E

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

WIPO/GRTKF/IWG/3/15
ORIGINAL: ENGLISH
DATE: JANUARY 28, 2011

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

Third Intersessional Working Group

Geneva, February 28 to March 4, 2011

COMPILATION OF COMMENTS ON DOCUMENTS AND MATERIALS RELATED TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Document prepared by the Secretariat

1. At its seventeenth session, held from December 6 to 10, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') "requested the Secretariat to make available copies of all relevant documents for the third Intersessional Working Group taking place from February 28 to March 4, 2011 (IWG 3), including: WIPO/GRTKF/IC/8/11, WIPO/GRTKF/IC/9/13, WIPO/GRTKF/IC/11/10, WIPO/GRTKF/IC/11/11, WIPO/GRTKF/IC/17/6, WIPO/GRTKF/IC/17/7, WIPO/GRTKF/IC/17/10, WIPO/GRTKF/IC/17/11, WIPO/GRTKF/IC/17/INF/10, WIPO/GRTKF/IC/17/INF/11, WIPO/GRTKF/IC/17/INF/12 and WIPO/GRTKF/IC/17/INF/13, as well as the WIPO Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge (WIPO publication No. 786)."[1]

2. In addition, the Committee "invited Committee participants who want their comments considered by IWG 3 to provide written comments on all relevant working documents before January 14, 2011 and requested the Secretariat also to make those comments available for IWG 3."[2]

[1] Draft Report of the Seventeenth Session of the Committee (WIPO/GRTKF/IC/17/12 Prov. 1)

[2] Id

3. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated December 21, 2010, recalling the decision and inviting participants to provide their comments before January 14, 2011.

4. Pursuant to the above decision, written comments were received from the following Member States: Argentina, Bolivia (Plurinational State of), Indonesia, Mexico and Switzerland; and the following accredited observers: Association des Étudiants et Chercheurs sur la Gouvernance des États Insulaires (AECG) and the Biotechnology Industry Organization (BIO), jointly with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

5. The comments are reproduced in the form received and contained in the Annexes to this document.

6. The IWG 3 is invited to take note of the comments in the Annexes to this document.

[Annexes follow]

ANNEX I

Comments made by the Delegation of Argentina

In relation to the forthcoming meeting of the Intersessional Working Group of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO), which will take place in Geneva, from February 28 to March 4, 2011, Argentina wishes to submit the following comments:

Analysis of documents

As has been reported in the note to which this report is attached, and in accordance with document WIPO/GRTKF/IC/17/Ref/Decisions, the documents analyzed are those connected with the list of options and objectives and principles.

(1) Options:

Document WIPO/GRTKF/IC/17/6: Revised List of Options

In this regard, it is considered that the three groups of options for continuing or promoting the work of the Committee, which the document describes, are important with a view to achieving harmonization between the patent system, access to genetic resources (GRs) and the equitable sharing of the benefits derived from the use thereof.

Specific comments for each of the subjects:

(a) Defensive protection of GRs:

In relation to the defensive protection of GRs, it should be highlighted that the three options listed in the document (Inventory of databases and information resources on GRs, Information systems on GRs and Guidelines on defensive protection) are conducive to achieving effective protection of GRs and avoiding the misappropriation thereof.

With respect to option A.3 (Guidelines or recommendations on defensive protection), it is suggested that attention be paid to the risk that might be involved by the possibility that national patent applications retaining a relationship with GRs are subject to an international search similar to that established in the Patent Cooperation Treaty (PCT), since this is a subject which should be analyzed in detail in order to evaluate the implications that would have for developing countries in general.

Without prejudice to the above, the expansion of databases relating to GRs, as well as the information systems relating thereto, should be accompanied by the creation of capacity building and technical assistance for countries that have difficulties in accessing or processing such information, based always on the national needs of each of the States which receive such training and/or assistance.

(b) Disclosure of origin of GRs in patent applications:

With respect to developing a disclosure requirement, we consider that the disclosure of the origin of GRs in patent applications will serve as a basis for establishing rules that protect the interests of developing countries.

The declaration of the origin of GRs in patent applications would facilitate the distribution of the economic returns derived from the enforcement of the patent. For this purpose, and as described in the document, consensus is essential on what is meant by "country of origin or source of the GRs", since on that basis the sharing of the monetary and/or non-monetary benefits resulting from access to genetic resources will be effective. In this sense, it is suggested that no changes are made to the preparation of definitions that have already been agreed at the international level, as is the case with "country of origin of the GRs", which is defined in Article 2 of the Convention on Biological Diversity (CBD).

(c) Intellectual property issues in relation to the fair and equitable sharing of benefits:

Additionally, with respect to the relationship between the patent system and the fair and equitable sharing of the benefits derived from the use of genetic resources, it is suggested that the work done by the CBD should be used as a basis, a sphere in which the Nagoya Protocol[1] on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization" and whose objective is specifically the fair and equitable sharing of the benefits derived from the use of genetic resources, taking into consideration for that purpose access thereto, has recently been adopted and will be open for signature by States on February 2, 2011.

(2) Objectives and principles

Document WIPO/GRTKF/IC/17/7: Submission by Australia, Canada, New Zealand, Norway and the United States of America

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.

[1] The articles to which the comments refer correspond to the version of the text certified by the United Nations, available at http://www.cbd.int/abs/doc/protocol/certified-text-protocol.pdf

Comment:

With respect to the first objective, it is suggested that the term “inventors” be replaced or followed by “user”. Similarly, in accordance with the Nagoya Protocol, reference should be made to the requirement of prior informed consent for access, and with regard to benefit sharing it should be included that the sharing must be “fair and equitable” and on “mutually agreed terms” (Articles 5 and 6 of the Nagoya Protocol).

With respect to the second principle, it should be borne in mind that Article 5 of the Nagoya Protocol obliges Parties to ensure that the benefits derived from the use of genetic resources are shared fairly and equitably and on mutually agreed terms, as well as those benefits derived from the use of traditional knowledge associated with genetic resources, for which reason not only should the owners be invited to participate in the work, but their participation should be ensured in the sharing of benefits in a fair and equitable manner and on mutually agreed conditions.

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:

The wording of the objective does not help to avoid biopiracy nor to ensure the fair and equitable sharing of benefits, for which reason it is suggested to state expressly that patents shall not be granted in cases where compliance with the requirement of disclosure has not been achieved or access to genetic resources and traditional knowledge associated therewith has not been gained with prior informed consent and subject to mutually agreed terms, as that is the way of ensuring the existence of provisions relating to the fair and equitable sharing of benefits.

For this purpose, the internationally recognized certificate of compliance, established by Article 17(4) of the Nagoya Protocol, shall play an important role.

