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Item 8 of the provisional agenda*

MEASURES TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT OF THE CONTRACTING PARTY PROVIDING GENETIC RESOURCES AND MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED IN CONTRACTING PARTIES WITH USERS OF SUCH RESOURCES UNDER THEIR JURISDICTION

Note by the Executive Secretary

I. INTRODUCTION

1. In paragraph 1 of recommendation 3/4, addressing measures to support compliance with prior informed consent and mutually agreed terms on which access was granted, the Working Group invited Parties and Governments, in preparation for its fourth meeting, to start or continue activities listed in decision VII/19 E. In paragraph 3 of the same recommendation, it invited Parties to submit information, analyses and views on these activities, and in particular the measures outlined in paragraphs 2 (a) to (g) of decision VII/19 E, and on the implementation of the Bonn Guidelines, to the Executive Secretary. It requested the Executive Secretary to compile this information and make it available through the clearing-house mechanism and other means, and to the fourth meeting of the Working Group.

2. In paragraph 5, the Working Group invited Parties to identify issues related to disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights and submit this information to the Executive Secretary, and requested the Executive Secretary to prepare a compilation thereon for examination by the fourth meeting of the Ad Hoc Working Group on Access and Benefit-Sharing, with a view to transmitting the results of this examination to the World International Property Organization (WIPO) and other relevant forums, such as the Food and Agriculture Organization of the United Nations (FAO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Environment Programme (UNEP), the International Union for the Protection of New Varieties of Plants (UPOV), and the World Trade Organization (WTO).

* UNEP/CBD/WG-ABS/4/5.

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3. In paragraph 8, the Working Group invited Parties, Governments, relevant international organizations, indigenous and local communities, and all relevant stakeholders to undertake analytical work on:

(a) The occurrence, nature, extent and cost of misappropriation of genetic resources, [derivatives] and associated traditional knowledge including, for countries with relevant legislation, the extent of non-compliance with their national legislation on prior informed consent and mutually agreed terms;

(b) The effectiveness, practicality and cost of measures to ensure compliance with prior informed consent and mutually agreed terms;

(c) Enforcement problems experienced under national access legislation, including capacity constraints and related need for capacity-building, including the capacity-building of indigenous and local communities; and to forward the outcome of this work to the Executive Secretary for compilation and dissemination through the clearing-house mechanism and other means.

4. In light of the above, the Secretariat issued notification 2005-044 on 14 April 2005 inviting Parties, Governments, relevant international organizations, indigenous and local communities and relevant stakeholders to submit information, analyses, views or the outcome of analytical work, in accordance with the relevant paragraphs of recommendation 3/4.

5. Section II contains a compilation of information, analysis and views received from Parties on measures taken to ensure compliance with prior informed consent and mutually agreed terms. Section III contains a compilation of information provided by Parties on issues related to the disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights. The Working Group may also wish to refer to the note by the Executive Secretary prepared for its third meeting, which contains an overview of measures taken by Governments to support compliance with prior informed consent and mutually agreed terms (UNEP/CBD/WG-ABS/3/5).

6. Section IV contains information related to cases of misappropriation of genetic resources and associated traditional knowledge. On a related issue, in response to decision VII/19 E, paragraph 10 (c), the Secretariat commissioned IUCN-Canada, as a consultant, to prepare a report on "the extent and level of unauthorized access and misappropriation of genetic resources and associated traditional knowledge". The report is available as an information note (UNEP/CBD/WG-ABS/4/INF/6).

II. INFORMATION, ANALYSIS AND VIEWS PROVIDED BY PARTIES ON MEASURES TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT OF THE CONTRACTING PARTY PROVIDING GENETIC RESOURCES AND MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED IN CONTRACTING PARTIES WITH USERS OF SUCH RESOURCES UNDER THEIR JURISDICTION

7. In accordance with decision VII/19 E, information on measures taken by Governments to assist with the implementation of ABS provisions was provided by Parties prior to the third meeting of the Working Group. An overview of these measures is included under section II of document UNEP/CBD/WG-ABS/3/5 and the submissions provided by Parties are contained in a note by the Executive Secretary (UNEP/CBD/WG-ABS/3/INF/1).

8. Following the third meeting of the Working Group and in light of recommendation 3/4, the following contributions were received from Canada, Costa Rica, the European Community, India, Mexico and Norway.

Canada

"*General Considerations around the Proposed Compliance measures:*

A series of measures are under discussion with a view to ensuring compliance with access and benefit-sharing principles. Without prejudice to the nature, scope and elements of a regime regulating this area, Canada submits the following observations relating to some of the compliance measures proposed in the terms of reference set out in Decision VII/19 D of the Conference of the Parties and Annex I of document UNEP/CBD/WG-ABS/3/7. The following analysis is guided principally by the question of practicality in implementation.

Compliance measures can be grouped under four main categories:

a. Measures to ensure Prior Informed Consent (PIC)
b. Measures to ensure the negotiation of Mutually-agreed Terms (MAT)
c. Documentation, including certificates of origin/source/legal provenance
d. Disclosure mechanisms, such as disclosure of origin of genetic resources (GR) and associated traditional knowledge (TK) in patent applications, international/ national/regional databases, clearing-house mechanism

Canada believes that the above mentioned measures are interrelated. Each set of measures must be in place in order to ensure that both users and providers of genetic resources and traditional knowledge are in a position to comply with ABS measures. Moreover, certain measures, such as those designed to ensure PIC and MAT, must have been properly developed by national authorities in a manner respectful of the interests of all concerned stakeholders and local and Indigenous communities, if the Convention's objectives are to be met.

Specific observations on the above mentioned compliances measures can be found in the following papers from Canada

- Submission by Canada : Specific Considerations relating to PIC
- Submission by Canada : Specific Considerations relating to MAT
- Submission by Canada : Specific Considerations relating to Documentation: certificates of origin/source/legal provenance
- Submission by Canada : Specific Considerations relating to Disclosure of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK)"

These papers are contained in the compilation of submissions provided by Parties and relevant organizations in document UNEP/CBD/WG-ABS/4/INF/3.

