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AD HOC INTERGOVERNMENTAL MEETING ON GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS

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MEMBER STATE PROPOSALS AND SUGGESTIONS REGARDING THE INVITATION TO WIPO FROM THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY ON ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

Compilation prepared by the Secretariat

1. At its Thirty-first Session the WIPO General Assembly considered an invitation from the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) (see document WO/GA/31/8) and decided that "WIPO should respond positively" and that, as a first step in the timetable and modalities which were adopted, "the Director General will invite all Member States of WIPO to submit proposals and suggestions before December 15, 2004".

2. Accordingly, the Member States of WIPO were invited to submit proposals and suggestions to the International Bureau of WIPO prior to the agreed deadline of December 15, 2004 (circular C.7092). A total of fifteen proposals and suggestions were received in response to the circular C.7092. A compilation of all the proposals and suggestions received is contained in the Annex to this document.

[Annex follows]

ANNEX

Member State Proposals and Suggestions Regarding the Invitation to WIPO from the Conference of the Parties to the Convention on Biological Diversity on Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications

Australia
Belize
Brazil
Colombia
Ghana
Islamic Republic of Iran
Japan
Kyrgyz Republic
Russian Federation
Switzerland
Turkey
United States of America

European Community and its Member States

African Group
Andean Community

AUSTRALIA
Received December 17, 2004

1. Australia appreciates this opportunity to provide comments relating to the invitation from the Convention on Biological Diversity (CBD) Conference of the Parties (COP) to the World Intellectual Property Organization (WIPO) to prepare a technological study, and to report its findings to the COP on methods consistent with obligations in treaties administered by the WIPO for requiring disclosure within patent applications of, *inter ali*a:

(a) Genetic resources utilized in the development of the claimed inventions;

(b) The country of origin of genetic resources utilized in the claimed inventions;

(c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;

(d) The source of associated traditional knowledge, innovations and practices; and

(e) Evidence of prior informed consent.

2. As a signatory and committed party to the CBD and Intellectual Property treaties (IP treaties), such as the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), the Patent Cooperation Treaty (PCT), the Paris Convention and the International Convention for the Protection of New Varieties of Plants, Australia reiterates comments it has made previously in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC), the CBD and other fora, that Australia sees no conflict between the CBD and IP treaties and considers that these can and should be implemented in a mutually supportive way.

3. Australia considers that while IP treaties are concerned with the creation of legal rights to protect inventive assets, the CBD, in so far as it impacts on intellectual property (IP) issues, could be characterised as creating the environment in which:

(i) inventors and others can access genetic resources and traditional knowledge to be used as inputs in inventive and other processes, and

(ii) the benefits from the use of those genetic resources and traditional knowledge are equitably shared.

While there are certainly overlapping interests involved there is no necessary conflict between the two as they currently stand.

4. Australia, is a mega-biodiverse country, with possibly the world's highest level of endemic genetic resources[1] , much of which has yet to be characterised. Additionally, Australia's indigenous peoples have accumulated traditional knowledge during their occupation of the land. Many specific genetic resources of Australian origin have been dispersed to other countries in whole-of-species form for example, eucalyptus trees can be found on most continents and the kangaroo, a national icon, is found in many zoos worldwide.

5. Australia is also a developed economy to which genetic resources are very important. For example, Australia has a burgeoning biotechnology industry, a large agriculture sector as

[1] Pages 26-29, 179-180 *Megadiversity* Mittermeyer *et al*.

well as large agricultural and environmental research sectors which are clearly reliant on access to genetic resources.

6. Australia therefore has a strong interest in:

– facilitating research;

– encouraging innovation and the capturing of benefits from that innovation;

– ensuring that it can exercise appropriate control over access to genetic resources and the use of traditional knowledge; and

– ensuring the benefits from granting access to genetic resources and traditional knowledge are shared equitably.

7. To do this successfully, it is important to balance the rights of those with interests in the different assets so that research and innovation prosper, and genetic resource and traditional knowledge owners are respected and obtain benefits, as appropriate. This requires that we balance the incentives and costs for all participants in any system that we adopt. In recognition of the importance of providing equitable access and benefit sharing arrangements in relation to genetic resources, the Australian government has taken important steps towards providing a framework to control access to, and use of, genetic resources on Commonwealth lands and waters through the preparation of forthcoming regulations to be introduced under the Environment Protection and Biodiversity Conservation Act 1999. Reflecting the federal nature of governance in Australia, the Australian government has reached an intergovernmental agreement on genetic resources management with all Australian States and Territories; the "Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources" (NCA)[2]. The NCA establishes a common basis for new or revised legislative, administrative and policy frameworks for Australia's implementation of the CBD "Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable sharing of benefits arising out of their Utilization." Australia views these guidelines as an important step in the process of developing equitable access and benefit sharing arrangements, and is working to ensure that there is appropriate use of other nation's genetic resources in Australia. On 4 November 2004, the Australian Government and the Australian States and Territories took a further step and established a body to facilitate the progressive implementation of the NCA.[3]

8. In line with this approach the Queensland State Parliament recently passed the "Queensland Biodiscovery Act 2004", establishing a framework for access to and use of Queensland's native biological resources for biodiscovery and other purposes. The Northern Territory government recently released for public comment a draft policy document on access to biological resources for bioprospecting in the Northern Territory. The Western Australian government has announced its intention to consider similar legislation and other States are also in various stages of introducing biodiversity arrangements.

9. Several suggestions have been made in international fora as to how the patent system might be used as a vehicle for the disclosure of the use of traditional knowledge and genetic

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[2] The text of this Agreement may be found at: http//ww.deh.gov.au/biodiversity/science/access/nca/index.html.

[3] This is the Biotechnology Australia: Biotechnology Liaison Committee Working Group on Biodiscovery.

resources accessed in the development of inventions[4]. Australia supports, in principle, the use of documentation associated with patent applications to disclose the source of relevant genetic resources. For example, there may be potential to use the patent publication system to improve the transparency of transactions involving access to genetic resources. Using this system would have the advantage of utilising a currently available and well-known regime which is readily accessible to a wide range of people in many countries. Given that the patents system has been developed over a long period of time and includes many checks and balances, any decisions on possible new measures must be carefully thought through to prevent adverse consequences arising and ensure objectives are met. Although Australia does not have a patent disclosure regime in place, Australia is of the view that any patent disclosure regime should:

- be easy to implement;
- not impose undue burdens and costs on IP right owners and administrators;
- encourage research and commercialisation;
- not affect the integrity of IP rights, especially since lack of disclosure should not be a bar to a patent, although there may be other legal ramifications outside the IP system (for example, transfer of ownership) for failing to disclose traditional knowledge and/or genetic resources;
- have a minimum impact on current IP systems;
- encourage creators to disclose the relevant inputs into their inventive process, while recognising there may be circumstances in which disclosure is not possible or appropriate; and
- provide useful information and be easily accessible to access providers.

10. If these broad parameters are not met in relation to proposed patent disclosure regimes then it is possible that unintended consequences may arise that would discourage research and innovation and risk undermining the objectives of a patent disclosure regime. For example, the invalidation or non-grant of patent rights could directly undercut any capacity to share benefits, as without the benefits that can accrue from strong patent rights the benefits to potential access providers could be dramatically reduced or nullified. Similarly without a valid patent right, individuals can still commercialise their IP without any obligation to disclose their invention to the public or to share the benefits unless there is an underlying regime ensuring benefit sharing.

11. It is also important, when considering modes for a patent disclosure regime, that there be some accommodation for what an inventor ought reasonably be aware of when conducting prior art searches. For example, an inventor may not be aware that relevant traditional knowledge exists and may have developed their invention independently of any such knowledge. This is particularly true in those circumstances where the traditional knowledge may not have been published as a result of cultural and/or religious sensitivities. Consideration could be given to a disclosure regime based on a subjective test (what the patentee knew) rather than an objective one (what the patentee ought to know). Insufficient consideration of this issue runs the risk of introducing unreasonable burdens on inventors. The issues around whether that material may have been part of the public domain in relation

[4] For example, from the European Communities and their Member States (IP/C/W/383) and Brazil et al (IP/C/W/429) which were submitted to the TRIPS Council of the World Trade Organization (WTO).

to the invention can be dealt with under the traditional patent concepts of novelty and inventive step.

12. Furthermore, there are often multiple sources from which a person may legitimately obtain access to a genetic resource or traditional knowledge and any patent disclosure regime or access and benefit sharing system must recognise this.

13. Thus it is imperative that any patent disclosure regime adopted should be able to deliver the benefits sought within the broad parameters described above.

14. Australia notes that a number of member states have recently introduced disclosure regimes. We encourage WIPO to prepare a questionnaire asking these members how they implemented their regime and seek a full and frank assessment of their regimes. Questions that would enable a full exploration of the issues arising under such regimes might include: how effective the systems are in meeting their objectives, what problems have been encountered, examples of particular successes experienced and, examples of where users and/or authorities that process the additional information have found it useful.

15. During the seventh session of the WIPO IGC, the European Community and its Member States indicated that it would be submitting a proposal relating to access regimes to WIPO by 15 December 2004 as a submission to WO/GA/31/8. Australia looks forward to the opportunity to give careful consideration to this proposal along with any other proposals that are put forward.

16. Finally, Australia would like to state its continued commitment to ongoing and constructive discussion of the issues surrounding the access to, and benefit-sharing of, traditional knowledge and genetic resources so as to ensure that effective and efficient measures can be implemented.

BELIZE
Received December 16, 2004

INTRODUCTION

1. The present communication from Belize contains proposals regarding the options for model provisions on proposed disclosure requirements, practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements, and options for incentive measures for applicants.

PROPOSALS REGARDING THE OPTIONS FOR MODEL PROVISIONS ON PROPOSED DISCLOSURE REQUIREMENTS

2. Belize holds the view that there is a need for *sui generis* intellectual property protection at the international and national level for traditional knowledge. Protection of traditional knowledge must not require any formalities or registration. The rights conferred by traditional knowledge must include the right to prevent the unauthorized commercial reproduction, imitation and use of traditional knowledge.

3. The model *sui generis* provisions must cover the licensing of traditional knowledge. There has been a proliferation of bioprospecting contracts between researchers and communities that own traditional knowledge or genetic resources. Good examples of such bioprospecting contracts can be found in the INBio-Sacro, INBio-CRUSA-Eli Lilly (Bio-Xplore) and INBio-EARTH (Chagas) bioprospecting contracts in Costa Rica. The provisions must provide for the filing of such licences with the Registrar, the recordal of such licences in the Register and the publication of such licences in the Gazette. In the absence of any contrary provision in the licence contract, a licensee may not extend, to another person, the authorization conferred on him or her, nor may the licensee assign or mortgage such licence.