With regard to the first principle, the wording of that principle does not add anything to what current international standards provide for. A requirement of compulsory disclosure in patent applications, the failure to respect which authorizes national authorities to refuse to grant the patent or to revoke it, should be established. The same effect should be established in cases where the applicant has provided false or fraudulent information.

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.

In this regard, it would be important to begin enhancing the possibility and viability of patent offices requesting the internationally recognized certificate of compliance, established in Article 17 of the Nagoya Protocol.

Similarly, principle number three does not appear to be a principle which must guide the negotiations on an international legal instrument ensuring the effective protection of genetic resources, traditional knowledge and folklore.

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.

As regards the relationship with other international agreements and processes, special relevance should be attached to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, the International Treaty on Plant Genetic Resources for Food and Agriculture and the International Convention for the Protection of New Varieties of Plants.

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.

With respect to objective 5, it should be clarified that from the development point of view, the IP system not only plays an innovation promotion role. The regulation of IPRs must be considered a public policy instrument which, in practice, may generate both variable benefits and costs, depending on the level of development of countries.

Furthermore, the same WTO Agreement on Trade-Related Aspects of Intellectual Property Rights recognizes that IPRs must not only contribute to the promotion of technological innovation, but also to the transfer and dissemination of technology, to the reciprocal benefit of producers and users of technological knowledge, so that the social and economic well being of countries is enhanced.

For such reasons, it is suggested to include, as functions of the IP system, the transfer and dissemination of technology to the reciprocal benefit of producers and users of technological knowledge so that social and economic well being is enhanced. Taking into account that the aim of the current negotiation is to ensure the effective protection of GRs, Traditional Knowledge and Traditional Cultural Expressions, and as proposed by the African Group, the IP system should also contribute to the protection of GRs, Traditional Knowledge and Traditional Cultural Expressions.

[Annex II follows]

ANNEX II

Comments made by the Delegation of Bolivia (Plurinational State of)

The Permanent Mission of Bolivia (Plurinational State of) to the United Nations and other international organizations in Geneva presents its compliments to the Secretariat of the World Intellectual Property Organization (WIPO) and, in relation to the Seventeenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, (IGC), hereby wishes to confirm that it requests inclusion of an additional paragraph in the section "Revised List of Options" of document WIPO/GRTKF/IC/17/6 in subparagraph A entitled "Options on defensive protection of genetic resources" which covers the interests of Bolivia (Plurinational State of) as regards genetic resources with the following wording:

"A. Options on defensive protection of genetic resources

A.4 The prohibition of patentability of all forms of life and parts thereof in order to protect genetic resources"

Description (beneath the paragraph)

"Request the Committee to produce legal rules in order to change international standards so as to prohibit the patentability of genetic resources and the private appropriation of all forms of life and parts thereof."

The Delegation of Bolivia believes that this addition should have been made automatically in the version of document WIPO/GRTKF/IC/17/6 (as occurred with similar documents dealt with by the IGC) emerging from the Seventeenth Session with a view to its treatment in subsequent sessions, including the intersessional meetings of experts. However, in order to avoid confusion in this regard, Bolivia reiterates its request formally by means of this letter.

The Permanent Mission of Bolivia (Plurinational State of) to the United Nations and other international organizations in Geneva takes the opportunity to reiterate to the WIPO Secretariat the assurances of its highest consideration.

[Annex III follows]

ANNEX III

Comments made by the Delegation of Indonesia

Proposed Amendment in Document WIPO/GRTKF/IC/17/7 "Submission by Australia, Canada, New Zealand, Norway and the United States of America"	Comments by Indonesia
~~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.~~ Objective 1: Ensure inventors, patent owner or user of genetic resources and any associated traditional knowledge comply with the requirement for fair and equitable sharing of benefits. Principle: - Recognize the sovereignty of state over the genetic resources and associated TK. - State should determine any requirements to ensure the prior informed consent and fair and equitable sharing of benefits are fulfilled	Indonesia is of the view that the principles of prior informed consent and fair and equitable benefit sharing should be the basic requirement for the use of genetic resources and associated traditional knowledge as these principles have been recognized in the relevant international instruments such as CBD and Nagoya Protocol. Indonesia also highlights the importance of sovereignty of states over the genetic resources and associated traditional knowledge in their territorial jurisdiction. In order to exercise the sovereignty, States must have the authority to determine any requirements needed for fair and equitable sharing of benefit of genetic resources and associated traditional knowledge in accordance with the relevant international instruments mentioned above. In this regard, Indonesia would like to propose the Objective and Principle 1 being replaced with the following: Objective 1: Ensure inventors, patent owner or user of genetic resources and any associated traditional knowledge comply with the requirement for fair and equitable sharing of benefits. Principle: - Recognize the sovereignty of state over the genetic resources and associated TK. - State should determine any requirement for prior informed consent and fair and equitable sharing of benefits.

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. - Prevent patents being granted where there is no compliance with other relevant international instruments related to 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.	Indonesia is of the view that the patent system must provide effective protection for genetic resources and associated traditional knowledge. In this regard, there should be a legal procedure to prevent patents being granted without compliance with other relevant international instruments such as CBD and Nagoya Protocol. Therefore, Indonesia would like to propose an additional proposal to be included in the Objective 2 as follows : Proposed Objective: Prevent patents being granted where there is no compliance with other relevant international instruments related to genetic resources and associated traditional knowledge
Objective 3: - Ensure patent offices have available the information related to the source of genetic resources as the basis 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.	Indonesia highlights that the importance of relevant information related to the source of genetic resources should be the basis to make proper decisions on patent grant related to genetic resources and traditional knowledge.
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~~	Indonesia is of the view that the existing international agreements related to genetic resources and traditional knowledge should be a fundamental source to deal with this matter. In this regard, we are not in favour to include the word “processes” since it could lead to legal uncertainty.

Objective 5: ~~Maintain the role of the IP system in promoting innovation.~~ Recognize the role of the IP system in balancing innovation and the protection of genetic resources and associated traditional knowledge. Principles: - Promote certainty and clarity of IP rights. - Protect creativity and reward investments made in developing a new invention. - Provide transparency, research capacity, access to, transfer and dissemination of technology to the owners/knowledge holders/beneficiaries of the genetic resources and traditional knowledge ~~by publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.~~	Indonesia considers the role of IP system is important in balancing the innovation and the protection of genetic resources and associated traditional knowledge. In order to achieve this objective, the IP system should protect and promote the invention based on genetic resources and associated traditional knowledge as well as provide transparency, research capacity, access and transfer technology to the owners/knowledge holders/beneficiaries of such genetic resources and traditional knowledge. Therefore, Indonesia would like to include the aforementioned elements to be included in the Principles and Objectives 5

[Annex IV follows]

ANNEX IV

Comments made by the Delegation of Mexico

The Permanent Mission of Mexico to the United Nations and other international organizations in Geneva presents its compliments to the World Intellectual Property Organization (WIPO) and has the honor to refer to the third meeting of the Intersessional Working Group of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, to be held at the Organization's headquarters, from February 28 to March 4, 2011.