Costa Rica

"With regard to paragraphs 4 and 5 of point 3/4 mentioned above, Costa Rican legislation determines, with regard to applications for intellectual property rights and their relationship to disclosure of the origin/source/legal provenance of genetic resources and related traditional knowledge, as a mesure among others to support compliance with prior informed consent and mutually agreed terms, the following:

a) Biodiversity Law No. 7788

This Law determines that the Government of Costa Rica recognizes the validity of these forms of knowledge and innovations, and the need to protect them with the proper legal mechanisms for each specific case. It furthermore establishes that intellectual property rights shall be regulated by specific legislation and establishes that these rights are consistent with biodiversity conservation objectives.

The Law establishes that it is mandatory for both the *Oficina Nacional de Semillas* (National Seed Bureau – the national body that grants plant-breeder rights) and the Intellectual Property and Industrial Property registries to consult the *Oficina Técnica de la Comisión Nacional para la Gestión de la Biodiversidad* (Technical Bureau of the National Commission for Biodiversity Management – the national body that regulates access to the genetic resources of biodiversity in Costa Rica), before granting

intellectual or industrial property protection to innovations that involve elements of biodiversity. The interested party is obligated to show the certificate of origin issued by the National Authority and the prior informed consent. If the National Authority presents justified opposition, the protection or patent for the innovation cannot be registered.

Under Costa Rican legislation, intellectual property rights are protected by: patents, commercial secrecy, plant improver rights, *sui generis* community intellectual rights, copyright, farmers' rights –

With regard to "*sui generis* community intellectual rights", the Costa Rican State expressly recognizes and protects, under this heading: the knowledge, practices and innovations of indigenous peoples and local communities linked to the use of elements of biodiversity and related knowledge. The Biodiversity Law furthermore determines the establishment of a registry or inventory of specific *sui generis* community intellectual rights for which communities request protection from the National Authority. **Recognition of these rights in the Registry is voluntary and free of charge, to be done informally or at the interested party's request, without being subject to any formality. Once recognition has been established, the National Authority is forced to turn down any consultation regarding intellectual or industrial rights over the element or knowledge that the community wishes to protect.**

With regard to obtaining plants, the country does not have legislation in effect. There is a draft Law written by the National Seed Office, based on the provisions of the Model Law of the International Union for the Protection of New Varieties of Plants (UPOV). Nevertheless, Biodiversity Law No. 7788 puts the bodies that grant intellectual property rights under the obligation to demand the certificate of origin/legal provenance issued by the National Authority.

In November 2003, a draft Law titled "*Protección de los Derechos de los Fitomejoradores"* (Protection of Plant Improvers' Rights) was tabled in National Congress by a national organization called Red de Biodiversidad (Biodiversity Network). The proposal is quite different from UPOV provisions. In general terms, it proposes a stamp that would grant exclusive rights to the holder only if it is used simultaneously with the name and material."

The European Community and its Member States

"As regards paragraphs 3 and 5 of recommendation 3/4, the EU already provided extensive information in its submission to ABS WG-3 (see UNEP/CBD/WG-ABS/3/INF/1, pages 22-23, 29-30). Since then, further efforts have been undertaken at both the level of the European Community and at the level of Member States.

The European Community has successfully established an internet-based portal to information on access and benefit sharing 1/ as an integral part of the EC Biodiversity Clearing House Mechanism. The EC ABS Portal is used to disseminate information relevant to the implementation of the Bonn Guidelines to ABS focal points in Member States and to a growing group of registered stakeholders from governments, research institutes, private companies and NGOs….

In early 2005, the **United Kingdom** communicated to the CBD Secretariat and made available to the Parties at WG ABS3, copies of the 'Review of the Experience of Implementation by UK Stakeholders of Access and Benefit Sharing Arrangements under the Convention on Biological Diversity'. The Review's recommendations relate in particular to the advantages in the short to medium term of awareness raising of the concept ABS and its requirements, and they were endorsed by UK Environment Ministers. Later in 2005 a Working Party tasked with prioritising and implementing these recommendations, will meet.

1/ The EC ABS Portal can be accessed at: http://abs.eea.eu.int.

A **French** review of existing judiciary mechanisms available to address potential cases of non-compliance with ABS mutually agreed terms was briefly mentioned in document UNEP/CBD/WG-ABS/3/5. It could be related to mechanisms existing in other countries.

In 2005, the **German Ministry for the Environment** published a study on "Users of genetic resources in Germany", which was made available to participants of the WG ABS 3.The study is an analysis of the level of awareness and knowledge of ABS regulations of users of genetic resources in Germany and gives recommendations on how to improve stakeholders involvement. As follow-up, workshops with specific user groups will be held to offer them a platform to get in depth information and to exchange experiences.

Another project in **Germany** "Process-oriented development for a fair benefit-sharing model for the use of biological resources in the Amazon lowland of Ecuador" (ProBenefit, www.probenefit.de) aims at developing a suitable procedure for equitable benefit sharing for the use of biological resources and the associated indigenous knowledge in line with the principles of the CBD. To this end the project partners, together with the Ecuadorian government, the local Indian organisations and other relevant groups in society, as well as interested non-governmental organisations, will explore new models for the sustainable use of biodiversity in the Ecuadorian Amazon region."

Developments related to the issue of disclosure of origin/source/legal provenance in applications for intellectual property rights are addressed under section III below.

Section II of document UNEP/CBD/WG-ABS/3/5 also includes information provided by the European Community regarding measures adopted by its member states prior to the third meeting of the Working Group.

India

"Implementation of the Bonn Guidelines

The Bonn guidelines, because of their voluntary and non-binding nature, have not been able to create an enabling environment and confidence that could prevent biopiracy, and ensure compliance of PIC stipulations and equitable sharing of benefits as visualized in the Convention. Further national action alone is not sufficient to ensure realization of benefits to the country or origin, particularly in cases where genetic material sourced from one country is utilized in another country for developing products and processes on which patent protection is obtained. Therefore, developmental of a legally binding IR on ABS should be accorded high priority."