4. The model provisions must include clauses relating to the fair and equitable sharing of benefits including profit sharing, royalty payments, access to and transfer of technologies, the granting of free licenses to the community, and the development of local human resources. Also, the model provisions must outline enforcement measures that are expeditious and preventive, and constitute a deterrent to further infringements. Such enforcement measures must cover civil judicial procedures, provisional measures, border measures, and criminal procedures. However, such enforcement measures must not create barriers to free trade and must meet the basic principles of due process.

5. Also, Belize proposes that related provisions must be included in a wide array of intellectual property legislation such as patents and plant variety legislation. Patent applicants must be required to disclose the source and geographical origin of the biological material in their specifications and to demonstrate that they have secured prior informed consent to use the material. The traditional knowledge of indigenous communities should qualify as prior art that is capable of anticipating an invention that is claimed in a specification. The traditional knowledge holder must also be treated as a person “skilled in the art” in order to determine the obviousness of an invention.

6. Such model patent law provisions must also cover the area of opposition and revocation. Belize proposes that an invention should be refused or revoked if the invention is anticipated by traditional knowledge or if the complete specification does not disclose or wrongly mentions the source of the biological material used for the invention.

7. Similar provisions must be included in the model provisions for plant varieties legislation.

PRACTICAL OPTIONS FOR INTELLECTUAL PROPERTY RIGHTS APPLICATION PROCEDURES WITH REGARD TO THE TRIGGERS OF DISCLOSURE REQUIREMENTS

8. Belize is of the view that the most effective way of triggering the disclosure requirement will be to require industrial property offices to conduct searches for “traditional prior art”. However, this requirement will never be effective unless certain practical steps are taken. Firstly, technically uniform digital databases will have to be created of existing traditional knowledge. Secondly, such documentation must be recognized for national and international prior art searches. This entails the incorporation of such data in international classification systems such as the International Patent Classification (IPC), and the recruiting of traditional knowledge experts by International Search Authorities (ISA).

OPTIONS FOR INCENTIVE MEASURES FOR APPLICANTS

9. Belize proposes that fee reductions should be instituted at national patent offices and under the Patent Cooperation Treaty (PCT) system in order to encourage applicants to disclose the origins of the genetic material that is contained in their complete specifications. Nevertheless, Belize is of the view that the most effective incentive measure for applicants will be the “negative incentive” invoked by the threat of revocation of a patent that was granted based on the non-disclosure or misleading disclosure of the source of the origins of the genetic material that is contained in the complete specification.

BRAZIL
Received December 16, 2004

BRAZIL'S POSITION ON THE PRINCIPLES AND METHODOLOGY OF WORK THAT SHOULD BE EMPLOYED IN THE PREPARATION OF THE RESPONSE BY WIPO

1. The Conference of the Parties to the Convention on Biological Diversity (CBD) has invited WIPO and other international organizations to examine, and where appropriate address, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications.

2. A number of different fora, both within and outside WIPO, are currently engaged in discussions on the issue of the interaction between access to genetic resources and disclosure requirements in IP applications, particularly patent applications. Alternative proposals and views have been expressed on how to approach the issue.

3. The response to be prepared by WIPO to the CBD should be fully mindful of all such discussions in all relevant fora, including those within WIPO itself (Standing Committee on the Law of Patents and Working Group on Reform of the PCT), and should be inclusive of all positions. The best way to fulfil the principle of inclusiveness is to ensure that WIPO's response clearly and comprehensively sets out and reflects all proposals and views regarding patent disclosure requirements and genetic resources that may have been presented by WIPO Member States in different fora. Only in this way could WIPO make a useful contribution to the current discussions of the CBD on access and benefit sharing.

4. In this regard, the simplest and most realistic way to proceed may be for WIPO to elaborate a table of comparison that would list in some detail the different aspects of the various proposals. Given the current state of play of discussions in different fora, within and outside of WIPO, it would not be advisable for WIPO to pass judgment on the different options and to seek to advocate specific approaches to the detriment of others, as such a course of action could be prejudicial to the positions of its Member States.

5. These considerations should be borne in mind, in particular, with respect to the invitation to examine "options for model provisions on proposed disclosure requirements". The elaboration of any options for model provisions that would in any way leave out aspects of proposals tabled by Brazil and other developing countries in different fora, as described below, would be unacceptable.

6. In preparing its response, WIPO should also be guided by the terms of the invitation of the CBD, all of which were carefully negotiated at the 7th Conference of the Parties. The CBD invitation, in particular, notes that WIPO should address certain issues "*where appropriate*", and that this should be done in a manner that is "supportive of and does not run counter to the objectives of the CBD".

7. As a mega-diverse developing country, Brazil takes a great interest in discussions on the interaction between intellectual property and access to genetic resources and strongly supports the establishment of effective global measures to address the grave international problem of "bio-piracy". In this regard, Brazil is among the proponents of measures designed to ensure a harmonious and mutually supportive relationship between the patent system and the CBD. In

the World Trade Organization (WTO), Brazil's contribution to the discussions on this issue have taken the form of a proposal to amend the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which it has tabled together with other developing countries in the context of the current Doha Development Round. The views and positions of Brazil on this matter are reflected in the following WTO documents: IP/C/W/356, IP/C/W/403, IP/C/W/420, IP/C/W/429Rev.1 and IP/C/W/438. It is expected that these documents will be supplemented by new submissions to the WTO TRIPS Council in the near future.

8. The substantive views regarding disclosure of origin reflected in the proposal tabled by Brazil and other developing countries in respect of the WTO TRIPS Agreement are relevant to other international instruments in the field of patent law, such as those administered by WIPO, as well as other instruments under negotiation. They are directly relevant to the general discussion on the interaction between access to genetic resources and disclosure requirements in intellectual property applications, as well as the negotiations in the CBD on the international regime on access and benefit sharing. Brazil insists, therefore, that the substance of its proposals should be properly reflected in the response of WIPO to the invitation of the 7th COP of the CBD.

Position of Brazil on patent disclosure requirements and genetic resources

9. Brazil is of the view that patent applicants for inventions relating to biological materials and/or associated traditional knowledge, under the existing relevant international treaties, should be required, as a condition for acquiring patent rights, to disclose:

(a) the source and country of origin of the biological resources and associated traditional knowledge used in the invention;

(b) evidence of compliance with prior informed consent under the relevant national regime; and

(c) evidence of compliance with fair and equitable benefit sharing under the relevant national regime.

10. The following is a summary of the main aspects of the position of Brazil on this issue, as expressed, *inter alia*, in the WTO TRIPS Council and relevant WIPO bodies (Standing Committee on the Law of Patents and Working Group on Reform of the PCT), as they may relate to different parts of the invitation of the CBD:

I. Options for model provisions on proposed disclosure requirements

Disclosure of origin, prior informed consent and fair and equitable benefit sharing (henceforward, "disclosure of origin") should be a mandatory requirement, to be imposed on patent applicants in all jurisdictions, preferably through an amendment to relevant international intellectual property treaties, such as the WTO TRIPS Agreement.

II. Practical options for intellectual property rights applications procedures with regard to the triggers of disclosure requirements

– Functions of the requirement:

It is envisaged that the establishment of a mandatory, universal disclosure of origin

requirement will contribute to the attainment of the following objectives:

(a) Improve the substantive examination of patent applications, by:

(i) helping to ensure that all relevant prior art information is available to the patent examiner;
(ii) helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under, for example, Article 27, paragraphs 2 and 3, of the TRIPS Agreement, as well as related provisions of other international agreements;
(iii) helping to systematize available information on biological resources and associated traditional knowledge that will continuously build the prior art information available to patent examiners and the general public.

(b) It is foreseen, furthermore, that the disclosure requirement will also be relevant to the determination of inventorship or entitlement to the claimed invention, and would be useful in cases relating to challenges to patent grants, including disputes on inventorship or entitlement, as well as infringement cases;
(c) In some cases, disclosure of origin may also facilitate or permit the actual execution of the invention, such as where a biological material is endemic to a specific location;
(d) Disclosure of origin would, moreover, constitute a necessary and effective incentive measure for patent applicants to comply with the access and benefit sharing legislation of countries of origin of the biological resources, in a manner that would contribute to the realization of the principles and objectives enshrined in provisions of international IP treaties, such as Articles 7 and 8 of the TRIPS Agreement. More generally, it would constitute an important realization of the principle of *equity*.
(e) As a transparency measure, disclosure of origin would help keep track of the commercial exploitation of biological materials for the purposes of benefit sharing.

– Triggers of disclosure requirements:

11. The disclosure requirement would have both substantive and formal implications. Any use of biological resources and associated traditional knowledge, the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention, would be sufficient to trigger the disclosure obligation. Even where the use was only incidental, it would be sufficient to trigger the obligation, if the disclosure were relevant for prior art, inventorship or entitlement determinations, the scope of the claim and/or for understanding or carrying out the invention. Among others, the uses that would be relevant for prior art, inventorship or entitlement determinations, the determination of the scope of the claims and/or for understanding or carrying out the invention could include, among others, where the biological resources and/or traditional knowledge is used:

(a) to form part of the claimed invention;
(b) during the process of developing the claimed invention;
(c) as a necessary prerequisite for the development of the invention;
(d) to facilitate the development of the invention; and
(e) as necessary background material for the development of the invention.

12. While there will be administrative implications and there may be cost implications for applicants as they are expected to at least employ all reasonable measures to determine

the country of origin and source of the material to meet this obligation, it is not foreseen that administrative procedures and costs related to meeting the obligation would be in any way burdensome.

– Nature of the requirement:

13. A patent application will be deemed to comply with a disclosure of origin requirement if it contains a declaration, in a prescribed form, indicating the source and country of origin of the biological resources and/or associated traditional knowledge used in an invention, as well as a declaration that prior informed consent and fair and equitable benefit sharing have been complied with under the relevant national regime. These declarations should be accompanied, where relevant, by the actual evidence of prior informed consent and benefit sharing, for example, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin.

III. Options for incentive measures for applicants

– Legal effects of non-compliance with the requirement:

14. As already noted, the proposed disclosure of origin requirement will have both formal and substantive components and implications. The nature of the legal effect of insufficient, wrongful or no disclosure of origin, and of evidence of prior informed consent and fair and equitable benefit sharing, will depend on whether one is dealing with a formal or substantive component of the disclosure and whether it is at the level of pre or post-grant.

15. In this context, where the insufficient, wrongful or no disclosure is discovered before the examination or grant of a patent, the legal effect could be that the application would not be processed any further until the submission of the necessary disclosure declarations and evidence. This could be accompanied with penalties and time limits within which the proper disclosure declarations and evidence should be provided, otherwise the application could be deemed withdrawn. In essence, the insufficient, wrongful or no disclosure of the source and country of origin of the biological resources and/or traditional knowledge, as well as failure to provide evidence of prior informed consent and fair and equitable benefit sharing, should justify the non-processing of the application.

