

WIPO/GRTKF/IC/17/INF/10 ORIGINAL: ENGLISH DATE: SEPTEMBER 15, 2010

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

Seventeenth Session Geneva, December 6 to 10, 2010

COMPILATION OF COMMENTS ON WIPO/GRTKF/IC/16/7
"SUBMISSION BY AUSTRALIA, CANADA, NEW ZEALAND, NORWAY AND
THE UNITED STATES OF AMERICA"

Document prepared by the Secretariat

- On May 6, 2010, the Delegations of Australia, Canada, New Zealand, Norway and the United States of America submitted a working document, which was issued as WIPO/GRTKF/IC/16/7, in relation to agenda item 10 ("Genetic Resources") for the sixteenth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the IGC").
- 2. At its sixteenth session, held from May 3 to 7, 2010, the Committee "invited IGC participants to provide written comments on document WIPO/GRTKF/IC/16/7 before July 31, 2010 and requested the Secretariat to compile such comments in an information document [...]".
- Further to the decision above, the WIPO Secretariat issued a circular to all IGC
  participants, dated June 23, 2010, recalling the decision and inviting participants to make
  their comments before July 31, 2010.

- 4. Pursuant to the above decision, written comments were received from the following Member States: Chile, Colombia and the Russian Federation; and the following accredited observers: Association des Étudiants et Chercheurs sur la Gouvernance des États Insulaires (AECG), the Biotechnology Industry Organization (BIO) jointly with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and the Eurasian Patent Organization (EAPO).
- 5. The comments are reproduced in the form received and contained in the Annexes to this document.
  - 6. The IGC is invited to take note of the comments in the Annexes to this document.

[Annexes follow]

#### ANNEX I

#### Comments made by the Delegation of Chile

DRAFT Genetic Resources Objectives and Principles

#### Objective 1:

 Ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for access, use and benefit-sharing.

#### Principles:

- Sovereign states have the authority to determine access to genetic resources in their jurisdiction.
- Subject to national legislation, persons accessing traditional knowledge associated with genetic resources from the knowledge holder and applying that knowledge in the development of an invention should obtain the approval from the knowledge holder and seek their involvement.

## Comment:

It appears to us to be a fundamental general principle which, on the one hand, is designed to cover the concern with avoiding illegal access to genetic resources and associated traditional knowledge and, on the other, confirms the sovereignty of each State in defining the procedures and means to achieve this.

With regard to the second principle, it would be relevant to indicate that the use of traditional knowledge relating to genetic resources must be obtained from its owner, given that the current wording may imply that in those cases in which it was obtained by other means, there is no obligation for benefit-sharing.

As regards the final phrase "...the knowledge holder and seek their involvement ...": we would be grateful for clarification as to the types or degrees of participation which those making the proposal are considering. This is above all because reference is made to involvement in the work and not the sharing of the benefits derived therefrom. We consider that without prejudicing the fact that the wording must be broad, so as to cover various options, it must also be clear.

#### Objective 2:

 Prevent patents being granted in error for inventions that are not novel or inventive in light of genetic resources and associated traditional knowledge

## Principles:

- Patent applicants should not receive a monopoly on inventions that are not new or inventive.
- The patent system should provide certainty of rights for legitimate users of genetic resources.

#### Comment:

This objective appears to us to be of the greatest relevance for the intellectual property system. Achieving a situation where patent offices have high standards of assessment for the granting of rights is beneficial not only in relation to the subject matter with which we are dealing but also on a general level.

Furthermore, it is of the greatest relevance to promote the filing of patent applications with a finalized and complete indication of all the supporting technical information so as to understand perfectly the prior art and elements on which the specific innovation develops. This undoubtedly promotes the granting of better quality rights and, in the long term, provides greater certainty for their owners.

As to genetic resources, our discussions on this subject should ideally be designed to define minimum elements for consideration in the access to such resources.

## Objective 3:

 Ensure patent offices have available the information needed to make proper decisions on patent grant.

## Principles:

- Patent offices must have regard to all relevant prior art when assessing the patentability of an invention.
- Patent applicants must indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention.
- There is a need to recognize that some holders of TK may not want their knowledge documented.

## Comment:

We consider that in this area having shared databases would make the examination process more efficient and would avoid duplication of work, as well as providing an incentive for joint work and communications between the different offices. Methods facilitating these principles should be included in order to give those principles specific form.

However, we also believe it is necessary to define how it would be possible to guarantee to knowledge holders that their interests will be respected so that the knowledge is ready for incorporation in a database.

## Objective 4:

Relationship with relevant international agreements and processes.

#### Principles:

- Respect for and consistency with other international and regional instruments and processes.
- Promotion of cooperation with relevant international and regional instruments and processes.

#### Comment:

This objective is central, considering the large number of fora in which subjects more or less related to the theme of genetic resources are discussed. On the other hand, it is obvious that the most effective solution will be that agreed within the international community, providing a general system of minimum principles shared by all.

## Objective 5:

Maintain the role of the IP system in promoting innovation.