México

The views of Mexico regarding this issue are included in the comments provided in relation to the International Regime in document UNEP/CBD/WG-ABS/4/INF/3.

Norway

"On 20 April 2001, on the recommendation of the Ministry of the Environment, a committee was appointed by Royal Decree to review the legislation relating to biodiversity. In it's report of December 7th 2004 – NOU 2004: 28, the committee presented a draft Act on the protection of the natural environment, landscape and biological diversity (referred to as the draft Act or the new Act).

According to the committee's proposal, the new Act will replace the current Nature Conservation Act, but it has a considerably wider scope than classical nature conservation. Thus, the Act also includes provisions on access to genetic material. The committee's proposals on access to genetic material deal with two main issues. The first of these is how access to Norwegian genetic material should be regulated. The second is what part Norwegian legislation can play in ensuring that genetic material from other countries is utilised in accordance with the provisions of the Convention on Biological Diversity.

The committee has expressed as its goal to maintain genetic material in Norway primarily as a common resource, which through research and development can be used to develop new knowledge and

new inventions for the benefit of people and the environment. For this to be achieved, access to and utilisation of genetic resources must be in accordance with the conservation targets of the draft Act, and traditional use by indigenous peoples and local communities must be respected.

The committee's proposal as regards Norwegian genetic material obtained from the natural environment entitles any person to explore for, extract and utilise genetic material within the framework provided by the draft Act and other relevant legislation. The draft Act distinguishes between property rights to the biological material – i.e. the organism – containing the genetic material, and rights to the genetic material as such. Thus, organisms that are obtained legally, for instance by being freely available through the right of access to and passage through uncultivated land, may be utilised regardless of the purpose for which they are collected. For example, a flower may be picked to put it in a vase, to grow new plants from the seeds, or for biotechnological research.

The draft Act includes a provision requiring the competent authority to be notified if genetic material that has been collected from the natural environment is later used for commercial purposes. The committee proposes a separate provision on access to genetic material in public collections in Norway. This requires any person who manages such collections to do so in accordance with the objective of the draft Act for access to genetic material, and to register any genetic material removed from a collection. It is also proposed that any person who receives genetic material from such collections shall refrain from claiming intellectual property rights or other rights to the material that would limit its use for food or agriculture. Among other things, the latter requirement implements one of the provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture.

The committee also proposes further provisions to ensure that collection and utilisation of genetic material from other countries is carried out in accordance with the Convention on Biological Diversity. These include the provision that if genetic material is imported for utilisation in Norway from a state that requires consent for collection or export of such material, the import may only be permitted if such consent has been given and in accordance with the conditions laid down for such consent. This will make it possible to enforce the requirement for consent in Norway.

The committee further proposes that information on the providing country or country of origin shall accompany genetic material that is utilised in Norway. Information on any use of indigenous peoples' traditional knowledge shall also accompany the material if regulations requiring this have been laid down. Even though these provisions should improve documentation of the origins of genetic material and give a certain degree of control, it is difficult to enforce rules on access to genetic material unilaterally at the national level. The committee therefore stresses that it is necessary to continue the development of multilateral and bilateral agreements. The committee's proposals have been subject to a broad public hearing. The government will consider a proposal of law to be presented to Parliament based on these hearings."

III. ISSUES RELATED TO DISCLOSURE OF ORIGIN/SOURCE/LEGAL PROVENANCE OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN APPLICATIONS FOR INTELLECTUAL PROPERTY RIGHTS IDENTIFIED BY PARTIES

A. Developments at the national level

Costa Rica

Biodiversity Law No. 7788: The Law establishes that it is mandatory for both the *Oficina Nacional de Semillas* (National Seed Bureau – the national body that grants plant-breeder rights) and the Intellectual Property and Industrial Property registries to consult the *Oficina Técnica de la Comisión Nacional para la Gestión de la Biodiversidad* (Technical Bureau of the National Commission for Biodiversity Management – the national body that regulates access to the genetic resources of biodiversity in Costa Rica), before granting intellectual or industrial property protection to innovations that involve

elements of biodiversity. The interested party is obligated to show the certificate of origin issued by the National Authority and the prior informed consent. If the National Authority presents justified opposition, the protection or patent for the innovation cannot be registered.

European Community

"Belgium has amended its patent laws with the aim to contribute to transparency with regard to the geographic origin of the genetic source on which inventions are directly based. The amended law include a new formal requirement "that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention"".

India

"At the national level, India has enacted the Biological Diversity Act (2002) which provides that prior approval of National Biodiversity Authority is necessary before applying for any kind of IPRs based on any research or information on a biological resource obtained from India. Further, the Patents (Amendment) Act provides for disclosure of the source and geographical origin of the biological material / associated knowledge which used in an invention. It also provides for opposition to the grant of patent or revocation of the patent in case of non-disclosure or wrongful disclosure of source of biological material and associated knowledge."

Norway

"The Norwegian Patent Law was amended in 2003. The amendments entered into force the 1st of February 2004. A new para. 8 b) was included to address disclosure of origin. It states that the patent application shall include information on the country from which the inventor collected or received the biological material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from in-situ sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall state this in the application.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents."

B. Information and views provided by Parties on the issue of disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge

Canada

"Specific Considerations relating to disclosure of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK)

One proposal designed to help track the origin of genetic resources and associated TK is a requirement to disclose of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK) in patent applications. This issue has been the subject of intense debate both at WIPO and WTO TRIPS-Council.

In this context, further assessment of the impacts of such a requirement is needed, both on the existing national and international IP systems as well as on the users of genetic resources and associated

TK. Canada has taken seriously the views expressed by many countries in their proposals to WIPO and WTO TRIPS-Council and supports the continuation of discussions in these fora as well as the CBD, as appropriate.