16. Where the insufficient, wrongful or lack of disclosure of source and country of origin is discovered after the grant of a patent, the legal effect could include:

– Revocation of the patent where it is determined that the proper disclosure would have led to the refusal to grant the patent either on the grounds of lack of novelty due to the existence of prior art or on grounds of *ordre public* or morality and where there is fraudulent intention for the insufficient, wrongful or lack of disclosure. In addition to revocation, criminal and/or administrative sanctions may also be imposed, for example, where the insufficient, wrongful or lack of disclosure amounts to a false representation.

– Full or partial transfer of the rights to the invention where full disclosure would have shown that another person or community or governmental agency is the inventor or part inventor or would otherwise be entitled to all or part of the claimed invention; and,

– Narrowing the scope of the claims where parts of the claims are affected due to lack of novelty or fraudulent intention or where full disclosure would have led to refusal to admit those parts of the claims.

17. Similarly, where the failure to provide evidence of prior informed consent is discovered after the grant of a patent, the legal effect could include:

– Revocation of the patent. In addition to revocation, criminal and/or administrative sanctions may also follow, outside the patent system, in particular, to ensure adequate compensation where it is eventually determined that no prior informed consent was obtained.

– Criminal and/or civil sanctions, including the possibility of punitive damages, could follow, again outside the patent system, where it is determined that the patent holder in fact obtained prior informed but did not provide the evidence in the application.

18. Additionally, sanctions should also apply in cases of failure to provide evidence of fair and equitable benefit sharing. These shall be elaborated upon at a later time.

19. While a certain level of leeway may be given here on the exact legal effect for each infraction, every State should nevertheless have an obligation to ensure that the effect of insufficient, wrongful or lack of disclosure, and/or of failure to provide evidence of prior informed consent and fair and equitable benefit sharing, is effective in terms of its deterrent, compensatory and equity value.

IV. Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties

20. The proposals for a mandatory, universal, disclosure of origin requirement may have implications for WIPO-administered treaties, as well as treaties under negotiation. Many of these implications have not yet been fully discussed by WIPO Member States. Discussions, nevertheless, have taken place on the matter in the context of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and the draft Substantive Patent Law Treaty (SPLT). Brazil has made specific proposals with respect to the draft SPLT in the Standing Committee on the Law of Patents and has, moreover, expressed itself on the issue of disclosure of origin, in the context of the PCT, in past sessions of the Working Group on Reform of the PCT, as well as in the WIPO General Assembly.

V. (Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance

21. Discussions on certificates of origin/source/legal provenance are still ongoing in other fora. Brazil would approach this matter in the context of the positions expressed with respect to items (a), (b) and (c) above.

COLOMBIA
Received December 16, 2004

1. In response to the invitation issued by the Conference of the Parties to the Convention on Biological Diversity (CBD) for WIPO to "study and, in the appropriate cases, resolve, taking into account the need for the work in question to support and not to infringe the aims of the CBD, matters concerning the relationship between access to genetic resources and requirements for disclosure of information in applications for the provision of intellectual property rights", the Government of Colombia proposes the following:

(a) with respect to the model options on the proposed requirements for disclosure:

2. We consider that the grant of patents which relate to inventions developed from biological and genetic resources, and their products, derived from a country of origin which is a party to the CBD, should be subject to access being granted thereto in accordance with the requirements of Article 15 of the CBD, and the national and international standards specific to the subject. The disclosure should state clearly the place, quantity and date of collection of the material.

3. In this regard, we endorse the proposal put forward by Switzerland at the fourth session of the Working Group for Reform of the Patent Cooperation Treaty (PCT) in May 2003 (PCT/R/WG/4/13), in addition to the proposal for amendment of the Patent Law Treaty (PLT), which are based on the following principles:

– transparency measures must be effective and efficient;
– transparency measures should guarantee legal security, be practical, and avoid major charges and costs for patent applicants, as well as for patent authorities;
– the measures should allow States to introduce solutions to take effect at the national level, and which relate to national interests and needs;
– transparency measures should be consistent with the relevant international agreements.

4. The proposed amendment to (g) of Rule 51bis.1 of the Regulations under the PCT is as follows:

"(g) The national law applied by the designated Office may, in accordance with Article 27, require the applicant to:

(i) declare the specific origin of the genetic resource to which the inventor has had access, if the invention is directly based on said resource; if the origin is unknown, this shall also be declared;

(ii) declare the origin of the knowledge, innovations and practices of indigenous and local communities, relevant to the conservation and sustainable use of biological diversity, if the inventor knows that the invention is directly based on said knowledge, invention or practice; if said origin is unknown, this shall be declared accordingly".

5. In general terms, we consider that this proposal is consistent with the language used and the agreements reached at the international level under the CBD. Similarly, it should be emphasized that the proposed text envisages the possibility that the applicant does not know the origin of the genetic resource, in which case the applicant shall make a declaration to that effect. However, we should point out that in our opinion, contrary to the Swiss proposal, the requirement of disclosure should in all cases be compulsory. In other words, a declaration to the effect that the origin of the genetic resource is unknown would not suffice for the purposes of fully satisfying the disclosure requirement.

6. In similar vein, we consider that the heading of the proposed text should not refer to the "national law applied by the designated Office", but to any Member State, thereby confirming the binding nature of the requirement of disclosure.

(b) With regard to the practical options for the procedures for intellectual property rights applications in relation to the activation of disclosure requirements:

7. Firstly, we suggest that the analysis of a patent application, insofar as it is based on a genetic resource, and the study of legal access thereto should be incorporated in the guidelines for patent examiners. Thus, each Party will require the disclosure or revelation of the following elements at the time when a patent application is filed with the patent office:

(a) The biological and genetic resources and their derived products as used, together with the individual certificate of legal provenance;
(b) The country of origin of said resources; and
(c) Proof of the prior informed consent of the country of origin with regard to (b).

8. The national intellectual property authorities should include, in the determination of the prior art, information referring to biological and genetic resources and their derived products belonging to the Parties.

9. In addition, the documented information which has been submitted on these subjects by the competent intellectual property authorities of the other Party should be taken into account in the corresponding examinations.

10. The information referred to in the previous paragraph will be intended for the exclusive use of the national intellectual property authorities for the purposes of examining patent applications.

11. As regards the options for activation of the disclosure requirement, we would like to state the following: the first option would be the activation of the disclosure in the formal study of the application. This would allow the competent national office to send a notification in the event that the applicant has not produced the access contract or the certificate of origin of the genetic resource. Thus, continuation of the other phases of the application procedure would be avoided, until such time as the due disclosure is made available.

12. The alternative option would be for the competent national office to analyze the subject when carrying out the patentability study. Although in this case it is also viable to send a notification to the applicant, this option would be less beneficial, since the processing of the application would be at a more advanced stage.

(c) With respect to the options for incentive measures designed for applicants:

13. The main incentive for the applicant to disclose, in timely fashion, the origin of the genetic resource is the processing of his application, since without the fulfillment of this requirement the patent may not be granted. Even where the patent is granted, it would be likely to be invalidated.

14. A further incentive is that of time, since the application process in this case would be four months shorter, in view of the process in which the applicant is required to submit the access contract.

15. Similarly, the incentive which the applicant has to disclose the origin of the genetic resource is that the subject matter of the patent application will be much clearer and more precise, and consequently so will the subject matter of the applicant's right. In other words, the applicant would have legal security for his patent.

16. Recognition could be given to the legal work done and to that which benefits nature, with mechanisms including those whereby the applicant and/or holder has the opportunity to promote his invention as biodiversity friendly.

17. For applicants or patent owners who have made unlawful use of the genetic resources of a Party, without satisfying the requirements of Article 15 of the CBD, each Party will establish compensation mechanisms such as the following, in order to legalize use in the countries which are party to the CBD:

a. The applicant must pay royalties from the date on which the patent application was submitted for the use of the inventions derived from said genetic resources.

b. The applicant shall recognize the use of the genetic resource and the place of origin in the description of the patent application and/or on the label attached to the product, claimed in said application and/or patent, for marketing purposes.

(d) With respect to determining the repercussions of the operation of the disclosure requirements contained in the different treaties administered by WIPO:

18. The national intellectual property authorities will cooperate with the WIPO Secretariat in the exchange of information on patent applications and patents granted for inventions, based on the use of biological and genetic resources, and their derived products, with a view to appropriate fulfillment of the requirement of disclosure, to be established in the following Treaties:

- Patent Cooperation Treaty (PCT) (1970)
- Patent Law Treaty (PLT), and
- Substantive Patent Law Treaty (SPLT).

19. The determination to disclose these requirements would provide an incentive for greater participation by the megadiverse countries in the treaties, through the signing of pending agreements, there would be a greater flow of biotechnology applications, and above all there would be greater confidence in the system on the part of developing countries, since there would no longer be a sense of exploitation but of cooperation.

(e) With respect to the intellectual property issues raised in the proposed international certificates of origin/source/legal provenance:

20. Although our legislation does not provide for the intellectual property issues which may be raised in the contracts for access to genetic resources, contrary to the situation in the United States, we consider it a very important possibility for said contracts to include provisions under which the participation of those administering the genetic resources in the intellectual property rights which may be derived from said resources is envisaged.

GHANA
Received December 16, 2004

INTRODUCTION

1. Most Patent Laws, as they relate to biodiversity, prohibit the granting of patents in respect of plants and animal varieties or essentially biological processes for the production of plants or animals other than microbiological processes and their products. Patents cannot be issued for inventions, the publication or exploitation of which would be contrary to public order or morality. Furthermore, the issue of ownership of plant varieties under the existing plant protection laws do not protect wild varieties, which constitute the primary source of medicinal plants and food crops.

2. Another pertinent issue is whether the formal system of intellectual property rights, based on modern conceptual and legislative frameworks can create mechanisms that will protect the traditional, collective body of knowledge that has become commercially useful at the global level. This is in view of the fact that there is currently no legal protection for the TK/GR and innovations of local communities and farmers as envisaged by Article 8j of the CBD.

3. With respect to the Ghana Patent Law, Section 5(5) of the Law provide for the disclosure of origin in a limited manner. Patents, which claim the use of biological source materials, in some cases indicate the country of origin of the plant and its traditional uses in the description of the specification, especially where the information is necessary to carry out the invention. Such disclosures are usually made for the genetic resources that are not common in nature and are exotic. In the case of well-known and widespread genetic resources, the applicants decide whether to disclose the origin of the genetic resources in patent applications

4. It is within this vein that the following responses are provided:

(a) Options for model provisions on proposed disclosure requirements
There are generally about 3 options available on the proposed disclosure requirements. These are:

(i) Mandatory requirements for disclosure of origin and legal access (this takes into account prior informed consent and mutually agreed terms)

(ii) Disclosure requirements without legal consequences in cases of noncompliance

(iii) Stand alone disclosure requirements linked to public law – Access legislation etc.

Most developing countries prefer the 1st option. What has not been clarified is whether to make the disclosure mandatory as a formality in the patent procedure or as substantive patentability criterion.