In that regard, the Permanent Mission of Mexico is forwarding to the Organization a copy of the comments made by Mexico on the following documents: WIPO/GRTKF/IC/17/6: Genetic Resources: Revised List of Options and Factual Update, and WIPO/GRTKF/IC/17/7: Submission by the Delegations of Australia, Canada, New Zealand, Norway and the United States of America.

The Permanent Mission of Mexico to the United Nations and other international organizations in Geneva takes the opportunity to reiterate to the WIPO the assurances of its highest consideration.

WIPO/GRTKF/IC/17/6: Genetic resources: Revised list of options and factual update

It is important for the Delegation of Mexico to express the following opinion on the subject of genetic resources:

1. Considering the mandate granted to the Committee by the General Assembly at its 38th (19th ordinary) series of meetings, which states:

> *"The IGC will, during the next budgetary biennium (2010-2011), and without prejudice to the work pursued in other fora, continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs."*

For this reason, it is fundamental that both the Committee and the IWG begin the discussion on what would be the "legal international instrument" that will guarantee the effective protection of genetic resources or whether amendments would be required to the instruments already existing within WIPO. What would said instruments be?

2. Following the approval of the Nagoya Protocol on Access to Genetic Resources and the Sharing of Benefits arising from their Utilization, by the last Tenth Conference of the Parties to the Convention on Biological Diversity (CBD), the Committee should include in the discussions the subject of genetic resources, the relationship between the Nagoya Protocol and WIPO, in particular as it refers to Articles 12[1] and 12bis[2], on measures to ensure that the use of genetic resources, and where this applies to associated traditional knowledge within its jurisdiction, complies with the principle of prior informed consent and that mutually agreed terms (MAT) have been established; as well as in relation to the

[1] Note from the Secretariat: It is Article 15 of the certified true copy of the Nagoya Protocol

[2] Note from the Secretariat: It is Article 16 of the certified true copy of the Nagoya Protocol

checkpoints at the different stages of research, development, innovation, pre-marketing and marketing (Article 13[3]).

3. It should be recalled that the mandate given to the Committee by the General Assembly was that "(a) the IGC will, during the next budgetary biennium (2010-2011), and without prejudice to the work pursued in other fora, continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs." In the case of GR, the protection of said resources should be focused on avoiding the misappropriation and misuse thereof with respect to industrial property rights.

4. In that sense, it is important for the options established to be analyzed jointly with the aim of achieving true protection for genetic resources, considering also that there will be no single means of ensuring such protection. In view of the above, the list of options cannot be seen in isolation between sections (A, B and C) nor can the alternatives established within each of the sections. It should be noted that the last comment is reflected in the comments made on this document both by Mexico and by many other countries.

Cluster B: Disclosure requirements in patent applications for information related to genetic resources used in the claimed invention

1. It is important that Member States that have expressed an opinion against disclosure be asked the following question:

   a. If the disclosure of the origin of the source and/or origin of the genetic resource involved in a patent claim is not considered useful, what would the measures be to avoid the misappropriation and misuse of genetic resources with respect to intellectual property rights?

2. Options B1, B2 and B3 have been analyzed during various meetings of the Committee and have led to the production of different documents on the requirement of disclosure; however, we consider that the time has come for both the Committee and the experts to discuss in detail the questions relating to what in particular is involved by Option B1, in order to be able to take a decision in that regard. The above is of greater relevance in view of the Nagoya Protocol.

3. With respect to the decisions taken in the group of experts on genetic resources, one of the fundamental subjects should be what is meant by "disclosure of origin", if it is the source of the resource and what is understood by source, if it is the country from which the resource was obtained, etc.

<u>WIPO/GRTKF/IC/17/7: Submission by Australia, Canada, New Zealand, Norway and the United States of America</u>

Comments: In view of the recently approved Nagoya Protocol, negotiations within WIPO on genetic resources should promote the implementation of that Protocol.

[3] Note from the Secretariat: It is Article 17 of the certified true copy of the Nagoya Protocol

DRAFT Genetic Resources Objectives and Principles

Comments: This document containing objectives and principles is a good starting point for launching negotiations on the subject of genetic resources. In that connection, it should be noted that one of or the FUNDAMENTAL OBJECTIVE of the protection of genetic resources should be to "avoid the misuse and misappropriation of these resources". In that regard, we could propose a new objective.

Proposed objective:

- Avoid the misappropriation and misuse of genetic resources with regard to industrial property rights.

Objective 1:

Comments: Include the reference to avoiding misappropriation and misuse of both traditional knowledge associated with genetic resources and the specific genetic resources, so that the text reads as follows:

- ~~Ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for access, use and benefit sharing.~~ Ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for access, use and benefit sharing, in order to avoid the misuse and misappropriation of those resources and/or associated traditional knowledge.

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.

Objective 2:

Comments: We consider it fundamental that the protection of genetic resources and/or traditional knowledge associated with those resources is not restricted only to the industrial property rights granted by patents and that therefore other types of inventions are included. We propose the following wording:

- Prevent industrial property rights ~~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.

Objective 3:

- Ensure industrial property ~~patent~~ offices have available the information needed to make proper decisions on patent grant.

Principles:

- Industrial property ~~Patent~~ offices must have regard to all relevant prior art when assessing the patentability of an invention.

- Industrial property rights ~~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.

Comments: Include the following principle in order to promote cooperation between WIPO and the CBD prior to the Nagoya Protocol being approved.

- Promote cooperation between WIPO and the CBD.

Comments: We do not consider it appropriate to reiterate the mandate of WIPO within these objectives, and so we suggest the deletion of Objective 5 and its principles.

~~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 V follows]

ANNEX V

Comments made by the Delegation of Switzerland

COMMENTS BY SWITZERLAND WITH REGARD TO CIRCULAR C. 7917

TABLE OF CONTENTS

1. INTRODUCTION

Switzerland welcomes the substantive discussions on genetic resources that have taken place during the last several meetings of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Switzerland also welcomes the numerous documents submitted in this regard, in particular the documents submitted to IGC 17 and the numerous information documents on regional, national and community policies, measures and experiences regarding intellectual property and genetic resources submitted to IGC 16. On this occasion, Switzerland submitted document WIPO/GRTKF/IC/16/INF/14, which contains explanations on the mandatory disclosure requirement introduced in the Swiss Patent Law. Furthermore, we are confident that the several proposals on genetic resources submitted to WIPO, including the proposals by Switzerland on the disclosure of the source of genetic resources and traditional knowledge in patent applications as summarized in document WIPO/GRTKF/IC/11/10, will be conducive to the future work of the IGC on this important issue.