Should there be a requirement to disclose the origin of a genetic resource in a patent application or other database, accurate information on the origin of the resource will be needed all along the genetic resource "use chain", from *in situ* collection to research to, where applicable, commercialization. The burden of such a system would likely have to be carried even by those who may not be obtaining a direct financial benefit. The burden of responsibility for ensuring proper disclosure should be shared by all actors along the "use chain", including, and most importantly, the country of origin of the resource. How that burden should be divided is a question that remains little explored. Evaluating the practicality of the obligation would require a preliminary two-tier approach; the nature of the information that would need to be disclosed and the consequences that would follow from non-compliance. For instance, different burdens would likely be entailed depending on whether disclosure was of country of origin or of source. In the context of a patent application, the former would require that the resource was tracked from where it was first discovered while the latter would require that the resource was tracked only from where it was most recently accessed. Likewise, sanctions could vary between cases of insufficient, wrongful or lack of disclosure.

The selection of the appropriate mechanism regarding compliance with an ABS system presents a challenge as it may entail consideration of issues such as organization, monitoring, administrative costs, effectiveness and jurisdiction. Then would follow the determination of whether disclosure of origin/source of genetic resources is the optimal solution for ensuring benefit-sharing and complying with an ABS system. Indeed, other solutions have been put forward both nationally and internationally in order to achieve such compliance. Continued further analysis of such options in the appropriate contexts would make a useful contribution in considering optimal policy choices.

Nevertheless, until other key elements for compliance with an ABS system –i.e. PIC and MAT systems-- are in place, the practicality of disclosure, whether mandatory or voluntary, remains unclear."

European Community

"The European Community and its Member States on 16 December 2005 formally submitted a proposal on the "Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications" to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization. This proposal (in the attached annex) calls for the establishment of a multilateral requirement for patent applicants to disclose the country of origin or, if it is not known, the source of genetic resources on which an invention is based. A patent applicant who refuses to disclose this information would simply not obtain a patent: its application would not be processed until he/ she discloses. In case a patent applicant disclosed but provided incorrect information, effective, proportionate and dissuasive sanctions would apply outside the field of patent law. The creation of such a requirement, when agreed internationally, would entail changes in two intellectual property rights treaties administered by the World Intellectual Property Organization." The proposal submitted to WIPO is included in annex to this document.

Japan

"I. Current situation of business relating to genetic resources in Japan

Genetic resources are a fundamental component of biotechnology research and the commercialization of it. In order to ensure the sound development of biotechnology and bioindustry, it is essential to create an environment that facilitates access to genetic resources.

In recognition of the current situation, *the BT Strategies* notes the following objective regarding genetic resources, "In the spirit of the CBD, we must achieve coordination and cooperation with countries

in the gathering, securing, and provision of genetic resources2". A number of scientific and commercial projects have been in progress in recent years in Japan.

For instance, the National Institute of Technology and Evaluation (NITE), an independent administrative corporation under the Ministry of Economy, Trade and Industry (METI), established the NITE Biological Resource Centre (NBRC), which actively collects biological resources, preserves and distributes them. For example, based on the CBD, the NBRC concludes Project Agreements (PA) and Material Transfer Agreements (MTA) with other countries to establish systems for the efficient utilization of biological and genetic resources and for related benefit sharing. Moreover, some private companies in Japan have also been conducting similar projects with other countries along the lines of the CBD.

Japanese companies possess high level technology and research performance from a global perspective in the field of efficient use of technology for generic resources. Our survey shows that to make utmost use of the resources available, companies have a sense of responsibility to conduct fair and equitable benefit sharing with providers of genetic resources. Moreover, companies are willing to promote and undertake genetic resource-based research projects with providers of genetic resources according to their agreement.

In addition, Japanese government prepared the document "Guidelines for Access to Genetic Resources" which assists Japanese companies and research institutes to deepen their understanding of the CBD and to promote win-win relationships between GR-providing countries and Japan through international access to genetic resources.

We believe that the steady progress of these approaches will help to materialize access to genetic resources and fair and equitable benefit-sharing based on the spirit of CBD.

Needless to say, huge risks and increases of cost adversely affect business. This is particularly true in business sectors that require very substantial monetary expenditures and long-term R&D to earn profits. If stringent regulations to take genetic resources out of the GR-providing country are introduced and unpredictable procedures cause cost increases, the business sector will hesitate to use genetic resources. As a result, there is little, by way of benefits, to share with providers of genetic resources.

II. Points before discussing disclosure requirements in Intellectual Property applications

Several proposals have been introduced in international fora that mandatory disclosure requirements (e.g. source/country of origin of genetic resources and/or associated traditional knowledge used in inventions, evidence of prior informed consent (PIC), evidence of benefit sharing) in patent applications should be adopted in order to achieve the CBD objectives. However, before such proposals are discussed outside of the context of the CBD, we should firstly deepen our understanding of the problems and current situation regarding access to genetic resources and its benefit sharing in the CBD context.

CBD member states have implemented various efforts to comply with CBD objectives. The "Bon Guideline" is one of those efforts. In addition, some countries have already introduced a domestic regime related to ABS. However, the reality of the situation is that the scope of the genetic resources and definitions of terms used in the CBD are still not clear, and there is not actual uniformity of each domestic system required to be introduced under the CBD.

2/ BT Strategies (BT Strategy Council, December 2002)
Biogenetic resources including animals, plants, microorganisms, human cells / tissues and genes are extremely useful, yet at the same time limited, in industrial applications and research. Enhancing these resources is truly important from the viewpoint of international competition. All relevant parties must join forces in gathering, securing and providing biogenetic resources, including genetic information, so as to strengthen the foundation of industrial competition, and help our nation to protect our rights in this area.
In the spirit of the Biodiversity Convention, we must achieve coordination and cooperation with countries in the gathering, securing, and provision of such resources.

For example, there are various genetic resources ranging from those newly discovered during resource inspections to those easily obtained through the markets. So, the scope of genetic resources for which the PIC and benefit sharing are necessary should be clarified. Additionally, the definition of "derivatives" is still unclear. With regard to "traditional knowledge," there is still not complete agreement on the definition, and there is also the difficulty of identifying the source or origin of traditional knowledge because it is shapeless. In order to respond to the regulations for obtaining the PIC, systems which are highly transparent and have simple procedures are needed. However we have to say that, at present, the system of the member states lack uniformity.