(b) Practical options for intellectual property rights applications procedures with regard to the triggers of disclosure requirements.

5. The need to establish a trigger for the application of disclosure requirements

should be based on the relationship between the invention and the GR/TK. If the invention is essentially derived from the GR/TK, then it should trigger the application of disclosure requirement. This should be made independent of whether the material used is well known (Public domain) or not (undisclosed information).

(c) Options for incentive measures for applicants:

– Refusal for non-compliance with disclosure requirements should not be Applied.

– Provide additional incentives

(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-Administered Treaties:

– Paris Convention Art 2 (national treatment)

– Attribution of ownership

– Disclosure requirements will need to account for multiplicity of sources

– Extent of obligation could place undue burden on the applicant to disclose the origin of all genetic resources and TK used in the invention- Reasonable effort may be necessary

– Establishment of disclosure requirements minimum standards??

– Enforcement mechanisms required to deal with GR/TK of multicultural nature and those that cut across national boundaries

(e) Intellectual property-related issues raised by a proposed international certification of origin/source/legal provenance.

Elements stated in (d) above may be applicable.

ISLAMIC REPUBLIC OF IRAN
Received December 17, 2004

1. In response to the decision of the General Assembly of Member States of WIPO in its thirty-third (19th extraordinary) session which took place from 27th September to 5th October 2004, the comments of the Islamic Republic of Iran responding to the invitation of the Conference of Parties (COP) of CBD on its decision VII/19, regarding the interrelationship of access to genetic resources and disclosure requirements in intellectual property rights applications are as follows:

2. Lack of clarity

– There are some ambiguities in the invitation of the Conference of Parties (COP) of CBD on its decision VII/19 as reflected in paragraph 6 of the document WO/GA/31/8.

– It is not clear whether intellectual property rights' applications means the existing applications or the applications to be discussed later on.

Regarding document WO/GA/31/8 paragraph 6(d), it is not clear which body or bodies have the main responsibility for the identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties.

– In essence, there is no specific body in WIPO to address the subjects mentioned in paragraph 6 (a. b. c) of the document WO/GA31/8.

Furthermore, the existing applications are not sufficient to meet the expectation of the CBD in its request.

3. Points that should be considered

– While taking into account the ambiguities mentioned in "A" above, the Islamic Republic of Iran welcomes the positive answer to CBD and recognizes the previous works of CBD as an international UN initiator body. In this regard, the work of WIPO on Access to Genetic Resources and disclosure of requirements should complement and be supportive of the objectives of the CBD.

– Furthermore, on the relationship between access to genetic resources and disclosure of requirements, due to the lack of clarity on the requested issues, we believe WIPO, at the present stage, preferably limit its work on the comments made by delegations in various bodies rather than going to details before the decision of WIPO General Assembly in 2005.

– Any response to the CBD's questions should be regarded as technical input to facilitate policy discussion and it should not be considered as a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States.

– Since at this stage, it is not clear which body with which quality or with which mechanism should work on the interrelationship of Access to Genetic Resources and

disclosure requirements in WIPO regarding the CBD's request, it is more suitable that the preliminary response be general and limited to the existing discussions in different bodies of WIPO in the context of CBD objectives.

– The method of identifying the implications in different WIPO-administered treaties should be decided upon by the Member States.

– The work and provision of reports on the above-mentioned issues to CBD should be concurrent and compatible with the speed and trend of all of the work of the related committees.

JAPAN
Received December 17, 2004

I. CURRENT SITUATION OF BUSINESS RELATING TO GENETIC RESOURCES IN JAPAN

1. Genetic resources are a fundamental component of biotechnology research and 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.

2. *The BT Strategies* notes the importance of the Convention on Biological Diversity (CBD), which is the basis on which Japan cooperates with other countries[5]. A number of scientific and commercial projects have been in progress in recent years in Japan.

3. 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 efficient utilization of biological and genetic resources and for related benefit sharing. Besides, some private companies in Japan have also been conducting similar projects with other countries on the lines of the CBD.

4. Our survey shows that companies have a sense of responsibility and 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 with whom conditions can be arranged for the proper implementation of contracts based on mutual understanding and trust.

5. 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.

6. 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, and, if stringent regulations to take out genetic resources are introduced and unpredictable procedures caused cost increases, the business sector will

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[5] 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.

hesitate to use genetic resources. As a result, there is little, by way of benefits, to share with providers of genetic resources.

II. MANDATORY DISCLOSURE REQUIREMENTS IN IP APPLICATIONS

7. Several proposals have been introduced in international fora thatmandatory 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 is skeptical about introducing such mandatory disclosure requirements.

(1) Disclosure requirements in patent applications

8. A patent system provides for two categories of disclosure requirements (i.e. substantive and formative requirements) as a prerequisite for granting patent right for an invention. The necessity to disclose the source/country of origin cannot be explained by the 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

9. Even when the source/country of origin of a genetic resource is disclosed in an application, it is practically impossible to ensure that any 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 the depository institution which acquires the status of the 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.

10. 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).

11. 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).

12. Moreover, as for a person who wishes to obtain a patent, information contained in prior art documents is indispensable for comparing and judgingthe 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.

13. On the other hand, information about the source/country of origin of genetic resources might 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

14. Such entries as applicant names are to be made formative requirements only when such requirements are regarded as reasonable (see Article 62.1 of the TRIPS Agreement). As regards the disclosure of the source/country of origin of genetic resources, therefore, we are not convinced that disclosure requirement is regarded as reasonable procedures and formalities. 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.

15. The Patent Law Treaty (PLT), which has yet to come into effect, is aimed at the 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 the source/country of origin of genetic resources is not necessary.

(2) Burden on patent applicants

16. 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 prior informed consent (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 would be required to acquire a PIC from the country.

17. If the disclosure the source/country of origin of genetic resources in a patent application should be made an obligation, it would increase the burden of applicants applyingfor a patent for an invention based on genetic resources because there would be an additional risk where a patent would be invalidated only on the grounds that disclosure requirements were not met. In cases in which an applicantcould not immediately specify thesource/country of origin of a genetic resource (e.g. a corporation directly purchased the resource from a genetic resource traders or 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. Such a burden 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.

18. 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 lack of disclosure requirement, the adoption of these requirements could be considered as falling under the scope of “discrimination as to the field of technology.”

KYRGYZ REPUBLIC
Received December 10, 2004

1. We are pleased to send the response on WIPO's request with regard to the matters related to genetic resources and associated traditional knowledge protection as well as interrelation with the Convention on Biological Diversity (CBD).

(a) We are realizing the importance of this matter which is, as it is known, has an interdisciplinary nature on technical, political, economical and social aspects.

2. Along with it, development of the processes does not allow at present time to give uniform answer to the first question. It is necessary to analyze this matter deeper.

3. However, from our point of view, matters related to access to genetic resources has no direct legal links to the protection of genetic resources and associated traditional knowledge.

4. The Convention on Biological Diversity (CBD) provides for the right of each member state to make independent decisions related to genetic resources on the national level.

5. With regard to the disclosure requirements or designation of the biological material used in the process of the subject matter creation on which protection is claimed, it has a purely technical nature and does not contrary to the CBD provisions and goals. We deem that disclosure requirements as to the biological materials, could allow developing, on the national level, provisions to regulate matters related to the access to genetic resources and equitable sharing arising from the use of genetic resources.

(b) With regard to the procedures on intellectual property rights subject matters in the light of disclosure requirements, we deem that this matter has to be considered on a step by step basis, namely:

1. It is necessary to develop relevant legal basis to regulate genetic resources and associated traditional knowledge protection on the national and international levels, and

2. Develop legislation with regard to the access to genetic resources;

(c) Options for incentive measures for applicants can be regulated according to common basis of such kind of practice in the field of IPR's;

(d) Disclosure requirement with regard to subject matters created with use of genetic resources, from our point of view, could not considerably impact various WIPO-administered treaties. However, taking into account the fact that genetic resources and traditional knowledge protection matters are still on the stage of consideration, approach to these matters could vary depending on the circumstances;

(e) International certificate of origin/source/legal provenance could be used to monitor the use of certain genetic resources as well as during the process of creation of the terms and conditions on access to genetic resources and equitable sharing arising from the use of genetic resources. Matters related to the scope of IPR's on objects from flora and fauna,

has to be considered on the national level, taking into account all advantageous and risks associated with implementation of these type of legal practices.

RUSSIAN FEDERATION
Received December 17, 2004

1. The Russian Federation takes a close interest in the work of the World Intellectual Property Organization (WIPO) linked to matters of protection of traditional knowledge.

2. On behalf of the Russian Federation, the Federal Service for Intellectual Property, Patents and Trademarks (Rospatent) takes an active part in the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and expresses its opinion on issues examined by the Committee.

3. As has been pointed out in the statements made by the Delegation of the Russian Federation, we support the cooperation between WIPO and the Convention on Biological Diversity (CBD) on the scheme proposed at the seventh session of the Conference of Parties:

"…to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia:

(a) Options for model provisions on proposed disclosure requirements;
(b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
(c) Options for incentive measures for applicants;
(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;
(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

4. We consider that the matters listed above require a careful detailed discussion which has not yet been conducted by the Committee.

5. The documents prepared by the Committee may be taken as a basis for discussion:

– on the subject in subparagraph (a) – document WIPO/GRTKF/IC/7/9, comments on which will be submitted, in accordance with paragraph 41 of document 7/9, by February 28, 2005;

– on the subject in subparagraph (b) – the proposals by Switzerland contained in documents WIPO/GRTKF/IC/7/INF/5 (and also in PCT/R/WG/6/11) and relating to this subject;

– on the subject in subparagraph (c) – proposals on this subject for subsequent discussion may be requested from participants in the Committee sessions;

– on the subject in subparagraph (d) – discussion of the subject may be commenced once any conclusions from the discussion of the first three subjects have been drawn; in addition, there is a need for further analysis of current regional and national legal documents

and systems linked to access to genetic resources, and joint use of benefits and experience accumulated during their production, including gaps occurring and the relevant consequences;

– on the subject in subparagraph (e) – additional information, relating directly to the actual international certificate, is required for discussion of the question of an international certificate of origin/source/legal provenance.

6. In addition, as we have observed we agree with the statements made by certain delegations at the seventh Committee session regarding the fact that the draft guidelines examined in document WIPO/GRTKF/IC/7/9 do not constitute an international agreement. We consider, however, that this is a very effective instrument of protection which is required, including during examination of the matter relating to disclosure in patent application documents of sources of genetic resources and related traditional knowledge, as well as when obtaining prior informed consent for the use of such genetic resources. The requirements in question (requirements of disclosure of source in application documents) have already been introduced into the patent legislation of certain countries.

7. The draft agreement examined in document 7/9 is precisely the kind of mechanism which allows prior informed consent to be obtained.