In view of the upcoming third Intersessional Working Group (IWG 3, February 28 to March 4, 2011) on genetic resources, IGC 17 invited Committee participants to provide written comments on all relevant working documents on genetic resources (see Circular C. 7917 in this regard). Switzerland welcomes this opportunity and provides the comments below.

2. PROPOSALS BY SWITZERLAND ON THE DISCLOSURE OF THE SOURCE

a) Background

Switzerland submitted detailed and specific proposals to WIPO on the disclosure of the source of genetic resources and traditional knowledge in patent applications. A summary of these proposals is contained in document WIPO/GRTKF/IC/11/10.[1]

[1] More detailed explanations on these proposals can be found in documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11/Rev., PCT/R/WG/6/11, and PCT/R/WG/7/9.

Switzerland welcomes that IGC 17 decided[2], among others, to make available document WIPO/GRTKF/IC/11/10 to the upcoming IWG 3 meeting. Switzerland looks forward to discussing the Swiss proposals on the disclosure of source together with all other proposals on genetic resources at IWG 3 in greater detail.

b) Summary of proposals

Switzerland proposes to amend the Regulations under the Patent Cooperation Treaty (PCT Regulations) to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if the invention is directly based on such resources or knowledge. Furthermore, Switzerland proposes to afford patent applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. Under present Rule 48.2(a)(x) of the PCT Regulations, such declaration of the source would be included in the international publication of the international application concerned.

To further strengthen the effectiveness of the proposed requirement, Switzerland proposes to establish an online list of government agencies competent to receive information about patent applications containing a declaration of the source. The patent office receiving such a patent application would inform the competent government agency in a standardized letter about the respective declaration of the source.[3]

The proposed wording of the amendments to the PCT Regulations can be found in Appendix I of document WIPO/GRTKF/IC/11/10.

3. DISCLOSURE REQUIREMENTS AT THE NATIONAL LEVEL

Numerous Committee participants submitted documents on their national experiences to IGC 16. This includes document WIPO/GRTKF/IC/16/INF/14 submitted by Switzerland, which provides explanations on the mandatory disclosure requirement introduced in Switzerland for patent applications in relation to genetic resources and traditional knowledge. This disclosure requirement implemented at the national level is in line with the Swiss proposal to amend the PCT Regulations.

4. RELEVANT INTERNATIONAL DEVELOPMENTS

In their discussions on genetic resources, the IGC and also the IWG 3 should pay due regard to the latest developments in other international fora, in order to ensure mutual supportiveness with the results of these other fora. This includes in particular the Convention on Biological Diversity (CBD) and the World Trade Organization (WTO).

a) Convention on Biological Diversity (CBD)

In October 2010, the 10th Conference of the Parties to the CBD adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits

[2] http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm

[3] In this regard, Art. 17.1(a)(iii) of the Nagoya ABS Protocol is of relevance, which reads as follows: “Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate.”

Arising from their Utilization to the Convention on Biological Diversity[4] (the Protocol). This Protocol includes several provisions of relevance to the work underway in WIPO's IGC and in IWG 3 on genetic resources, including in particular:

- Article 4 on the relationship with international agreements and instruments,
- Article 5 on fair and equitable benefit-sharing,
- Article 6 on access to genetic resources,
- Article 7 on access to traditional knowledge associated with genetic resources,
- Article 10 on a global multilateral benefit-sharing mechanism,
- Article 11 on transboundary cooperation,
- Article 15 on compliance with domestic legislation or regulatory requirements on access and benefit-sharing
- Article 16 on compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources
- Article 17 on monitoring the utilization of genetic resources
- Article 19 on model contractual clauses
- Article 20 on codes of conduct, guidelines and best practices and/or standards

b) World Trade Organization (WTO)

Also relevant are the discussions in the on-going Doha Trade Round of the WTO on Paragraph 19 of the Doha Ministerial Declaration[5], which "instruct[s] the Council for TRIPS, […] to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity[.]" In this regard, Switzerland recalls document TN/C/W/52[6], which contains proposals by 108 Members for a negotiation mandate concerning the introduction of a mandatory disclosure requirement in the TRIPS Agreement.

In the view of Switzerland, the proposed approaches in WTO and WIPO on the disclosure requirement are complementary, not mutually exclusive. In other words, for disclosure requirements to be effective in national as well as international patent applications, Switzerland holds amendments of TRIPS as well as the PCT to be necessary.

5. OTHER IGC DOCUMENTS

Switzerland views all documents submitted to IGC 17, including documents WIPO/GRTKF/IC/17/10 and WIPO/GRTKF/IC/17/11, to be helpful inputs to the discussions in the IGC and in IWG 3 on genetic resources. Switzerland is positive that these new documents, in addition to the documents submitted at previous sessions of the IGC on genetic resources, will serve as a good basis for our upcoming discussions on genetic resources.

[4] http://www.cbd.int/decision/cop/?id=12267

[5] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

[6] http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm

In the view of Switzerland, a single approach will not allow for the effective protection of genetic resources as the IGC is mandated to undertake text-based negotiations until the WIPO General Assembly 2011. Switzerland thus supports continued discussions on all three clusters contained in document WIPO/GRTKF/IC/17/6. Since Switzerland considers all three clusters to be equally relevant, it sees no priority among these clusters and, instead, supports to address these clusters on an equal footing.

[Annex VI follows]

ANNEX VI

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

WIPO/GRTKF/IC/8/11 (Submitted by the European Community and its Member States)

3. The country of origin or, if unknown, the specific source of the genetic resource should be disclosed

Paragraph 5: The proposed term, "source", is fine. However, we would like to comment that many plant species originate in their natural surroundings to be grown in laboratories or research centers. This distance does not correspond to the *in situ* condition required by the Convention on Biological Diversity (CBD). As a result, research laboratories would be allowed to cite their research center as a "country of origin". We would like to comment that this situation removes a great deal of recognition from genuine countries of origin. We are not in favor of this proposal and would prefer that the genuine "country of origin", as per the CBD, be recognized and disclosed.

4. Disclosure of associated traditional knowledge

We completely agree with the requirement to disclose an invention directly based on traditional knowledge (detailed in *8*(e) of *8.* Summary). The notion of traditional knowledge has become somewhat clearer since WIPO/GRTKF/IC/16/5 and the discussions resulting therefrom.