Therefore, Japan considers it essential to discuss the matters which are unclear in the field of the CBD and to deepen understanding of the problems and current situations regarding access to genetic resources and benefit sharing based on the national experiences. On the basis of such understanding, in other words, only after the field of CBD is no longer unclear, will it be useful to study the possible solutions in fields outside of the CBD, and those solutions may be the basis of the discussion of the disclosure requirements of genetic resources in patent applications.

III. Mandatory disclosure requirements in Intellectual Property applications

Several proposals have been introduced in international fora that mandatory disclosure requirements in patent applications should be adopted as part of the measures to secure access to genetic resources and to provide fair and equitable benefit-sharing. However, Japan considers that introducing such mandatory disclosure requirements does not stem from the patent system and that there is no logical necessity.

(1) Disclosure requirements in patent applications

A patent system provides for two categories of "disclosure" requirements (i.e. substantive and formative requirements) as a prerequisite for granting a patent right for an invention. The necessity to disclose the source/country of origin of genetic resources and/or associated traditional knowledge used in inventions, evidence of PIC, and evidence of benefit sharing cannot be explained by these two categories of "disclosure" requirements of a patent system. Unless the need for such disclosure is clearly explained, any administrative sanctions including invalidation of a patent right should not be incorporated into a patent system.

(a) Substantive requirements

Even when the source/country of origin of a genetic resource is disclosed in an application, it is practically impossible to ensure that a third party, who has seen the application, can access the same genetic resource. In many countries, therefore, the description requirements (including enablement requirements) for "inventions based on genetic resources" are secured under a "deposit system." Under the Japanese Patent Law, for example, an applicant for an invention based on a microorganism (in many cases, new microorganisms), which a person skilled in the art cannot easily access, is required to deposit the microorganism with a depository institution which has been granted the status of an international depository authority under the Budapest Treaty or which is designated by the Commissioner of the Japan Patent Office (JPO), and to submit to the JPO a copy of the receipt of the deposit issued by the depository institution (Section 27bis of the Regulations under the Patent Law). The purpose of a deposit system is not to disclose the source/country of origin of genetic resources but to solve the problem of third-party inaccessibility to microorganisms, since there are some cases in which information about the completion of an invention or the publication of technology cannot be adequately secured in the description of an invention based on a microorganism which appears in the application. Specifically, therefore, by depositing the microorganism related to an invention with a depository institution and by enabling the institution to provide the microorganism to any third party, the problem of inaccessibility can be solved. Currently, the microorganism deposit system has been able to fully satisfy the application description requirements (including enablement requirements). Therefore, imposing a new obligation to disclose the

source/country of origin of genetic resources in patent applications cannot be considered to be such a meaningful approach.

For an application for an invention based on a microorganism, which any person skilled in the art can easily access, the applicant is not required to deposit the microorganism. The applicant just has to describe how the invention can be worked, using such a microorganism which is accessible to the public, in a manner for any person skilled in the art to be able to work the invention. Information about the source/country of origin of genetic resource cannot be used to satisfy application description requirements (including enablement requirements). Therefore, as for microorganisms made accessible to the public with which the application deals, imposition of a new obligation on applicants to disclose the source/country of origin of genetic resources in their patent applications cannot be considered a meaningful approach in terms of application description requirements (including enablement requirements).

Thus, due to the reasons cited above, disclosing the source/country of origin of genetic resources in a patent application cannot serve as an alternative to a deposit system in terms of application description requirements (including enablement requirements). The same is true for disclosing the evidence of PIC and benefit sharing.

Moreover, as for a person who wishes to obtain a patent, information contained in prior art documents is indispensable for comparing and judging the level of technology used in the applicant's application with the technical standards at the time of filing, for technological contributions made by the applicant's invention, and for the novelty and inventive steps of the invention. If an applicant describes information about prior art in the detailed description of the invention, this will help expedite the examination process. It will also help establish more stable rights because such information enables examiners to make an accurate comparison between an invention for which an application has been filed and relevant prior arts.

On the other hand, information about the source/country of origin of genetic resources, evidence of PIC, and evidence of benefit sharing should be unnecessary for judging the level of novelty and inventive step of an invention. Such information could not be considered as essential for prior art searches, either. Therefore, there is no reason why such information should be furnished as an additional disclosure requirement from the perspective of the examination process.

(b) Formative requirements

Such entries as applicant names are to be made formative requirements only when such requirements are regarded as reasonable (see Article 62 of the TRIPS Agreement). As regards the disclosure of the source/country of origin of genetic resources, evidence of PIC and evidence of benefit sharing, therefore, we are not convinced that disclosure requirement should be regarded as a reasonable procedure and formality. Even without its disclosure, there is no problem in carrying out the patent procedure and such lack of disclosure does not make the patent procedure ineffective.

The Patent Law Treaty (PLT) is aimed at streamlining and harmonizing the procedures in the patent examination process, and in Article 5, stipulates the following.

> "A Contracting Party shall provide that the filing date of an application shall be the date on which its Office has received all of the following elements, filed, at the option of the applicant, on paper or as otherwise permitted by the Office for the purposes of the filing date:
>
> (i) an express or implicit indication to the effect that the elements are intended to be an application;
>
> (ii) indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office;

(iii) a part which on the face of it appears to be a description."

From the aspect of formality, therefore, disclosure of the source/country of origin of genetic resources is not necessary.

(2) Burden on patent applicants and influence on access to genetic resources

To secure access to genetic resources and fair and equitable benefit-sharing, a system in the country of origin should be established to enable recipients of genetic resources to obtain a PIC from the country. If transparency of the procedures of such a system is not secured, genetic-resource recipients will have to shoulder a serious burden because they will be required to acquire a PIC from such a system. Furthermore, this will place the patent applicants in a situation in which it will be difficult for them to disclose the origin/ country, evidences of the PIC, and benefit sharing.