## Principles:

- Maintain the role of the IP system in promoting innovation.
- Promote certainty and clarity of IP rights:
- Protect creativity and reward investments made in developing a new invention.
- Promoting transparency and dissemination of information by publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.

## Comment:

Within the second principle we highlight the importance of public access to technical information relating to inventions in that it allows standards of knowledge to be raised and different ways of transferring technology to be promoted.

## General final comment:

As was demonstrated at the session in which the proposal was put forward, Chile considers that the document submitted by the Delegations of Australia, Canada, New Zealand, Norway and the United States of America constitutes an excellent starting point from which to work on the subject of genetic resources.

Apart from the first objective, the remaining objectives appear to be drafted in quite general terms and we urge that through dialogue we should achieve a greater level of specification in defining those terms. We believe that it is important that at least one of the objectives deals specifically with GRs and their particular features. Chile will work on alternatives to be included in that regard at the following session.

[Annex II follows]

# ANNEX II Comments made by the Delegation of Colombia

PARAGRAPHS IN THE SUBMISSION (text in bold and brackets has been added by the Delegation of Colombia)		RECOMMENDATIONS BY THE DELEGATION OF COLOMBIA	
Objective 1:			
-	Ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for access, use and benefit-sharing.	With regard to objective 1, it is necessary to specify that the conditions for access and benefit-sharing should be based on mutually agreed terms, prior informed consent and the national	
Principles:		legislation.	
_	Sovereign states have the authority to determine access to genetic resources in their jurisdiction.		
-	Subject to national legislation, persons accessing traditional knowledge associated with genetic resources from the knowledge holder and applying that knowledge in the development of an invention should obtain the [prior] approval from the knowledge holder and seek their involvement [and reach an agreement on benefit-sharing].		
Objective 2:			
_	Prevent patents being granted in error for inventions that are not novel or inventive in light of genetic resources and associated traditional knowledge.	With regard to objective 2, it is necessary to state expressly that patents will not be granted in cases of misappropriation or misuse of genetic	
Principles: resources and associated traditional knowledge.		resources and associated traditional	
_	Patent applicants should not receive a monopoly on inventions that are not new or inventive.	Mowiedge.	
_	The patent system should provide certainty of rights for legitimate users of genetic resources.		
Objec	Objective 3:		
_	Ensure patent offices have available the information needed to make proper decisions on patent grant.	With regard to objective 3, we consider that it should be stated that intellectual property systems should contribute to the application of national standards on access.	

## Principles: Patent offices must have regard to all relevant prior art when assessing the patentability of an invention. Patent applicants must indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention. There is a need to recognize that some holders of TK may not want their knowledge documented. Objective 4: Relationship with relevant international agreements and processes. Principles: Respect for and consistency with other international and regional instruments and processes. Promotion of cooperation with relevant international and regional instruments and processes. Objective 5: Maintain the role of the IP system in promoting innovation. Principles: Maintain the role of the IP system in promoting innovation. Promote certainty and clarity of IP rights. Protect creativity and reward investments made in developing a new invention. Promoting transparency and dissemination of information by publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.

[Annex III follows]

#### ANNEX III

#### Comments made by the Delegation of the Russian Federation

At the Sixteenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the Committee (IGC) decided that Committee participants would submit to the Secretariat written comments on document WIPO/GRTKF/IC/16/7 "Submission by Australia, Canada, New Zealand, Norway and the United States of America" for their further discussion.

The above document, which relates to the Committee (IGC) agenda item "Genetic resources", constitutes a draft of the objectives and principles relating to genetic resources.

In the document five objectives are put forward, together with principles which must be applied when trying to achieve the corresponding objectives.

The Russian Federation supports the proposed draft objectives and principles.

We consider that all the objectives are interlinked and aimed at resolving issues relating to the enforcement of intellectual property rights, subject to conditions of fair and equitable sharing of benefits resulting from the use of genetic resources.

On the one hand, the objectives and principles provide for the observance by inventors using genetic resources and any associated traditional knowledge of any conditions for access, use and fair benefit-sharing (Objective No. 1), and on the other hand are aimed at maintaining the role of the IP system in promoting innovation (Objective No. 5).

One of the most important conditions is the provision of Objective No. 2 – "Prevent patents being granted in error for inventions that are not novel or inventive in light of genetic resources and associated traditional knowledge. Patent applicants should not receive a monopoly on inventions that are not new or inventive". The logical continuation of the fulfillment of this condition is the need to "Ensure patent offices have available the information needed to make proper decisions on patent grant", put forward in Objective No. 3.

Therefore, in our opinion, one of the priorities of the Committee's work is cluster "A" (see document WIPO/GRTKF/IC/16/6), relating to the protection of genetic resources and including an analysis and broader recognition of other sources of already disclosed information on genetic resources, i.e. the compilation of an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources.

An effective solution for this purpose will, as previously noted in the statements given by Committee participants, be the creation of a database for genetic resources and traditional knowledge, which will be available to experts in any country in order to avoid patents being granted in error for genetic resources and associated traditional knowledge.