5. A standardised and formal requirement

"*Patent offices, are not required to make an assessment on the content of the submitted information*…": this would mean that the role of Offices is limited to registering the information provided by the applicant. This limited role is a risk since the applicant is obliged from the time of filing to act as if everything is valid.

We cite in this instance the case of *curcuma* (Patent US 540 1 504) and *neem* (Patent EP 436257) which have been a source of great problems after it was declared that the patents were granted in error.

Additionally, the information submitted may also be false and this cannot be controlled by Offices. Item 6: "What should happen…" states that incorrect or incomplete information would not affect the validity of the patent granted. We would like to comment that this provision paves the way for the validation of any false patent and penalizes applicants who have taken all the necessary steps and made the efforts to validate their patents. We are not in favor of the proposal to [disclose or declare] "*the source of genetic resources"* contained in *8*(a) and *8*(c) of *8. Summary*.

WIPO/GRTKF/IC/9/13 (Japan)

Page 3 – Paragraph 11: Many countries have already legislated in the sense of disclosing the "country of origin". This corresponds to a combination of several international and national texts with the aim of achieving the goals set by the CBD. We therefore believe it is necessary to maintain the requirement to disclose the source of genetic resources in order to strengthen the goals of the CBD.

Page 3 and 5 – Paragraphs 16 and 22: The example of Japan in disseminating guidelines is in fact very instructive and should be shared and adopted by all. We are in particular thinking of Pacific Island Countries (Papua New Guinea, the Solomon Islands, Vanuatu, New Caledonia, Fiji, Samoa, Tonga, Niue, the Cook Islands…).

Page 7 – Paragraph 39: We agree with the principle of "one-stop search" in order to avoid erroneously granting patents and we are very interested in it. In New Caledonia, we are currently undertaking programs to collect traditional knowledge through several groups. The result of such collections is spread over these groups and there is also the conservation issue. Much traditional knowledge concerns plant species. In fact, the first step would be to compile at the national level before moving on to the international level. We are waiting to see more details as to the arrangements for creating and implementing such a "one-stop search".

Page 8 – IV. Disclosure of the country of origin, prior informed consent and benefit-sharing

These three principles are very important to indigenous peoples and we prefer that they are maintained in the texts and practices.

Page 9 – Paragraph 46: We would like to comment that a single plant species located in different areas may have different properties. This is explained by the change in climate or area exposed to the sun, or again, by the nature of the soil in which its roots grow. Consequently, there are many different uses for the same plant.

Page 10 – Paragraph 51: The fictional case is a general case on which we agree. Conversely, we would like to comment that the situation is very delicate as regards endemic species. Taking New Caledonia as an example, whose surface area is approximately 18,600 km^2 and which contains 3,350 plant species, the latest 2010 studies estimated that 74 per cent of these plants are endemic to New Caledonia. Since such species should be exploited, it is necessary to hold discussions with the indigenous peoples and to obtain their consent to use their living spaces. In this regard, they should receive financial guarantees that they would not be expelled from their tribes and find themselves in financially and socially difficult situations.

<u>WIPO/GRTKF/IC/11/10 (Switzerland)</u>

We agree with the proposed new Rule 51*bis*.1(g).

Page 6 of the Annex: Disclosure is required but at a significant price which might hinder developing countries. Such disclosure is a source of trust between Contracting Parties but also, as long as sources are clearly identified, builds bridges towards equitable sharing.

In fact, it is desirable for disclosure first to be implemented at the national level with recognized organizations which will work together to agree on a unique source of disclosure. Contrary to the concerns of Switzerland *in letter (d) on page 6 of the Annex,* we are convinced that excluding developing countries from such disclosure will slow progress down considerably. We believe that it would be preferable to grant technical assistance to such countries which have a great wealth of traditional knowledge.

Page 5 – Source: Acceptance of the term "source" suits us since many people are likely to own traditional knowledge. However, they may also be entitled to benefit sharing.

We agree with the proposal of the new drafting of Article 51*bis*.1(g) and 51*bis*.(d).

WIPO/GRTKF/IC/11/11 (Japan – Additional explanation)

Page 1 – Paragraph 4: We find the explanations very interesting. The technical assistance proposed is certainly a good initiative.

We are waiting to see other comments from colleagues at a later stage of the discussions.

WIPO/GRTKF/IC/17/7 (Australia, Canada, USA, Norway and New Zealand) and WIPO/GRTKF/IC/17/10 (African countries)

Objective 1:

- Ensure inventors/users ~~using~~ of genetic resources or any associated traditional knowledge comply with the requirements of prior informed consent and fair and equitable benefit sharing.

Principles:

- Recognize the sovereign rights of States to legislate and determine the conditions of access to their genetic resources or their associated traditional knowledge.

Objective 2:

- Prevent patents being granted where there is no prior informed consent, no fair and equitable benefit sharing and disclosure requirements have not been met.

Principles:

- The relevant administration or judicial authority shall have the right to prevent (a) the further processing of an application or (b) the granting of a patent as well as (c) ~~to revoke~~ the revocation, subject to Article 32 of the TRIPS Agreement, or the authority to render unenforceable a patent when the applicant has either failed to comply with these objectives and principles or provided false or fraudulent information.

Objective 3:

- The information should allow patent offices to include measures to ensure that prior informed consent has been obtained through a mandatory disclosure requirement and an internationally recognized certificate of compliance.

Objective 5:

Principles:

- Promote certainty and clarity of IP rights and obligations with respect to the protection of traditional knowledge, genetic resources and traditional cultural expressions, as well as to protect creativity, encourage inventions and guarantee the rights of users and suppliers with due respect for prior informed consent, fair and equitable benefit sharing arising from such uses.

WIPO/GRTKF/IC/17/11 (Australia, Canada, Norway, New Zealand and the United States of America)

Objective 1:

C.1: Launch of online database.

WIPO/GRTKF/IC/17/INF/10 – ANNEX VI (Comments made by the Association des Étudiants et Chercheurs sur la Gouvernance des États Insulaires (AECG))

We would like to add the following comments. We would first like to thank each and every participant in the work of the IGC who have shown great interest in all of our concerns, wherever we live.

The five Objectives proposed in WIPO/GRTKF/IC/17/7 are interconnected to such an extent that they cannot be separated.

Objectives 2 and 3: It is true that if patent offices had the necessary information on prior art, there would be few patents granted in error. We again stress the importance of collaboration between the different authorities concerned, both in terms of national and international legislation but also in terms of the different experiences of each individual. Patent offices should be able to assess the patentability of an application as proposed by the Delegation of the Eurasian Patent Office (EAPO).