If the proposed disclosure requirement in a patent application should be made an obligation and lack of the disclosure should lead to invalidation of the patent right, it would increase the risk and burden on patent applicants applying for an invention based on genetic resources and/or associated traditional knowledge. In cases in which an applicant could not immediately specify the source/country of origin of a genetic resource (e.g. (i) a company directly purchased the resource from a genetic resource trader or (ii) researchers exchanged genetic resources through a network of researchers), an applicant would have to directly investigate the source/country of origin of the genetic resources. In addition, it seems that there is an abundance of confidential business information in the PIC documents or benefit sharing contracts. Disclosing such confidential business information will be another burden of patent applicants. Those burdens might discourage inventors from conducting research into inventions based on genetic resources due to the huge expense or from obtaining a patent for such inventions. As a result, fewer and fewer genetic resources would be utilized, and, in the end, access to genetic resources as well as fair and equitable benefit-sharing would not be facilitated. This might bring serious consequences not only to user countries but also to providing countries/countries of origin.

(3) Relation to the TRIPS Agreement

Article 27.1 of the TRIPS Agreement stipulates that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology…." Therefore, if disclosure requirements are made applicable only to genetic resource-related inventions and invalidation of patents for such inventions is made allowable on the basis of a lack of disclosure requirement, the adoption of these requirements could be considered as falling under the scope of "discrimination in the field of technology."

IV. COMPILATION OF ANALYTICAL WORK PROVIDED BY PARTIES, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STRAKEHOLDERS ON THE OCCURRENCE, NATURE, NATURE EXTENT AND COST OF MISAPPROPRIATION OF GENETIC RESOURCES: EFFECTIVENESS, PRACTICALITY AND COST OF MEASURES TO ENSURE COMPLIANCE; AND ENFORCEMENT PROBLEMS UNDER NATIONAL LEGISLATION

Contributions related to the misappropriation of genetic resources were received from India and jointly from the International Federation of Organic Agriculture Movements (IFOAM), the Research Foundation on Science, Technology and Ecology (New Delhi, India) and the Greens/EFA in the European Parliament (Brussels, Belgium).

India

Analytical work undertaken on misappropriation of genetic resources and associated traditional knowledge from India

The National Institute of Science Communication and Information Resources (NISCAIR), India, has undertaken detailed studies in the years 2000 and 2003 on misappropriation of genetic resources and associated traditional knowledge from India. The year 2000 study has considered patents granted at USPTO, and the year 2003 study has considered patents granted at USPTO, EPO & UKPTO. A brief summary of these studies is given below.

In the year 2000, there were 4869 references on 90 medicinal plants in the USPTO database of which 80% of the references were on the seven medicinal plants, Kumari, Mustaka, Tamraparna, Garjara, Atasi, Jambira, and Kharbuza. 408 references were available on Aloe vera for March 2000 itself.762 patents on medicinal plants were studied, about 360 could be categorized as traditional.

In the year 2003 there were More than 15000 references on 53 medicinal plants in USPTO, EPO databases and hence a threefold increase in the no of granted patents.

In the year 2004 the study was carried out on 119 Priority Medicinal Plants for the no of granted patents, which further validates the fact on the increasing no's of biopiracy cases.

Year	Patents granted at USPTO on 119 Medicinal Plants	% Increase
2000	17329	
2002	20835	16.8
2004	23956	13.0

Study reveals that Aloe vera has the maximum number of granted patents among them with the figure of 1063 in 2000, 1458 in 2002 increasing to 1811 in 2004. Similarly, Cyperus rotundus had 872 granted patents in 2000, 924 in 2002, and 954 in 2004. The details of the patent applications filed and the patents granted are given in the table below.

Botanical Name	Patent application/patent no	References cited for	Year of filing/grant
U: Badam,E: Almond B: *Prunus amygdalus* Batsch	20010006666	Unani	2001
U: Babuna,E: Wild Chamomile B: *Matricaria chamomilla* Linn.	US 20020198580	Unani	2002
	US 20020177535	Unani	2002
	US 20020176876	Unani	2002
U: Badam,E: Almond B: *Prunus amygdalus* Batsch	US 20020035046	Unani	2002
U: Darchini,E: Cinnamon B: *Cinnamomum zeylanicum* blume	US 20020111280	Unani	2002
U: Hina/Mehndi E: Henna B: *Lawsonia inermis* Linn.	US20020166182	Unani	2002
	US20020155069	Unani	
	US20020136702	Unani	
U: Hulba/Methi E: Fenugreek B: *Trigonella foenum-graecum* Linn.	US20020173510	Unani	2002
U: Kafoor E: Camphor B: *Cinnamomum camphora* Nees & Eberm.	US 20020197228	Unani	2002
	US 20020187108	Unani	2002
	US 20020176879	Unani	2002
U: Katan/Alsi E: Linseed B: *Linum usitatissimum* Linn.	US20020136712	Unani	2002
U: Nankhwah/Ajwayin E: Ajowan/Bishop's weed B: *Trachyspermum ammi* (Linn) Sprague	US20020136783	Unani	2002
U: Sana E: Senna B: *Casisa angustifolia* Vahl.	US 20020071872	Unani	2002
U: Sandal Safaid E: Sandal wood B: *Santalum album* Linn.	US20020049257	Unani	2002
U: Babuna.E: Wild Chamomile B: *Matricaria chamomilla* Linn.	US 20030064120	Unani	2003
	US 20030017179	Unani	2003
U: Gul-e-Surkh/Ward,E: Rose B: Rosa damascena Mill.	US20030054019	Unani	2003
Botanical Name	Patent application/patent no	References cited for	Year of filing/grant