8. In addition, we consider that detailed guidelines on access and equitable benefit sharing may be used when obtaining prior informed consent for the use of traditional knowledge connected not only with genetic resources but also in other traditional knowledge fields.

SWITZERLAND
Received December 17, 2004

Reply by Switzerland to Note C. 7092 related to the invitation of the Convention on Biological Diversity (CBD) to the World Intellectual Property Organization (WIPO) to examine, and where appropriate address, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications

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EXECUTIVE SUMMARY

The seventh Conference of the Parties (COP-7) of the Convention on Biological Diversity (CBD) invited the World Intellectual Property Organization (WIPO) "to examine, and where appropriate address, […] issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications[.]" In Note C. 7092, WIPO invites its Member States to present their proposals and suggestions with regard to these issues. This present document contains the reply by Switzerland to Note C. 7092.

In the context of disclosure requirements, Switzerland recalls the proposals it submitted to WIPO with regard to the declaration of the source in patent applications.[6] More specifically, Switzerland proposes to amend the Regulations Under the Patent Cooperation Treaty (PCT-Regulations) to explicitly enable the Contracting Parties of the PCT to require patent applicants to declare the source of genetic resources and traditional knowledge, if an invention is directly based on such resources or knowledge.

With regard to the issues to be examined and addressed by WIPO, the views of Switzerland can be summarized as follows:

(a) *Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties*: Switzerland considers the requirement to disclose the source of genetic resources and traditional knowledge in patent applications to be in the nature of a formal requirement. Due to this formal nature, the PCT and the Patent Law Treaty (PLT) are the two treaties clearly in the foreground with regard to the introduction of a disclosure requirement in patent law. In order to explicitly enable the Contracting Parties of these treaties to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications, Switzerland proposes to amend the PCT-Regulations.[7]

(b) *Options for model provisions on proposed disclosure requirements*: The proposals by Switzerland to amend the PCT-Regulations are sufficiently specific and clear to be directly implemented at the national level. Accordingly, Switzerland sees no need for model provisions on proposed disclosure requirements.

(c) *Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements*: According to the proposals by Switzerland, the trigger of the disclosure of the source should be designed according to the differing characteristics of genetic resources and traditional knowledge: With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) of the PCT-Regulations makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the inventor must have had physical access to this resource, that is, its possession orat least contact which is sufficient enough to identify the

[6] See WIPO documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11, and WIPO documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

[7] For an overview of the Rules of the PCT-Regulations proposed to be amended, see Appendix of WIPO document PCT/R/WG/7 Paper No. 7.

properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51*bis*.1(g)(ii) of the PCT-Regulations makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

(d) *Options for incentive measures for applicants*: In the view of Switzerland, the sanctions currently allowed for under the PCT and the PLT should apply to failure to disclose or wrongful disclosure of the source of genetic resources and traditional knowledge in patent applications.

(e) *Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance*: Since the elaboration and negotiation of the international regime as mandated by COP-7 has not yet begun, the intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance cannot be anticipated at this point in time. In the view of Switzerland, the international regime and its elements, including any certificate of origin/source/legal provenance, should be mutually supportive with the existing international legal order and the relevant international instruments. Furthermore, any intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance are to be dealt with by the competent international fora, in particular WIPO.

I. BACKGROUND

1. Switzerland holds the view that with regard to genetic resources, traditional knowledge and intellectual property rights a fair and balanced approach must be taken: On one hand, Switzerland supports the effective protection of biotechnological innovations through intellectual property rights, in particular patents. On the other hand, a fair and balanced approach necessitates effective, efficient, practical and timely solutions to the issues arising in the context of access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization. This is why Switzerland has been actively supporting efforts to find these solutions in various international fora, including the Convention on Biological Diversity (CBD); the Food and Agriculture Organization (FAO); the "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" (IGC) and the Working Group on Reform of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO); and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council).

2. One crucial issue that these international fora have been addressing is the need for and the realization of measures that increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, in particular with regard to the obligations of the users of genetic resources and traditional knowledge (hereinafter "transparency measures"). Transparency measures will enhance the mutual supportiveness of the applicable international agreements and can only be successfully realized if all relevant international fora coordinate their efforts closely and strive for coherent results.

3. The CBD does not contain specific provisions on transparency measures that the Contracting Parties should introduce in their national legislation.[8] Such measures are addressed in greater detail in para. 16(d) of the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" (Bonn Guidelines) and in several decisions of the CBD's Conference of the Parties.[9] Furthermore, disclosure of the source is one of the elements to be considered by the CBD's Ad Hoc Open-ended Working Group on Access and Benefit-sharing for inclusion in the international regime on access to genetic resources and benefit-sharing.[10]

4. Switzerland holds the view that transparency measures are an important element in the fair and balanced approach advanced above. It views transparency measures not only as increasing transparency in the context of access and benefit sharing, but also as building trust among the various stakeholders involved. Switzerland considered in detail the various options available for such measures and their possible modalities and implications. Based on these considerations, it elaborated proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. In summary, Switzerland proposes to amend the Regulations Under the PCT (PCT Regulations) to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.

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[8] Art. 15.7 of the CBD states that "[e]ach Contracting Party shall take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

[9] See para. 46 of Decision VI/10 and para. 1 of Section C of Decision VI/24. Furthermore, para. 8 of Section E of Decision VII/19 "[i]nvites the World Intellectual Property Organization to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the Convention on Biological Diversity, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:

(a) Options for model provisions on proposed disclosure requirements;
(b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
(c) Options for incentive measures for applicants;
(d) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;
(e) Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the Convention on Biological Diversity on its work, in particular on actions or steps proposed to address the above issues, in order for the Convention on Biological Diversity to provide additional information to the World Intellectual Property Organization for its consideration in the spirit of mutual supportiveness[.]"

[10] See para. (d)(xiv) of the Annex to Section D of Decision VII/19.

5. Switzerland presented its proposals to the fourth session of WIPO's Working Group on Reform of the PCT in May 2003.[11] In order to further advance the discussions on its proposals, Switzerland presented two more submissions to the Working Group on Reform of the PCT containing additional comments and further observations, respectively, in May 2004 and October 2004.[12] The additional comments address the use of terms, the concept of the „source" of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, and the possible legal sanctions for failure to disclose or wrongful disclosure of the source. The further observations address the formal vs. the substantive nature of the disclosure requirement, the optional vs. the mandatory introduction of the disclosure requirement at the national level, and the concept of the "source."

II. PROPOSALS AND SUGGESTIONS BY SWITZERLAND CONCERNING THE INVITATION OF THE CBD TO WIPO ON ISSUES REGARDING THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS[13]

(a) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties[14]

(1) Relevant treaties administered by WIPO

6. The policy objective of the disclosure requirement is to increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization. To achieve this policy objective, the disclosure requirement has to be examined for the purposes of determining if a complete patent application has been filed. However, this policy objective neither requires nor justifies that the disclosure requirement is linked to the search, examination or grant of patents, or to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement.

7. Due to the formal nature of the disclosure requirement, Switzerland considers the PCT and the Patent Law Treaty (PLT) to be in the foreground with regard to the disclosure of the source of genetic resources and traditional knowledge in patent applications. Both treaties are administered by WIPO and deal with the formal aspects of international (PCT) and national and regional (PLT) patent applications.

8. According to Art. 27.1 of the PCT, "[n]o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this treaty and the regulations." In this regard, Rules 4.1 and 51*bis*.1 of the Regulations under the PCT are of particular importance:

- Rule 4.1 enumerates the mandatory and optional contents of the request of an international patent application. According to Rule 4.1(c)(iii), such request may contain

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[11] See WIPO documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11.

[12] See WIPO documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

[13] In order to facilitate cross-references with the Swiss Proposals, the order of the questions has been modified accordingly.

[14] See para. 8(d) of Section E of Decision VII/19.

"declarations as provided in Rule 4.17." Rule 4.17 deals with certain declarations that are required by national laws in accordance with Rule 51*bis*.1(a). Rule 4.17 permits applicants to include in the request certain declarations corresponding to the matters set out in Rule 51*bis*.1(a)(i) to (v), relating to which designated Offices may require evidence or documents. According to Rule 4.18(a), "[t]he request shall contain no matter other than that specified in rules 4.1 to 4.17 [...]"; furthermore, Rule 4.18(b) requires the receiving Office to delete ex officio any such additional matter.

- Present Rule 51*bis*.1 lists in subparas. (a) to (f) a number of matters relating to which the applicant may be required to furnish documents or evidence under the national law applicable by the designated Office. This rule provides clarity for both applicants and designated Offices that such items may be required to be furnished by the applicant under the national law applicable by the designated Office.

9. The current Rule 4 of the Regulations under the PCT does not require the declaration of the source of genetic resources and/or traditional knowledge in international patent applications. Furthermore, Rule 4 prevents patent applicants submitting an international patent application from voluntarily including any such information as part of the PCT procedure, except in the specification, that is, the description, of the invention. Furthermore, Rule 51*bis*.1, as currently worded, does not expressly mention the possibility of designated Offices to require the applicant to furnish information on the source of genetic resources and/or traditional knowledge under the national law applicable by the designated Office.

10. Art. 6.1 of the PLT, which deals with the form and contents of national patent applications, states that

"[e]xcept where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:

(i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;

(ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started[.]"

11. In this context, Rules 4.1 and 51*bis*.1 of the Regulations under the PCT are of particular importance.

12. Art. 10 of the PLT states that "[n]on-compliance with one or more of the formal requirements referred to in Articles 6(1) [...] with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention." The validity of granted patents is thus not affected should the patent applicant not comply with the formal requirements enumerated in Art. 6.1. The only exception to this general rule is where such non-compliance results from fraudulent intention. Art. 10 of the PLT, however, only applies once a patent is granted, whereas it does not apply to the national patent granting procedure as such. Art. 10 does therefore not prevent Contracting Parties of the PLT from

introducing sanctions for non-compliance with formal requirements prior to the granting of a patent (see Art. 6.8 of the PLT).

(2) Proposals by Switzerland to amend the PCT Regulations

13. Based on the relevant developments at the international level and the provisions of the applicable international agreements, Switzerland considered in detail the various options available for transparency measures and their possible modalities and implications. These considerations were guided by the following principles: First, any such measure should allow to attain the desired transparency in an effective and efficient manner. Second, any transparency measure should ensure legal certainty, be practicable and avoid unnecessary administrative burdens and costs for patent applicants and patent authorities. Third, any measure should leave States with as much freedom as possible, enabling them to introduce solutions at the national level that take into account national needs and interests. And fourth, the proposed transparency measure should be mutually supportive with existing obligations of relevant international agreements. Based on these considerations, Switzerland submitted the following proposals to the Working Group on Reform of the PCT:

(*i*) Amendment of Rule 51*bis*.1 of the PCT-Regulations

14. Switzerland proposes to introduce a new subpara. (g) in Rule 51*bis*.1 of the PCT Regulations, which could read as follows:

> *"(g) Subject to Rule 51bis.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish:*
>
> *(i) a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource;*
>
> *(ii) a declaration as to the source of traditional knowledge related to genetic resources, if the inventor knows that the invention is directly based on such knowledge;*
>
> *(iii) a declaration that the source referred to in (i) or (ii) is unknown to the inventor or applicant, if this is the case."*

15. Rule 51*bis*.1(g) would only apply if the national law of a Contracting Party of the PCT requires patent applicants submitting an international patent application to declare the source of genetic resources and/or knowledge, innovations and practices, in their patent applications. It is thus the national legislator who decides whether such a declaration is required or not. In case an application does not contain the required declaration, the national law may foresee that the application is not processed any further until the patent applicant has furnished the required declaration; the national law may also foresee that non-declaration will not affect the processing of patents.