Objectives 4 and 5: We reiterate our wish to promote close collaboration in order to make headway on networking. We have stated that many patents are related to traditional knowledge and should therefore be processed together. The IP system should also be strengthened with respect to traditional knowledge so as to define clearly legal certainty and security. We are referring to a good definition of contractual requirements so that the rights of inventors are not infringed. Here we are dealing with the principles of prior informed consent and equitable benefit sharing.

WIPO/GRTKF/17/INF/10 – ANNEX II: Comments made by the Delegation of Colombia

Objective 2: Recommendations: We would add that any patent granted in error or granted due to lack of familiarity with guidelines should be withdrawn.

Objective 4: Recommendations: It is also important to emphasize again the importance of collaboration between national offices in order always to seek answers to conflict situations where two standards clash. This means that the requirement of prior informed consent described in the Bonn Guidelines should be effective. Owners should receive all the necessary legal information to be able to give their consent. Our experience on the ground relates to the language barrier, since many legal and chemical terms are untranslatable into indigenous languages. It can also occur that they have the opposite effect to what we expect from the owners. We insist on the fact that the parties should reach a sound agreement on the right to apply their consent and this requires a significant investment in terms of explanations which should not be overlooked.

WIPO/GRTKF/IC/17/INF/12: Genetic resources: Draft intellectual property guidelines for access and equitable benefit-sharing: Updated version.

Introduction – Page 12 – Paragraph 30: We would like to recall that the objective sought *in fine* is access to and use of these genetic resources and traditional knowledge for the common good of humanity. Therefore, these contracts should not be too restrictive to the point of closing off access to such resources. We have not lost sight of the three principles of the CBD (sustainable use, prior informed consent, equitable sharing) and of the Bonn Guidelines but, on the other hand, seek with the Contracting Parties to strike the right balance in contractual relations. The contractual rules which are in place and which govern co-contracting parties should take this objective into account: access to and use of resources for the good of all. We agree with the different positions which call for less restrictive rules as mentioned in document WIPO/GRTKF/IC/2/16.

Annex – Pages 9 and 11:

Sample Clause 1: Our experience has shown us that we always place the factor of TRUST in Clause 1. This implies customary protocols which entail presentations of each party and their project on the material in question. Sample Clause 2 presents the various possible uses of the material. The preamble to the contract presents both parties and states the request by the user for the possible use of material. This preamble seems to correspond to Sample Clause 9: Letter of Intent on page 15.

Sample Clause 3: It may also be stated that "the supplier authorizes the researcher/applicant (their address and position) to use/exploit the material for the following uses: ……". In our relations with the owners of knowledge, we always seek their authorization according to the simplified sample below:

Authorizes…….(user).

To:

- *collect the provided information by myself concerning the cultural heritage of ….. (tribe/clan) in the region of ….. . The information provided is my own responsibility and that of my heirs for a duration of ……. years;*
- *use the songs, dances, tales and legends and artisanal drawings, described in Annex (attach a description and an example of the drawings), for the purposes of conserving culture and for cultural events;*
- *meet with me for such purposes during the day of….. at….. (place).*

In exchange, the ADCK undertakes to mention my name and my position/profession in my clan and to prevent any uses it may so wish, excluding any use for commercial purposes.

Paragraph 11, letter D: Resources and definitions of goals: We have simplified our form and these goals and definitions are contained in the Annexes. They correspond to those indicated in I letter D, from the process of collecting material to its use. Where these uses are purely educational and instructive, then sharing a financial gain is of little importance.

This is why we have provided for another agreement for commercial uses with sharing based on a scale identical to that of Sample Clause No. 17 on page 23 of the Annex.

These individual annexes correspond to the information indicated in clauses 5, 6, 7 and 8. Our data are simplified since as indicated on *page 12, Paragraph 27(a),* legislation related thereto does not exist for traditional knowledge even though such knowledge was used for plant extracts for medical purposes. We are still searching for a *sui generis* text which might suit everyone, owners, suppliers and users alike.

Page 14, Paragraph 29(a) – Sample Clause No. 9: The preamble is highly detailed, doubtless due to the quality of the co-contracting institutions. It is necessary to adapt it to simpler situations. It is easier to have talks with one single representative of an organization but users still need to be incorporated in groups in official organizations. Whatever the situation (individual/organization), the presentation should be adapted for a better understanding.

Page 25, Sample Clause No. 21: Dispute settlement. It is important to give preference to mediation which prevents many conflicts. Our experience allows us to avoid many conflicts. We also advise all our colleagues to use the WIPO document on arbitration and mediation for support in such matters.

Page 29 – Paragraph 47: Sample Clause No. 21:

On (a): It is difficult under French legislation to recognize the right of employees to the inventions made in the context of their work and with work-related material. This is even clearly stated in their work contracts. The situation occurs in civil service departments but also within mining companies which mine Nickel in New Caledonia. The environmental study and conservation cells or units which are created also serve as research laboratories due to the exceptional biodiversity of the country (74 per cent of plants are endemic to New Caledonia).

However, we are keeping a very close eye on case law since we are aware that this is also the case in many neighboring countries to New Caledonia.

We are very concerned by this issue that we associate with equitable sharing of benefits resulting from discoveries.

Page 33, Paragraph 54: Copyright

On (b): We agree that an inventor/creator should be recognized as the author. This is explicit in the Intellectual Property Code under French legislation.

However, with respect to traditional knowledge, it is important to provide differently, since owners are often clans, that is, not individual persons but several people. This would need to be taken into account to ensure that benefit sharing, however small it may be, should benefit the whole community.

Page 34, Paragraph 55: Plant variety rights

The situation is complicated for the peoples living within a group of plant varieties officially recognized as useful to science. We are open to the responses of our colleagues for questions on this issue.

WIPO/GRTKF/IC/17/INF/13

We take note of the Glossary of Key Terms Related to Intellectual Property and Genetic Resources which is in the Annex to WIPO/GRTKF/IC/17/INF/13.

[Annex VII follows]

ANNEX VII

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

General Comments:

At its 17th session in December 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) invited IGC participants to submit comments on "all relevant documents" pertaining to the relationship of genetic resources and intellectual property. The Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) would like to express our appreciation to the IGC for the opportunity to submit comments on this very important topic.

BIO is a trade association representing over 1,100 companies, academic centers and related organizations involved in the research and development of biotechnology products for healthcare, agriculture, industrial and environmental applications. The majority of biotechnology companies are small and medium sized enterprises with no products yet on the market. Many BIO members are 5 to 10 years from commercialization, yet as a whole the biotechnology industry invests billions of dollars in research and development each year. The IFPMA is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 25 leading international companies and 46 national and regional industry associations covering developed and developing countries.