Botanical Name	Patent application/patent no	References cited for	Year of filing/grant
U: Hulba/Methi,E: Fenugreek B: *Trigonella foenum-graecum* Linn.	SU20030068372	Unani	2003
U: Kafoor,E: Camphor,B: *Cinnamomum camphora* Nees & Eberm.	US 20030045572	Unani	2003
	US 20030031730	Unani	2003
	US 20030024997	Unani	2003
	US 20030008805	Unani	2003
U: MomE: Beeswax	US 20030059450	Unani	2003
	US 20030054019	Unani	2003
U: Sandal Safaid,E: Sandal wood B: *Santalum album* Linn	US20030044368	Unani	2003
U: Seer/Lehsun,E: Garlic B: *Allium sativum* Linn	US 20030059487	Unani	2003
U: Shib/Phitkari ,E: Alum	US 20030010691	Unani	2003
U: Zanjabeel,E: Ginger B: *Zingiber officinale* Rosc	US 20030031737	Unani	2003
<u>Patents Granted</u>			
U: Gurmar E: Small Indian Ipecac B: *Gymnema sylvestre* R. Br.	US 5900240	Unani	1999
U: Huzuz/Rasaut,E: Indian Berberry B: *Berberis aristata* DC	US 5591436	Unani	1997
U: Jamun,E: Black plum B: *Syzygium cumini* (Linn.) Skeels	US5900240	Unani	1999
U: Karela,E: Bitter gourd B: *Momordica charantia* Linn.	US 5900240	Unani	1999
U: Neeb/Neem,E: Margosa B: *Azadirachta indica*	US 5591436	Unani	1997
Turmeric for treating skin disorders	US5897865	Ayurveda	1999
Herbal composition and their use as hypoglycemic agents (Syzygium cuminii, Momordica charantia, Cephaelis ipecacuanha)	US5900240	Ayurveda	1999
Plant based therapeutic agents with virustatic and antiviral effect (Delphiniun denudatum, Ellettaria cardamom)	US5725859	Ayurveda	1998
Herbal composition (Melia azardirachta, Centratherum anthelminthicum)	US5693327	Ayurveda	1997

Botanical Name	Patent application/patent no	References cited for	Year of filing/grant
Method and composition for treatment of diabetes. (Cinnamomum tamala, Azardichta indicia Tinospora cordifolia, Syzygium cumini)	US5886029	Ayurveda	1999
Method of treating musculoskeletal disease and a novel composition therefor (Withania somnifera, Boswellia serrata, Curcuma longa, Zingiber officinale,)	US5494668	Ayurveda	1996

In view of the above study, an illustrative study on patents granted on endemic plants from developing countries like China, India, South Africa, Mexico, Sri Lanka and Malaysia was carried out at USPTO, EPO databases for search of biopiracy. The study was carried out by studying the assignee/inventor's country and the original source of biological material. Given below are a few illustrative examples of biopiracy in India.

Turmeric (Curcuma longa Linn.)

The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and as a colour dye. As a medicine, it has been traditionally used for centuries to heal wounds and rashes.

In 1955, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric in wound healing. The Indian Council of Scientific & Industrial Research (CSIR), New Delhi filed a re-examination case with the US PTO challenging the patent on the grounds of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the USPTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

Neem (Azadirachta indica A. Juss.)

Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis. In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995 a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and thus was a prior art and unpatentable. In 1999 the EPO determined that according to the evidence all features of the present claim have been disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000.

Organizations

International Federation of Organic Agriculture Movements (IFOAM), the Research Foundation on Science, Technology and Ecology (New Delhi, India) and the Greens/EFA in the European Parliament (Brussels, Belgium)

In light of the negotiations of the international regime a joint contribution was provided by these organisations and is contained in document UNEP/CBD/WG-ABS/4/INF/3. In addition to views with respect to the negotiations of an international regime, the contribution provides detailed information regarding the legal history of the Neemfungicide case. On 8 March 2005, the Technical Board of Appeals of the European Patent Office (EPO) revoked in its entirety a patent on a fungicide made from seeds of the Neem tree. The information provided in this joint contribution, contained in document UNEP/CBD/WG-ABS/4/INF/3, may be of particular relevance in considering the misappropriation of genetic resources and associated traditional knowledge.

Annex

SUBMISSION OF EC AND ITS MEMBER STATES TO WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE ON 16 DECEMBER 2004

Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications

Proposal of the European Community and its Member States to WIPO

1. Introduction

This document outlines the basic features for a balanced and effective proposal on the disclosure of genetic resources and associated traditional knowledge (TK) in patent applications.

The European Community and its Member States already agreed in the 2002 Communication to the TRIPs Council to examine and discuss the possible introduction of a system, such as a self-standing disclosure requirement, that would allow States to keep track, at global level, of all patent applications with regard to genetic resources. 3/ Since 2002, several developments in WIPO, WTO, FAO, the CBD and other relevant fora have contributed to the discussion. More recently, the Conference of the Parties of the Convention on Biological Diversity has invited WIPO to examine issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*, options for model provisions on proposed disclosure requirements.4/ The WIPO General Assembly of 2004 decided that WIPO should respond positively to this invitation. The present proposals reflect the position of the EC and its Member States on this issue.

2. A binding disclosure requirement that should be applied to all patent applications

In the 2002 Communication to the TRIPs Council, the EC and its Member States expressed their preference for a requirement that should be applied to all patent applications. The EC and its Member States also consider that the disclosure obligation should be mandatory. This implies that the disclosure requirement should be implemented in a legally binding and universal manner. A global and compulsory system creates a level playing field for industry and the commercial exploitation of patents, and also facilitates the possibilities under Article 15(7) of the CBD for the sharing of the benefits arising from the use of genetic resources.

The introduction of such a scheme should take place in an efficient and timely way, and be related to the existing international legal framework for patents. In order to achieve such a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements such as the EPC will be necessary. The disclosure requirement then applies to all international, regional and national patent applications at the earliest stage possible.

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

It is suggested that, in order to provide patent applicants with a clear idea of what needs to be disclosed, the language used here should be the same as in the CBD definitions of country of origin, genetic resources and genetic material.5/

3/ Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3 (b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore (WTO document IP/C/W/383).

4/ See document WIPO/GRTKF/IC/6/13.

5/ This proposal does not include the disclosure of the source in patent applications based on genetic resources or traditional knowledge acquired before the entry into force of the CBD.