(*ii*) Proposal to amend Rule 4.17 of the PCT Regulations

16. Complementary to the new subpara. (g) in Rule 51*bis*.1, Switzerland proposes to introduce a new subpara. (vi) in Rule 4.17 of the PCT-Regulations, which could read as follows:

"(vi) a declaration as to the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in Rule 51bis.1(g)."

17. This proposal would give patent applicants the possibility of satisfying the declaration requirement under national patent law in accordance with the proposed new Rule 51*bis*.1(g) at the time of filing an international patent application or later during the international phase. This would further simplify procedures related to the declaration of the source of genetic resources and/or knowledge, innovations and practices, with regard to international patent applications.

18. The standard wording in the Administrative Instructions for such a declaration would have to be amended accordingly.

(*iii*) Other amendments to the PCT Regulations

19. In addition to the proposed new subpara. (g) in Rule 51*bis*.1 and subpara. (vi) in Rule 4.17, Switzerland proposes several other amendments to the Rules of the PCT Regulations.[15] These amendments concern the international publication (Rule 48: International Publication; Rule 51*bis*.2: Circumstances in Which Documents or Evidence May Not Be Required and Rule 51*bis*.3: Opportunity to Comply with National Requirements).

(b) Options for model provisions on proposed disclosure requirements[16]

20. Switzerland proposes several amendments to the PCT–Regulations in order to explicitly enable the Contracting Parties of this treaty to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications. These amendments concern the new subpara. (g) in Rule 51*bis*.1 and subpara. (vi) in Rule 4.17.

21. The wording of the proposed new provisions to be introduced in the PCT-Regulations, in particular the proposed new subpara. (g) in Rule 51*bis*.1 and subpara. (vi) in Rule 4.17, is sufficiently specific and clear to be directly implemented at the national level. Accordingly, Switzerland sees no need for model provisions on proposed disclosure requirements.

(c) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements[17]

22. With regard to the trigger of the disclosure requirement, the proposals by Switzerland distinguish between genetic resources and traditional knowledge:

23. With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) of the Regulations Under the PCT states that the invention must be "directly based" on "a specific genetic resource to which the inventor has had access," in order for the disclosure requirement to apply. This wording makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the

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15 For an overview of the Rules of the PCT-Regulations proposed to be amended, see Appendix of WIPO-document PCT/R/WG/7 Paper No. 7.

16 See para. 8(a) of Section E of Decision VII/19.

17 See para. 8(b) of Section E of Decision VII/19.

inventor must have had physical access to this 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. Thus, for example, the source of a plant would have to be declared in the patent application if the respective invention relates to a chemical compound which the inventor extracted from this plant.

24. With regard to traditional knowledge, the proposed new Rule 51*bis*.1(g)(ii) of the Regulations Under the PCT requires that "the inventor knows" that the invention is "directly based" on this knowledge. Like any other form of knowledge, traditional knowledge is of intangible nature. Thus, physical access is not possible and therefore not required. Instead, the inventor must know that the invention is directly based on such knowledge, that is, he must consciously derive the invention from this knowledge. This is to avoid cases where, for example, the inventor is using a chemical compound derived from a plant to develop a new pharmaceutical, without knowing that an indigenous community has knowledge concerning the pharmaceutical use of this plant.

(d) Options for incentive measures for applicants[18]

25. In the view of Switzerland, the sanctions currently allowed for under the PCT and the PLT should apply to failure to disclose or wrongful disclosure of the source of genetic resources and traditional knowledge in patent applications.

26. Accordingly, if the national law applicable by the designated Office requires the declaration of the source of genetic resources and traditional knowledge, Rule 51*bis*.3(a) of the PCT-Regulations requires the designated Office to invite the applicant, at the beginning of the national phase, to comply with the disclosure requirement within a time limit which shall not be less than two months from the date of the invitation. If the patent applicant does not comply with this invitation within the set time limit, the designated Office may refuse the application or consider it withdrawn on the grounds of this non-compliance. If, however, the applicant submitted with the international application or later during the international phase the proposed declaration containing standardized wording relating to the declaration of the source (see proposal by Switzerland for new subpara. (vi) of Rule 4.17), the designated Office must accept this declaration and may not require any further document or evidence relating to the source declared, unless it may reasonably doubt the veracity of the declaration concerned.

27. Furthermore, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, such failure to comply with the disclosure requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.

(e) Intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance[19]

28. COP-7 of the CBD mandates in Decision VII/19 "the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, ensuring the participation of

[18] See para. 8(c) of Section E of Decision VII/19.
[19] See para. 8(e) of Section E of Decision VII/19.

indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention[.]"[20] One of the elements to be considered by this Working Group for inclusion in the international regime is an "[i]nternationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge[.]"[21] The third meeting of this Working Group, to be held 14-18 February 2005, is foreseen to begin the elaboration and negotiation of the international regime.

29. Since the elaboration and negotiation of the international regime has not yet begun, the intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance cannot be anticipated at this point in time.

30. In the view of Switzerland, the international regime and its elements, including any certificate of origin/source/legal provenance, should be mutually supportive with the existing international legal order and relevant international instruments. Furthermore, intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance are to be dealt with by the competent international fora, namely WIPO, the WTO and the Union for the Protection of New Varieties of Plants (UPOV). WIPO is particularly well-suited to deal with these issues, in particular its "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore." As stated in para. 5 of Section D of Decision VII/19, these and other international fora are to cooperate with the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in elaborating the international regime.

III. DOCUMENTS BY SWITZERLAND ON ITS PROPOSALS

31. With regard to its proposals, Switzerland submitted the following documents to WIPO:

1. *Proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications*. See WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11.

2. *Additional Comments by Switzerland on Its Proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications*. See WIPO document PCT/R/WG/6/11.

3. *Further Observations by Switzerland on Its Proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications*. See WIPO document PCT/R/WG/7 Paper No. 7.

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[20] See para. 1 of Section D of Decision VII/19.

[21] See para. (d)(xiii) of the Annex to Section D of Decision VII/19.

TURKEY
Received December 17, 2004

1. Any patent application based on genetic resources or TK, should clearly disclose the source of origin in both the specification and description. We support any appropriate measure on this subject matter.

2. In regard to disclosure requirements on genetic resources and TK in patent applications, the following issues may also be taken into account: compliance with access and benefit sharing, penalties for provisions of false information, refusal of grant on formality grounds, invalidation of patent after grant, narrowing or invalidation of patent claims that would have been supported by information not disclosed and prior informed consent. In addition, a revision of the IPC is necessary for covering "Traditional Knowledge".

3. A draft law on the "Registration of Genetic Resources" has been prepared by the Ministry of Agriculture and Rural Affairs; when this draft law enters into force, our genetic resources will be registered, but only in Turkey under this law. Consequently we support all attempts for an international certification system of genetic resources. In this context, all genetic resources registered in member states may be collected in a central database, a system similar to CBD's biosafety clearing house mechanism. In this context, international minimum standards and components should be determined, international legal binding mechanisms should be formed, systems should be in compliance within each member state in this matter.

UNITED STATES OF AMERICA
Received December 17, 2004

1. In response to the WIPO General Assembly's decision at its Thirty-First Session and the Director General's invitation for Member States to submit to the WIPO International Bureau proposals and suggestions related to Decision VII/19 of the Conference of the Parties of the Convention on Biological Diversity before December 15, 2004, the United States offers the observations and suggestions below. We also provide a copy of a U.S. submission to the TRIPS Council* of November 26, 2004[22] that elaborates upon our general views, as well as our responses to the issues raised.

(a) Options for model provisions on proposed disclosure requirements

2. Existing disclosure requirements in the United States have been developed over a period of more than 200 years. Under U.S. law, an applicant is required to disclose the claimed invention and the manner and process of making and using it, in full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains to make and use the invention. The inventor is also required to disclose the best mode, or embodiment, of the invention that he or she is aware of at the time of filing.[23] The United States Patent and Trademark Office (USPTO) also requires each individual that is associated with the filing and prosecution of a patent application to disclose all information that he or she is aware of, which is material to the patentability of each pending patent claim.[24] We believe that these disclosure requirements are central to the determination of patentability and can be construed as "model provisions", as they appropriately balance the public interest in a full disclosure of the claimed invention with the inventor(s) knowledge and ability to disclose information that is material to patentability.

3. While the United States supports the goals of ensuring appropriate access and prior informed consent to genetic resources and equitable benefit sharing agreements and principles, we strongly believe that new disclosure requirements[25] in the patent system are not an effective means of achieving these goals. We believe that new disclosure requirements in the patent system would create uncertainties in the patent application process and in any patent rights granted without achieving the desired goals stated above. New disclosure requirements would create additional obstacles for patent applicants, increase uncertainties in patent examination, as examiners could not verify the provided information, increase administrative costs for patent offices and generate more post-grant litigation on patent rights. These increased burdens and uncertainties are not warranted in the patent system, especially since the new disclosure requirements would not achieve the desired outcome of appropriate prior informed consent and benefit sharing and, indeed, could lead to significant negative

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* The text of the submission is reproduced below.

22 United States, IP/C/W/434.

23 35 USC § 112.

24 37 CFR § 1.56.

25 By "new patent disclosure requirements," this paper refers to the proposed new requirements regarding source and/or origin, evidence of PIC, and evidence of equitable benefit-sharing that have been proposed by Members in the course of deliberations in WIPO on this matter.

consequences. In our view, there can be no model provisions for new disclosure requirements, as new disclosure requirements would only frustrate the objectives that they are intended to achieve.

(b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements

4. As mentioned in part (a), filing a patent application in the United States would trigger an obligation on behalf of the an applicant to disclose the claimed invention and the manner and process of making and using it, in full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains to make and use the invention. Upon filing, the inventor is also required to disclose the best mode, or embodiment, of the invention that he or she is aware of at the time of filing. Finally, the possession of any information that is material to patentability, during the pendancy of the patent application, would trigger an obligation on behalf of the applicant to disclose this information to the USPTO.