As such, all our members have a strong interest in the deliberations of the WIPO IGC and our organizations have been constructively engaged in the IGC's activities since its inception 10 years ago.

The Nagoya Protocol and the IGC

Since the beginning of the IGC, WIPO Members have recognized that the three topics of genetic resources, traditional knowledge and folklore "are closely interrelated, and none can be addressed effectively without considering aspects of the others."[1] In that light, we continue to support a robust discussion of all three of these topics in the IGC.

Although the three topics are inter-related, the relationship of intellectual property and genetic resources, in particular, has a specific relevance to the Convention on Biological Diversity (CBD). This relationship is primarily in the context of the access to, and the sharing of benefits from the use of, genetic resources. In October 2010, the Parties to the CBD adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization (Nagoya Protocol).[2] While it is still too soon to tell how extensive its membership will be or when it may enter into force, this new agreement should not be overlooked. Indeed, the decade-long discussion that culminated in the adoption of the Nagoya Protocol should inform the discussions relating to genetic resources in the WIPO IGC.

BIO and IFPMA members share the view expressed by the African Group in document WIPO/GRTKF/17/10 that the work of the IGC should be mutually supportive of the CBD

[1] Document WO/GA/26/6, para. 15

[2] CBD Conference of the Parties, Decision X/1

and the Nagoya Protocol and should not run counter to the objectives of the CBD and the Nagoya Protocol. The Nagoya Protocol was adopted to more effectively implement the CBD objective relating to the facilitation of access to genetic resources and the fair and equitable sharing of benefits from their use. Our associations actively participated in the negotiation process in coordination with other industry sectors. We recognize that appropriate access to genetic resources and the fair and equitable sharing of benefits from their utilization underlie many of the concerns raised in the IGC about the relationship of intellectual property and genetic resources.

The Nagoya Protocol reaffirms the importance of legal certainty, clarity and transparency in systems regulating access to genetic resources and the fair and equitable sharing of benefits from their use. As importantly, the Protocol does not interfere with intellectual property systems and other regulatory mechanisms. Instead, it notes the use of intellectual property, in those cases where it is applicable, as a means to facilitate the creation and sharing of benefits and therefore places intellectual property squarely within the context of mutually agreed terms relating to the access of the genetic resources and/or traditional knowledge at issue.[3] This character of the Nagoya Protocol should be preserved. If implemented appropriately, it can provide a solid framework for partnerships in access and benefit-sharing that can contribute to conservation and sustainable use of biodiversity.

The work of the IGC should strive to complement, rather than contradict, the Nagoya Protocol. For example, in past IGC discussions, widely differing views have been expressed in regard to the meaning of "misappropriation" or "biopiracy." This has been addressed in the Nagoya Protocol, which sets a framework that provides specific guidance for those countries that will seek to require prior informed consent for access to their genetic resources. Accordingly, there is now a concrete standard for the types of national legislation that are required to be in place for those countries that choose to require prior informed consent for genetic resources – as set forth in Nagoya Protocol Article 5.2. Thus, when the IGC is considering proposals, it should be with a view towards facilitating compliance with such regulations, e.g., through material transfer agreements and other mechanisms, and thereby counter "misappropriation" without undermining a robust intellectual property system which encourages innovation and generates benefits to be shared. As noted, several of the "options" presented in document 17/6 are consistent with this approach while others are not.

Comments Regarding Objectives and Principles (WIPO/GRTKF/17/11 and WIPO/GRTKF/17/10)

BIO and IFPMA view the adoption of clear objectives and principles to be an immediate and achievable goal of the IGC in respect of genetic resources. In this manner, we agree with the African Group and the co-sponsors of document 17/11 (Australia, Canada, Japan, Norway, New Zealand and the United States of America) regarding the need for such principles and objectives. As stated in our previous comments, we view the draft list proposed in document 17/11 as a good start, but not yet complete. For example, we have previously suggested that the objectives more specifically address matters concerning relevant intellectual property rights in mutually agreed terms and that all requirements concerning acquisition and use of genetic resources be made available in a clear and

[3] Nagoya Protocol, Article 5.2(f) includes the reference to intellectual property in the Protocol and provides that mutually agreed terms "shall be set out in writing and may include, *inter alia* … terms on benefit-sharing, including in relation to intellectual property rights."

transparent fashion.[4] In addition, proposed Objective 4 should be refined to refer to the mutually supportive nature of any resulting instrument with relevant international agreements. Despite the need for certain changes, in our view, the proposed format in document 17/11 is an appropriate basis for discussions at the Intersessional Working Group.

Thus, for the purposes of the following comments, the references to Objectives 1-5 proposed in document 17/11[5] are made on the understanding that these proposed objectives and principles, while largely non-controversial, are subject to refinement.

Comments on the Options for Future Work (WIPO/GRTKF/IC/16/6, 17/6 and other relevant documents)

There are several documents that should be considered in any work plan on genetic resources.

These include various proposals made by different delegations. We caution against using any specific proposal as a basis for negotiation. Such an approach may justifiably be viewed as prejudicial to the views of certain WIPO Members. In addition, our members give the highest priority to proposals that improve legal certainty and transparency, while maintaining the incentives of the patent system to induce innovative behavior. We understand that, even after several years of discussion, there are different views of how to achieve these goals.

In that light, we support the general approach articulated in document WIPO/GRTKF/IC/17/11, as we understand this to propose structuring the debate around the "objectives and principles". Thus, a successful work-plan would consist of a two-step approach:

- Agreement on text related to objectives and principles (using those articulated in document 17/11 as a basis for negotiations); and
- Identification of "options" relevant to each objective, and the subsequent negotiation and agreement of specific recommendations to implement these objectives and principles.

We believe this is consistent with the suggestion made by the IGC to the Intersessional Working Group and would make an appropriate starting point. A draft text of objectives and principles can be developed through discussions of the expert working group, using the proposed text in document 17/11 as a basis. In addition, a draft list of options for future work can be considered. However, instead of attempting to resolve differences between delegations to achieve a "consensus" list of options to limit the work of the committee – which appears to be the approach taken in document 17/6 – the Intersessional Working Group should draft up a list of options for discussion that would compare these options in respect of their ability to achieve particular objectives.

---

[4] See comments of BIO and IFPMA contained in document WIPO/GRTKF/IC/17/INF/10.