First, the material that would be the subject of the requirement: Article 15 (7) of the CBD states that access and benefit-sharing objectives must be met with regard to "genetic resources". It is therefore coherent to use the universally accepted CBD language. "Genetic resources" is defined in Article 2 CBD as "genetic material of actual or potential value". The same provision states that "genetic material" includes "any material, of plant, animal, microbial or other origin containing functional units of heredity". In this context, human genetic resources are excluded6, and this exclusion should be carried over to the proposed system.

Second, the origin of the genetic resource: a disclosure of origin requirement would assist countries providing access to genetic resources to monitor and keep track of compliance with national access and benefit-sharing rules. On this basis, the applicant should be required to declare the country of origin of genetic resources, if he is aware of it. No additional research on his part would be required. It is the disclosure of the country of origin that paves the way for monitoring the respect of the rules on access and benefit-sharing, where such rules are in place.

The CBD defines the "country of origin" as the country which possesses those genetic resources in *in situ* conditions. Under the CBD, "in situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties. 7/

It is clear that it may not always be possible for the patent applicant to indicate the country of origin. In these situations, it is suggested to make use of the broader notion of "source". If the country of origin is unknown, the applicant should declare the source of the specific genetic resource to which the inventor has had physical access and which is still known to him. The term "source" refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden. 8/

Third, the connection between the material and the patented invention: the applicant must have used the genetic resources in the claimed invention. A notion should be applied that makes it possible for the applicant to disclose the material used in the invention in an adequate way, without having the obligation to make further research on the origin of the resource, taking into account the interests of the applicant, the patent office and other stake holders. A good balance can be found by requiring that the invention must be "directly based on" the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource. The inventor must also have had physical access to the genetic resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource that are relevant for the invention. 9/

4. Disclosure of associated traditional knowledge

In this specific case, there are good reasons for an obligation to disclose that an invention is directly based on traditional knowledge associated with the use of genetic resources. According to Article 8(j) of the CBD, there is a commitment to respect, preserve and maintain traditional knowledge. 10/

6/ As clarified by the CBD COP decision II/11, paragraph 2.

7/ Article 2.

8/ This other source can include the "Multilateral System" as a source of genetic resources belonging to taxa included in annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture. According to Article 12.3 (b) of the International Treaty, "access shall be accorded expeditiously, without the need to track individual accessions". The Multilateral System is the source of the genetic resources, as well as the beneficiary of the sharing of profits from their commercialization.

9/ See similarly the additional comments by Switzerland on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, PCT/R/WG/6/11, paragraph 27.

10/ The Bonn Guidelines adopted under the CBD to implement its Articles 15 and 8(j) address specifically all genetic resources and associated TK.

Traditional knowledge is of intangible nature and the obligation to disclose cannot be based on physical access. It could therefore be proposed that the applicant should declare the specific source of traditional knowledge that is associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge. In this context, the European Community and its Member States refer to Article 8(j) of the CBD where the notion “knowledge, innovations and practices” is used.

However, there are concerns about the possibly unclear scope of the term "traditional knowledge". In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary.

5. A standardized and formal requirement

In order to become effective, the way that the relevant information will be submitted from the patent applicant to the patent offices must be standardized. This should be organized in a non-bureaucratic and cost-efficient manner. An overwhelming majority of patent applicants do not base their inventions on genetic resources and/or associated TK and for them the burden should be limited to an absolute minimum.

Competent patent authorities, in particular patent offices, are not required to make an assessment on the content of the submitted information. They must also not be obliged to keep track whether the patent applicant has obtained the relevant material in a way compatible with benefit-sharing and prior informed consent provisions. Their role can be limited to checking whether the formal requirements are fulfilled, in particular, whether the applicant who declares that the invention is directly based on genetic resources and/or associated TK has subsequently disclosed information.

The EC and its Member States propose that the disclosure of the information be organized by including questions to be answered in the standard patent application form. The applicant then can give either a negative or a positive response to the question whether the invention is directly based on genetic resources and/or associated TK. If the answer is negative, the applicant does not need to fulfill any other administrative requirement on this issue. A positive answer triggers the requirement to disclose the country of origin or source as foreseen. In the exceptional case that both the country of origin and the source are unknown to the applicant, this should be declared accordingly.

If the patent applicant fails to give a negative or positive response, or if he fails or refuses to disclose information on the country of origin or source in cases where he claims that the invention is directly based on genetic resources and/or associated TK, the patent application is not shaped in accordance with formal requirements, except where the applicant has declared that the country of origin and the source are unknown to him. An applicant should be given the possibility to remedy the omission within a certain time fixed under patent law. However, if the applicant continues to fail to make any declaration, then the application shall not be further processed and the applicant will be informed of this consequence.

6. What should happen in cases of incorrect or incomplete information?

Meaningful and workable sanctions should be attached to the provision of incorrect or incomplete information. Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.

It must be left to the individual Contracting State to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.

7. Exchange of information

An indispensable measure that makes the disclosure requirement outlined in the previous sections an effective incentive to comply with access and benefit-sharing rules is the introduction of a simple notification procedure to be followed by the patent offices. The latter, every time they receive a declaration disclosing the country of origin or source of the genetic resource and/or associated TK, should notify this information to a centralised body. This could be done, for instance, by means of a standard form. That would facilitate the monitoring – by countries of origin and TK holders – of the respect of any benefit-sharing arrangements they entered into. The relevant information must be made available in accordance with the present rules on the confidential nature of applications.

The notification should be as simple as possible and must not lead to an unnecessary administrative burden for patent offices. The exchange of information should also be managed in a cost-effective way and without unnecessary additional charges imposed on patent applicants. This could be achieved, for example, by using electronic means.

It would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the information available from the declarations on disclosure.

8. Summary

In summary, the EC and its Member States propose the following:

a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;

b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible;

c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;

d) the invention must be directly based on the specific genetic resources;

e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of "traditional knowledge" is necessary;

f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;

g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;

h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

These proposals attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications.