An indisputable condition when doing work on the agenda item "Genetic resources" is also the "relationship with relevant international agreements and processes" – Objective No. 4, in achieving respect for and consistency with other international and regional instruments and processes, and also the promotion of cooperation with relevant international and regional instruments and processes, in particular within the Convention of Biological Diversity (CBD) and the Food and Agriculture Organization (FAO). The importance of such cooperation has been noted at Committee sessions.

[Annex IV follows]

#### ANNEX IV

Comments made by the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

We would like to express our appreciation to the delegations of Australia, Canada, New Zealand, Norway and the United States of America for the document WIPO/GRTKF/IC/16/7, which provides draft objectives and principles for the topic of genetic resources. Although there has been considerable progress made in the IGC on issues relating to genetic resources, we recognize that this progress is not enough. We believe that document WIPO/GRTKF/IC/16/7 is an important initial step in moving toward a more robust and substantive work program on this issue. Our view is that an agreed set of objectives and principles constitutes an important building block for further, more substantive work.

It is important to note, however, that we view this draft list as not yet complete and merely as a basis for discussion. We believe that inclusion of objectives that recognize the importance of clarity, transparency and legal certainty for companies, particularly small and medium sized enterprises, will greatly improve the document.

To that end, we suggest that the following objectives and principles be considered by the IGC for addition to the list:

## Objective:

 Address matters concerning relevant intellectual property rights related to genetic resources, where appropriate, in mutually agreed terms governing the transfer of those resources in a clear and transparent fashion.

#### Principles:

- The patent system and the access and benefit-sharing system are mutually supportive, and should be implemented in a manner reflecting that relationship.
- Provisions relating to the access of genetic resources and benefit-sharing therefrom should be reflected in mutually agreed terms reached at the time of access, and may include provisions concerning intellectual property.

#### Objective:

 Ensure that all requirements related to the acquisition and use of genetic resources in national laws are made publicly available in a transparent fashion.

## Principles:

- Requirements concerning access and benefit-sharing of genetic resources should be clear, transparent and consistent with legal certainty.
- Information concerning requirements relating to access and benefit-sharing of genetic resources should be made widely available and easily understood.

[Annex V follows]

#### ANNEX V

## Comments made by the Eurasian Patent Organization (EAPO)

The Eurasian Patent Organization (EAPO) hereby submits its comments relating to document WIPO/GRTKF/IC/16/7 "Submission by Australia, Canada, New Zealand, Norway and the United States of America", made at the sixteenth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF), held in Geneva from May 3 to 7, 2010.

## Objective 1:

Instead of the concept "Any conditions for access", we propose using the term "Specific conditions for access".

Regarding Principle 2, it should be specified which consent from the knowledge holder is being referred to. It is rather a question of consent from the holders of genetic resources and associated traditional knowledge for their use.

#### Objective 2:

Word as follows:

"Prevent patents being granted in error for inventions relating to genetic resources and associated traditional knowledge, that are not novel or inventive".

Principle 1 should be clarified as follows:

"Patent owners should not be granted exclusive rights... (text continues)".

We propose moving this to the section "Principles" of Objective 1, i.e. making it the second principle of Objective 1 from Objective 2, principle 2 (the patent system should provide certainty of rights for legitimate users of genetic resources and associated traditional knowledge). In our opinion, it is more closely connected with Objective 1.

## Objective 3:

Word as follows:

"Ensure patent offices have available the information on genetic resources and associated traditional knowledge needed to make proper decisions on patent grant".

Principle 1 should be clarified as follows:

"Patent offices must take into account all relevant prior art when assessing the patentability of an invention".

In Principle 2 after the words "Useful for the understanding" add the words "Of the essential features of the invention" (useful for the understanding of the essential features of the invention).

Principle 3 should be worded as follows:

"There is a need to recognize that some holders of genetic resources and associated traditional knowledge may not want their knowledge documented".

## Objective 4:

The opening wording should be as follows:

"Guarantee a relationship ...".

## Objective 5:

In this section reference appears to be made to two objectives, since the structure of the section differs from the structure of the previous sections. In the subsection "Principles" there is a heading worded "Promote certainty and clarity of IP rights", after which there again follow two principles.

We propose deleting from this section the principle "Maintain the role of the IP system in promoting innovation", which coincides with the wording of Objective 5, and wording the section "Objective 5" as follows:

## Objective 5

Maintain the role of the IP system in promoting innovation.

## Principles:

- protect creativity and reward investments made in developing new inventions.
- promote transparency of enforcement of IP rights.
- promoting the dissemination of information by publishing and otherwise disclosing information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.

[Annex VI follows]

#### ANNEX VI

## Comments made by the Association des Étudiants et Chercheurs sur la Gouvernance des États Insulaires (AECG)

The objectives are clear. Objective 1 will without a doubt be an important point in relation to the principle of benefit-sharing. As indicated in the discussions of documents 16/5 and 16/6, the concept of sharing would need to be made clear.

Objective 4: Would it be possible to cite the most relevant ones?

Objective 5: The IP system should not be the only one applied and should be supplemented with other regional and international instruments.

[End of Annexes and of document]