[5] These Objectives are identified as follows:

1. Ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for use, access and benefit-sharing;
2. Prevent patents from being granted in error for inventions that are not novel or inventive in light of traditional knowledge associated with genetic resources
3. Ensure patent offices have available the information needed to make proper decisions on patent grant.
4. Relationship with relevant international agreements and processes
5. Maintain the role of the IP system in promoting innovation

Each of the selected "options" should be further discussed in a manner to permit the IGC to continue its text-based negotiations based on the effectiveness of those options to achieve the proposed objective or principle. It is our view that fact-based discussions, enhanced through analysis of specific case scenarios, within the scope of assessing such proposals and their ability to reach the agreed objectives in the manner described above, may help to resolve differences.

This process will also provide better legal certainty, transparency and clarity, by working through scenarios and particular examples, rather than a simple political determination of pursuing one option in place of another.

Comments on Particular Options Presented in Document 17/6

BIO and IFPMA have previously expressed specific views on the options contained in document 16/6.[6] We have expressed support for the following "options" presented in documents 16/6 (and also reproduced in document 17/6) and provide some suggestions for the placing of such options by the Intersessional Working Group.

A.1 (Inventory of Databases and information resources on GR),
A.2 (Information systems on GR for defensive protection), and
A.3 (Guidelines or recommendation of defensive protection);

Further compilation of information resources concerning genetic resources are an invaluable tool for researchers and patent offices alike. Thus, we view these proposals as having a strong correlation to the goal of ensuring patent offices have available information needed to make proper decisions on grant as well as preventing erroneous grant of patents for inventions that are not novel.

Thus, we would suggest that A. 1 also be included in the list of options relevant to Objective 3.

We note that at least one delegation suggested amending these options to include references to the "disclosure of the origin" of genetic resources. As explained below, we remain opposed to such proposals and believe these references should not be included. Furthermore, we discern little, if any, relationship between such proposals and the compilation of information for defensive purposes. Thus, even if such proposals are included as options for discussion elsewhere, it does not appear to be appropriate in this instance.

Option B.4 (Alternative mechanisms concerning the relationship of IP and genetic resources – e.g., the "one-stop-shop" proposal in document 9/13)

This category of other work on provisions for national or regional patent laws to facilitate consistency and synergy between ABS measures and international patent law practice should be pursued further – and should be included in respect of each objective, as its scope is broader than that proposed in document 17/11. For example, the creation of a dedicated international information system on genetic resources as presented in document 9/13 is directly related to ensuring compliance with ABS regimes and may be considered in tandem with the centralized "checkpoint" system for monitoring and transparency envisioned under the Nagoya Protocol (e.g., a system that monitors the access permits

[6] WIPO/GRTKF/IC/17/6, see, e.g, comments by BIO and IFPMA.

through a centralized authority such as a competent national authority or a collection of agencies relevant to the regulation of ABS in the particular country). However, it is also directed to the prevention of erroneous patent grants, for example, as specifically noted in document 9/13 itself.

Thus, we suggest including Option B. 4 as an "option" for discussion under all objectives 1-5 as this proposal has a direct relation to achieving each of these objectives.

Similarly as noted above, at least one delegation suggested adding a reference to "disclosure of origin" requirements in respect of this option in comments reflected in document 17/6. However, such a proposal is not consistent with the nature of option B. 4 (which is directed to "alternatives" to patent disclosure) nor the specified example in document 9/13 and should be deleted.

C.1 (Draft guidelines for contractual practices – documents 7/9 and 17/INF/12)
C.2 (Online Database of IP clauses in mutually agreed terms on ABS), and
C.3 (Study on licensing practices on genetic resources).

Each of these options are directed toward the management of intellectual property rights that may be related to genetic resources and, in particular, to Objective 1 regarding ensuring compliance with relevant ABS regulations – particularly concerning mutually agreed terms.

Proposals for Special Patent Disclosure Requirements (Options B.1 – B.3) Are Not the Answer

Our members share the views expressed by several others through the work of the IGC[7] that new disclosure requirements in the patent system will not achieve the purported objectives and would have significant negative consequences. Instituting special new requirements in the patent laws creates significant legal uncertainty. An environment of legal uncertainty is antithetical to business investment and, by extension, research and development. Biotechnology research and development is very risky and often unsuccessful. While a predictable legal and regulatory environment does not eliminate these risks, it mitigates them to help create an enabling environment for innovation. Furthermore, the case has not been made that disclosure of origin or source of particular genetic resources that may be related in some fashion to the invention would be able to facilitate whether (a) appropriate access or benefit-sharing was achieved in the relevant case, or that (b) the information would be relevant, much less helpful, to prevent erroneous patenting. In our view, such proposals should not be included in the final work product of the IGC. In addition, such requirements are not consistent with the notion of a "checkpoint" in the Nagoya Protocol as the checkpoints described are directed to "monitor and enhance transparency about the utilization of genetic resources" covered by that Protocol. Special

[7] *See, e.g.,* statements by Japan (WIPO/GRTKF/IC/12/9 Prov., para. 234), the United States of America (WIPO/GRTKF/IC/12/9, Prov., para. 236), the Republic of Korea (WIPO/GRTKF/IC/11/15, para. 527), Canada (WIPO/GRTKF/IC/12/9 Prov., para. 230), Australia (WIPO/GRTKF/11/15, para. 520), New Zealand (WIPO/GRTKF/11/15, para. 513), the Russian Federation (WIPO/GRTKF/IC/11/15, para. 537), Singapore (WIPO/GRTKF/IC/11/15, para. 529), the Eurasian Patent Office (WIPO/GRTKF/IC/12/9, para. 235), the International Chamber of Commerce (WIPO/GRTKF/IC/11/15, para. 237), the Intellectual Property Owners Association (WIPO/GRTKF/IC/10/7, para. 211), and the American BioIndustry Association (WIPO/GRTKF/IC/10/7, para. 210). BIO has also made statements to this regard. *See, e.g.,* WIPO/GRTKF/IC/7/15, para. 198.

requirements in patent applicants would be backward-looking requirements that would not effectively “monitor use” under the Protocol but rather would interfere with legitimate intellectual property rights in a manner counter to the objectives of the CBD. Such requirements are contained as option B.1 and B.3 in document 17/6, and are embodied through proposals contained in documents 8/10 and 8/11, along with the suggested amendments referred to in document 17/10.

We support deleting references to Options B.1, B.2 and B.3 based on these views.

Conclusion

BIO and IFPMA will continue our constructive engagement in this process as the IGC moves forward with text-based negotiations with the objective of reaching agreement on a meaningful international instrument that will complement the Nagoya Protocol while maintaining its structure to ensure a constructive relationship between robust intellectual property rights and the generation of benefits that can be shared in a fair and equitable manner. In this manner, IGC participants may contribute to the conservation of biodiversity and the sustainable use of its components while, at the same time, incentivizing innovation.

[End of Annexes and of document]