5. As mentioned in part (a), we do not support new patent disclosure requirements.

(c) Options for incentive measures for applicants

6. Patents provide a strong incentive for innovation. They also provide an incentive to disclose new, useful and unobvious information to the public. We believe that new disclosure requirements would detract from this incentive by making it more difficult for applicants to obtain a patent and by introducing uncertainties into patents.

(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties

7. Various WIPO-administered treaties and the TRIPS Agreement require disclosure requirements that are material to the determination of basic patentability standards (e.g., novelty, non-obviousness, enablement, utility). PCT Article 5 requires that a patent description disclose the invention in a manner sufficiently clear and concise for the invention to be carried out by a person skilled in the art. PLT Article 5 requires a submission, which on its face appears to be a description of the invention, in order to obtain a filing date. Under TRIPS Article 29 WTO Members must require that patent applicants disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. WTO Members may also require that applicants indicate the best mode for carrying out the invention known to the inventor at the filing date, or where priority is claimed, at the priority date of the application.

8. On the other hand, we believe that new disclosure requirements may be inconsistent with, or may conflict with, WIPO-administered treaties such as the PCT and PLT, as well as the WTO-administered TRIPS Agreement.

(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance

9. We believe that any proposed certificate of origin, source or legal provenance should be separate from intellectual property protection. As noted in our paper, any new systems to promote access and adequate benefit sharing should be developed outside of the patent system to maximize their effectiveness and to avoid a negative impact on patents.

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Text of the communication of the United States to the TRIPS Council, dated November 26, 2004 entitled "Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore"

I. INTRODUCTION

1. The purpose of this paper is to permit progress in current discussions under agenda items pursuant to paragraphs 12 and 19 of the Doha Ministerial Declaration. It attempts to identify common ground where it exists, to provide more focus and structure to the discussions, and to help reduce differences in order to resolve concerns that have been expressed by various delegations.

2. In conjunction with paragraph 12, paragraph 19 of the Doha Ministerial Mandate clearly directs the "TRIPS Council, in pursuing its work programme … to examine the …relationship between TRIPS Agreement and the CBD, protection of traditional knowledge, and folklore". Some Members have expressed concerns about the difficulty in implementing both agreements and that there may be a conflict between these agreements. Advancing various reasons, some delegations have proposed new disclosure requirements in patent applications regarding: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regime; and (iii) evidence of fair and equitable benefit-sharing under the relevant national regime.[26]

3. On the other hand, the United States is one of a number of Members that see no conflict between the TRIPS Agreement and the CBD and that consider that these agreements can and should be implemented in a mutually supportive manner. As discussed in previous US submissions, while the objectives of these two agreements are distinct, they do not conflict.[27] Moreover, the United States views with the utmost caution any proposals that would add uncertainties in patent rights that may undermine the role of the delicately balanced patent system in its primary purpose of encouraging innovation, technological progress and economic development.

4. In an effort to help achieve progress in the discussions in the TRIPS Council, this paper sets out the concerns of the United States with regard to proposed new patent disclosure requirements, as well as our view of what mechanisms may be effective for achieving objectives widely shared by Members. A closer study of these widely shared objectives suggests that implementation of effective national laws that directly address the relevant goals is the most effective way to proceed.

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[26] See, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403.

[27] See United States, IP/C/W/257.

II. SHARED OBJECTIVES

5. Based on recent discussions in the TRIPS Council aimed at fulfilling the Doha Ministerial mandate, and written contributions submitted in that context, Members appear to share several broad policy objectives. These objectives include: (1) ensuring authorized access to genetic resources, i.e., that prior informed consent is obtained; (2) achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources; and (3) preventing the issuance of erroneously issued patents.

6. The United States supports these objectives and has consistently encouraged and supported the equitable sharing of benefits arising from the utilization of traditional knowledge and practices of indigenous and local communities. However, based on experience, our view is that the most effective means to achieve the stated objectives is through tailored, national solutions to meet practical concerns and actual needs. The introduction of new patent disclosure requirements will not achieve these important objectives and may have significant negative consequences.[28]

III. EXAMINING THE OBJECTIVES: NEW PATENT DISCLOSURE REQUIREMENTS ARE NOT THE ANSWER

A. Prior Informed Consent and Misappropriation

7. New patent disclosure requirements will not work to guarantee that prior informed consent was obtained. It must be recognized that it is the relevant prior consent agreement itself (usually constituting a contract between two entities), and not a disclosure in a patent application, that manifests prior informed consent. A researcher or collector needs to know where to go, who to contact and which persons are authorized to grant approval in order to receive prior informed consent. A completely separate, transparent mechanism needs to be established outside the patent system that implements these criteria regardless of any disclosure made in a patent application. If the goal is to ensure authorized access based on prior informed consent, only contractual obligations that establish the rights and obligations of the entities involved prior to any access to genetic resources can ensure prior informed consent is achieved.

8. In this light, a new disclosure requirement in the patent system also will not prevent misappropriation. Those with intent of acting in bad faith will not be deterred by disclosure requirements. Furthermore, a transparent prior informed consent regime is needed to ensure that the vast majority of researchers and/or collectors can conduct their research and activities in an appropriate manner. Some proponents of new patent disclosure requirements have suggested that "misappropriation has mainly taken the form of obtaining patents in, mostly, developed Members inconsistently with the will of the custodian communities".[29] However, misappropriation, in the context of these discussions, relates to the improper collection and/or use of genetic resources or traditional knowledge. The act of patenting, *per se*, does not

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[28] By "new patent disclosure requirements," this paper refers to the proposed new requirements regarding source and/or origin, evidence of PIC, and evidence of equitable benefit-sharing that have been proposed by Members in the course of TRIPS Council sessions.

[29] African Group, IP/C/W/404.

amount to misappropriation. Indeed, patent rights can be an effective tool, in conjunction with a benefit-sharing agreement, to transfer benefits.

B. Benefit-Sharing

9. Nor will a new disclosure requirement in the patent system ensure that benefits are equitably shared with the provider of the traditional knowledge or genetic resources. The proposed new patent disclosure requirements, *per se*, cannot transfer benefits, as such a requirement would merely convey the information requested but would have no mechanism to transfer benefits between parties. If the country of origin of the relevant traditional knowledge or genetic resources has no benefit-sharing infrastructure in place for the use of the traditional knowledge and/or genetic resources, there still would not be any compensation to the custodians of the relevant knowledge or resource even if a patent relating to these materials were identified. A mechanism to transfer benefits must be established.

10. Indeed, if such a requirement were adopted and a non-compliant disclosure were discovered that would invalidate a patent, or prevent a patent application from grant, because of a new patent disclosure requirement, any benefits from that invention would be greatly diminished:

- for example, if a patent issued, but was later invalidated, or if an application were published, but never issued, the invention has been disclosed to the public and third parties can most likely use and commercialize the knowledge or resources disclosed without any obligation of sharing benefits;

- further, if a patent is never issued and the information never published, the patent applicant may still be able to commercialize the invention without disclosing the invention to the public and without any obligation to share benefits;

- a new disclosure requirement could also have further significant, unintended consequences where a patent applicant has entered into a valid benefit-sharing agreement with the custodians of the traditional knowledge or genetic resources but, due to uncertainties in the law, a disclosure may be found invalid. For example, if there were improper disclosure that resulted in revocation of a patent due to litigation by a third party not affiliated with a traditional knowledge or genetic resources holder, this could actually upset the pre-existing benefit-sharing agreement.

11. Moreover, a new patent disclosure requirement would fail to address benefit-sharing resulting from commercialization that occurs outside the patent system. New patent disclosure requirements will be meaningless when products derived from or based on traditional knowledge or genetic resources are commercialized, but not patented. There are many ways of protecting ideas that lead to commercialization, including trade secret and unfair competition laws. In such cases, benefits would likely not flow to the relevant communities unless a domestic access and benefit-sharing framework is first put in place to facilitate a contractual arrangement that would lead to benefit-sharing.

C. Preventing Erroneously Granted Patents

12. Another objective raised by the proponents of disclosure requirements is that of preventing erroneously granted patents. Some have even suggested that they view a

disclosure of source and/or origin as "critical for ascertaining inventorship" and capable of enabling a better assessment by patent examiners of novelty and inventive step.[30] Indeed, these are laudable goals. The proposed new patent disclosure requirements, however, will be ineffective in achieving this objective and will only complicate an already overburdened patent system.

13. First, none of the suggested new patent disclosure requirements aim to ensure compliance with patentability requirements such as proper inventorship, novelty or inventive step. Second, disclosure of source and/or origin can be expressed in wide variety of ways.[31] Information indicating country of origin, *ex situ* collection sites, etc., would do little to ensure ascertainment of appropriate inventorship, novelty or inventive step, because such information does not generally address the considerations underlying these requirements, such as acts of invention or the state of the relevant art.

D. Additional Concerns Regarding New Patent Disclosure Requirements

1. Adding uncertainty to the Patent System

14. Furthermore, new patent disclosure requirements would add new uncertainties in the patent system.[32] Particularly where the sanctions for non-compliance include invalidation of a patent, this would create a "cloud" of uncertainty over the patent right by opening a new avenue for litigation and other uncertainties that would undermine the role of the patent system in promoting innovation and technological development. This could have negative effects on the economic development incentives that patents provide.[33] These uncertainties would likely also undermine any potential benefit-sharing.

2. Administrative Burdens

15. Moreover, new patent disclosure requirements may also lead to significant administrative burdens for the patent offices of Members that would in turn create additional costs, particularly with respect to those requirements that would demand compliance with foreign laws. A patent office is not positioned to examine documentation, unilaterally provided by applicants, in response to requirements such as those proposed regarding source and/or origin, prior informed consent, or evidence of benefit-sharing. To implement an appropriate standard of review within the patent system for these matters would create

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30 IP/C/W/403.

31 See Switzerland, IP/C/W/400/Rev.1.

32 These new patent disclosure requirements would generally be requirements untested to a great extent at the national level, leading to significant legal uncertainty, for which at least one proposed sanction is the revocation of the patent right. Concerns include, *inter alia*, situations in which the resource is indigenous to one country, but freely available in several other countries, the degree of relationship between the claimed invention and the relevant genetic resource or traditional knowledge, and whether national courts or national intellectual property offices would have to interpret other nation's laws. This would also lead to undue burdens on those applicants seeking to comply with such requirements, which, in turn, may discourage applicants from seeking protection and may thereby act as a disincentive to innovation and investment.

33 The patent system is designed to promote innovation and provides significant economic development incentives. *See e.g.*, *Kamil Idris* "Intellectual Property: A Power Tool for Economic Growth," describing a number of ways in which patents can stimulate economic development, including: (1) patent information facilitates technology transfer and investments, (2) patents encourage R&D at universities and research centres, (3) patents are catalysts of new technologies and businesses, and (4) businesses use patents in licensing, joint ventures and other revenue generating transactions.

significant new administrative burdens and substantial new costs, including training and system development, for the patent offices of all Members. Furthermore, even with the added resources and costs, it does not seem possible that patent examiners could make such determinations with any degree of legal certainty, particularly decisions involving interpretations of foreign laws to determine the validity of prior informed consent or adequate benefit-sharing according to the custodian country's legal regime, thereby compounding the uncertainties both in granted patent rights and in the process of granting patents. Courts and other authorities of those jurisdictions providing the genetic resources or traditional knowledge would be more appropriately situated to examine these matters.

