resources and traditional knowledge (TK), and especially the mechanisms for ensuring prior informed consent for access to such resources and any associated TK.

2. At the national level, these issues are dealt with, in many cases, through regulatory access regimes, contract law and licenses or other approval mechanisms. At the international level, the Convention on Biological Diversity (CBD) specifies that, "access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources." Countries have developed a range of legal regimes and specific legal tools, such as contracts and permits, which govern access to genetic resources. Various forums associated with the CBD have given especial consideration to these mechanisms. In this connection, the Conference of Parties (COP) of the CBD recently adopted the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.'[3] A number of case studies on mechanisms for access and benefit-sharing are available at http://www.biodiv.org/programmes/socio-eco/benefit/, together with other material about such mechanisms.

3. Many countries have introduced direct ways of regulating access and benefit-sharing through specific regulation, and contracts, permit schemes and similar tools have also been widely employed. A number of countries have recently established legal requirements for patent applicants to furnish information relating to genetic resources and/or TK relevant to the inventions claimed in their patent applications. This approach has not been followed by other countries, and certain concerns have been expressed about practical and legal issues raised by this approach. Accordingly there is an ongoing international dialogue about the need, value, implications and legal basis of mechanisms specifically linking access-related issues with the patent system.

4. This questionnaire aims to obtain information about existing national practices to provide factual input into this international dialogue. It therefore seeks input on two distinct regulatory requirements:

(a) Regulation of access to genetic resources and associated TK, including provisions for indicating the source of such material, and prior informed consent for access to it; and

(b) Disclosure requirements in connection with the obtaining of intellectual property rights.

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[3] UNEP/CBD/COP/6/20, decision VI/24

5. These two sets of requirements can possibly overlap in practice, even though they have different objectives. For instance, the description of an invention to enable a person skilled in the art to replicate the invention may entail giving an account of how genetic resources were obtained. Similarly, it may be necessary to disclose existing TK which is known to the applicant, on the basis that it is known prior art relevant to the claimed invention.

6. The following questions relate to existing legal provisions in national or regional law, although they may also apply to draft laws or other mechanisms in the course of development. This may include, as appropriate, the patent legislation that applies in your country, including national or regional patent law, legislation on environmental matters, and other legislation or administrative requirements, such as implementing regulations and administrative guidelines.

7. To some extent the questions relate to general patent law. Under national and regional patent law and related laws (and in line with established international standards), patent applicants are typically only required to furnish information in three general areas:

(a) Information that enables a person skilled in the art to carry out the claimed invention, and in some laws the disclosure of the best mode of carrying out the invention known by the inventor at the relevant date. For inventions involving a new microorganism, the disclosure obligation may also entail deposit of the microorganism itself;

(b) Other information relevant to the determination of novelty, inventive step or non-obviousness, and capability of industrial application or utility of the claimed invention, including search reports, and other known prior art; and

(c) Administrative or bibliographic information relevant to the claimed patent right, such as the name of the inventor, address for service, details of priority documents, etc.

QUESTIONNAIRE [4]

Contact Details

Name:

Title:

Office/Organization:

Member State:

Address:

Email:

Telephone:

Facsimile:

Question 1: Please identify any national and/or regional laws and/or regulations which regulate access to genetic resources and/or traditional knowledge (TK) in your national territory. Concerning these laws or regulations, please indicate:

(a) What genetic resources or TK the law and/or regulation applies to;

(b) What requirements are stipulated for obtaining prior informed consent or determining the conditions of access, such as benefit-sharing arrangements;

(c) Whether a distinction has been made between access for non-profit research and access for commercial purposes;

(d) Any requirements for disclosure, reporting or otherwise monitoring of access to genetic resources and associated TK; and

[4] Responses to this questionnaire may be sent, preferably by email, to the Global Intellectual Property Issues Division at grtkf@wipo.int or at WIPO, 34, chemin des Colombettes, 1211, Geneva 20 (Switzerland), Fax 41 22 338 8120.

(e) How these laws or regulations have been implemented in your national territory.

Question 2: Please itemize the information that a patent applicant is required to provide in the course of gaining a patent with effect in your country, and indicate the requirements for disclosure of the invention in a patent application. Please indicate the consequence of failure to meet such requirements.

Question 3: Is there a *specific* requirement, in any law and/or regulation that already applies to your country, or in any pending legislation, for a patent applicant to disclose:

- ☐ (a) Information about any genetic resources used in the development of the claimed invention;
- ☐ (b) The geographical origin (including country of origin) of genetic resources used in the claimed invention;
- ☐ (c) An indication or evidence of prior informed consent given by those granting access to genetic resources used in the development of the claimed invention;
- ☐ (d) The nature or source of associated TK used in isolating or distinguishing the genetic resources used in the claimed invention;
- ☐ (e) The nature or source of associated TK used in the development of the claimed invention; and
- ☐ (f) An indication or evidence of prior informed consent given by holders of TK that was used in the development of the claimed invention?

If your answer to all of questions 3(a) to (f) is 'no,' there is no need to answer questions 4 to 10; please go on to answer questions 11 to 14.

Question 4: Do the disclosure or information requirements covered by your answers to question 3 apply only to patent applications for inventions in a particular field or category of technology, or do they apply to patent applications for any inventions, regardless of the nature of the technology involved? Do the requireements apply equally to patent applications by domestic and foreign nationals?

Question 5: Are there particular guidelines defining the relationship that must exist between the genetic resources or TK and the claimed invention in order to trigger the obligation for disclosure; for example, in the case that access to the genetic resources is necessary for carrying out the invention, or the TK was integral to the invention or was known prior art relevant to the invention?

Question 6: If there is a requirement to disclose the geographical origin of genetic resources, as specified in question 3(b), does it apply only if the genetic resources have been obtained within the legal jurisdiction or territory of your country?

Question 7: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and 3(f), does it apply only if the granters of access to genetic resources or holders of TK are nationals of your country?

Question 8: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and (f), does it specify the required form of such evidence?

Question 9: What are the consequences for the patent applicant or patent holder of any failure to meet any of the requirements covered in your answers to question 3? What means are available for the applicant or patent holder to remedy any failure to meet the requirement(s)? If the initial patent application, as lodged by an applicant, fails to meet these requirements, until what time can this information be subsequently provided?

Question 10: Is all information provided in accordance with these requirements published or available for public inspection, or are there mechanisms for preserving confidentiality of such material; for example, in relation to a confidential contract by which prior informed consent is given?

Question 11: Are there any analogous requirements (similar to questions 3(a)-(f)) in the law that applies in your country for other registered industrial property rights, such as utility models, petty patents, trade marks, or industrial designs?

Question 12: This question concerns the conventional patent disclosure requirements that apply in your country, such as a requirement for the invention to be disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to carry it out, or a requirement to disclose the best mode known to the inventor of carrying out the invention.

(a) Are there circumstances in which these requirements have actually obliged, or may potentially oblige, a patent applicant to disclose any of the categories of information set out in questions 3(a) to (f)?

(b) Do you have information about any particular cases in which patent applicants have disclosed any of the categories of information set out in questions 3(a) to (f) in the normal course of meeting conventional patent disclosure requirements?

Question 13: What provisions apply in the event that information provided in a patent application in your country is false or misleading?

Question 14: If possible, please provide excerpts from or summary details of any legislative provisions, or judicial or administrative findings, that relate to your answers to any of the above questions. (Brief excerpts or quotations would be preferred over full texts of laws or regulations).

[End of questionnaire]