3. Ineffectual Monitoring System

16. Proponents of a new patent disclosure requirement also appear to wrongly assume it to be an effective monitoring system. Indeed, the proposal by Switzerland for a disclosure of source requirement in the context of the Patent Cooperation Treaty (PCT) appears to recognize the shortcomings of such a disclosure of source requirement in noting the difficulties posed by the various ways that information could potentially be disclosed, such as through databases, publications or *ex situ* collections.[34] Thus, the Swiss, apparently aware of the shortcomings of a disclosure of source requirement, *per se*, go so far as to suggest that it be implemented in conjunction with an apparently multilateral system of notification, in which national patent offices would identify and notify points of contact designated to receive such information in other governments. This would be coordinated through an office at WIPO that would create a list of notified contact points for each government.[35] Notwithstanding the complexity of issues surrounding the creation of such a system, including its associated costs and effectiveness, such an apparently multilateral notification system still does not address legal uncertainties in the patent system and consequent negative effects created by a disclosure of source and/or origin requirement nor does it address the fact that an access and benefit-sharing infrastructure in a country is necessary to enable the sharing of such benefits.

17. In light of these concerns, the United States is not convinced that new disclosure requirements in patent applications are an appropriate solution. However, the United States shares many of the objectives raised by various Members. The real challenge is how most effectively to achieve these objectives. As more fully described below, this challenge can best be met if countries establish separate legal and other frameworks that will directly and effectively address these issues.

IV. EXAMINING THE OBJECTIVES: OPTIONS TO ACHIEVE APPROPRIATE ACCESS AND EQUITABLE BENEFIT-SHARING

18. Experience shows that the most effective means to achieve the shared objectives of obtaining appropriate access and benefit-sharing is through development of national laws outside the patent system that can more directly and effectively regulate conduct relevant to these issues.

A. Achieving Prior Informed Consent

19. It is imperative that governments implement laws that require prior informed consent from clearly delineated points of contact, such as the government and/or indigenous representatives before a party seeks to use or collect traditional knowledge or genetic

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34 IP/C/W/400/Rev.1.

35 IP/C/W/400/Rev.1.

resources. Points of contact should include the persons authorized to provide access to materials. For example, countries could establish permit systems that impose civil and/or criminal penalties for extracting genetic resources without a permit, where the permit would serve as evidence of prior informed consent.

B. Achieving Equitable Sharing of Benefits

20. A contract-based system can be used to effectively control the collection of resources and ensure the sharing of benefits from their use. Contracts can provide a great deal of flexibility in determining benefit-sharing, both monetary and non-monetary. Within the contract, a party can require the researcher to report regularly to the point of contact regarding progress of his research. This informs the authorities of how the relevant traditional knowledge or genetic resource is being used and keeps communication channels open. The contract can also require mandatory disclosure to appropriate authorities of any future commercial application utilizing the relevant traditional knowledge or genetic resource, whether patented or not. This type of mandatory disclosure requirement can provide for an effective monitoring system by ensuring a specific type of disclosure of the particular commercial application involved. The contract can also specify choice of law provisions, so that all parties are aware of the law that will apply should disputes arise. Contracts can be specifically enforced, requiring adherence to its terms; damages for breach of contract can also be specified, including punitive damages.

21. It is also our understanding that many Members have not yet implemented access and benefit-sharing regimes. As described in previous US submissions to TRIPS Council, the United States has developed contract-based systems to ensure appropriate access and benefit-sharing.

22. In June of 2001, the United States introduced a paper[36] that described in detail the provisions of the CBD that might have some implications for the TRIPS Agreement,[37] and explained how those obligations might be implemented through the use of a contract-based regime for access to genetic resources. The paper suggested that, *inter alia*, contracts authorizing collection of genetic materials include provisions requiring reporting and benefit-sharing and that parties to such access agreements be obliged to notify the appropriate authorities in the event an invention was developed using genetic materials collected under the contract.

23. In March of 2002, the United States submitted another paper[38] describing in considerable detail the procedures used by the US National Cancer Institute in collecting genetic materials for screening for potential therapeutic uses related to cancer. Many US government agencies have established policies that embody the principles of appropriate access and equitable benefit-sharing. Further, in November of 2002, the United States submitted a paper describing the regime for access to genetic materials in US National Parks.[39] That paper includes a detailed description of the regime, including the use of Scientific Research and Collecting Permits as well as Cooperative Research and Development Agreements. This experience might be helpful to other Members, particularly those Members that have not yet implemented such a regime in their respective territories.

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36 United States, IP/C/W/257.
37 Specifically, Articles 8(j), 15, 16 and 19.
38 United States, IP/C/W/341.
39 United States, IP/C/W/393.

24. The access systems described in these papers are easily adaptable to other legal systems, and can provide countries the flexibility to protect their traditional knowledge or genetic resources without the risks mentioned earlier of undermining the economic development incentives of strong intellectual property protection and without the risk of undermining benefit-sharing, as discussed earlier.

C. Compliance With Access and Benefit-sharing Regimes

25. Many of the proponents of disclosure requirements do not challenge the necessity of effective, contract-based, access and benefit-sharing regimes.[40] However, some argue that patent disclosure requirements are necessary, in addition to such regimes, to improve compliance with such mechanisms.[41] The United States disagrees with such a policy approach as unnecessarily burdensome to the patent system. Such a legal regime, if in force, can be adequately enforced without resort to patent law requirements. Effective enforcement regimes for access and benefit-sharing should be part of civil and criminal codes specifically designed to enforce access and benefit-sharing laws. Such enforcement mechanisms can be appropriately tailored so as not have unintended, negative consequences on the intellectual property system. Patent law was not designed to regulate or enforce misconduct issues, such as misappropriation of traditional knowledge or genetic resources, but to promote the progress of the useful arts. Patent rights permit an inventor to exclude others from certain acts,[42] but do not permit an inventor to use the invention without restriction. Restrictions can and are placed on the use of certain inventions to ensure safety and efficacy (e.g. health regulations governing pharmaceutical products), to protect the environment (e.g., regulations governing emissions from automotive engines) or to protect domestic or national security (e.g., regulating firearms), for example. These restrictions, notably, are enforced outside the patent system by separate regulatory mechanisms.

26. While a few individuals could ignore the legal requirements of an access and benefit-sharing system, in the same way that individuals currently may violate health or safety regulations, the case has not been made for why a contractual system that would apply to the vast majority of those seeking access would not serve effectively, just as health and safety codes apply in their spheres. As is done in the case of these other distinct regulatory systems, criminal provisions and/or civil liability for failure to comply can be included in the country's laws for those few who might take genetic resources without entering into an access agreement with the required party.

27. In order for the TRIPS Council to more fully consider the concerns raised by the proponents of disclosure requirements, Members may want to more fully examine national experiences with respect to access and benefit-sharing systems currently in place in order to better understand the perceived shortcomings of such existing systems. In this light, the Council may also want to consider the extensive work that continues in the Intergovernmental Committee on Intellectual Property, Genetic Resources and Folklore of the WIPO, which was specifically created to deal with many of these, and related, matters.

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40 See Bolivia et al., IP/C/W/403, paragraph 18 states that "it is acknowledged that these mechanisms can and should be used, and several countries have already enacted laws to put in place an Access and Benefit-sharing (ABS) regime." Further, see paragraph 16 of Switzerland, IP/C/W/400, which notes that Article 15.7 of the CBD requires that sharing of benefits arising from utilization of genetic resources shall be on mutually agreed terms and that "generally, the mutually agreed terms will be laid down in a contract."

41 IP/C/W/403.

42 See, e.g. TRIPS Article 28.

V. EXAMINING THE OBJECTIVES: OPTIONS TO PREVENT THE ISSUANCE OF ERRONEOUSLY GRANTED PATENTS

28. Several tools can and are being used to address concerns regarding the issuance of erroneously granted patents. The TRIPS Council may want to consider these more fully.

A. Organized Databases

29. First, patent examiners world-wide could use organized searchable databases of genetic resources and traditional knowledge when examining patent applications. This could aid in the discovery of relevant prior art and thereby improve examination of patent applications in the relevant fields.[43]

B. Information Material to Patentability

30. Furthermore, Members way wish to consider a requirement such as that used in the United States for patent applicants to disclose any information known by the applicant to be material to patentability.[44] If the objectives are to truly to determine prior art, to ascertain inventorship and to prevent mistakenly granted patents, this type of requirement is directly related to achieving these goals, to the extent that the applicant may have such information. Inventorship is included here because US law clearly requires that inventorship be a requirement for entitlement to a patent.[45] This type of information is directly related to the questions of patentability and can aid examination of patent applications in a manner that disclosure of source and/or origin of genetic resources or traditional knowledge cannot.

C. Post-Grant Opposition or Re-Examination

31. Implementation of post-grant opposition or re-examination proceedings can rectify the situations in which patents are issued erroneously. These procedures are far less costly than litigation and can alert national patent authorities when new information is discovered that is relevant to the patentability of the invention. These procedures can directly bring information to the attention of patent authorities, as appropriate, in order to address questions of patentability with regard to issued patents. Indeed, a number of granted patents have been successfully challenged when it was demonstrated through existing opposition processes that these patents should not have been granted. This has included patents relevant to turmeric and neem in the United States and in the European Patent Office.[46]

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43 A number of initiatives are exemplary of this approach, including the China Traditional Chinese Medicines Database and the India Traditional Knowledge Digital Library (TKDL) of Ayurveda. See, e.g., the relevant web site of the World Intellectual Property Organization (WIPO) at http://www.wipo.int/tk/en/databases/tkportal/index.html.

44 37 CFR 1.56(a): Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [United States Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

45 See 35 USC 102(f): "A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented".

46 See Carlos Correa, "Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge", QUNO, November 2001.

32. We are unaware that any of the perceived instances of misappropriation have involved a wrongful determination of inventorship or prior art that could not be satisfactorily addressed by the above means, or that a patent disclosure requirement for source and/or origin would have corrected this.

VI. CONCLUSION

33. The patent system has been and continues to be a highly effective tool for technological and economic development. The WTO should be wary of upsetting the delicately balanced patent system, particularly when it is doubtful that any suggested changes will actually achieve their stated objectives.

34. Further, it would be wrong to assume that a new disclosure requirement within the patent system will accomplish the objectives of ensuring access and equitable benefit-sharing, preventing misappropriation and preventing erroneously issued patents. Rather than focusing on proposed new patent disclosure requirements, the TRIPS Council should focus with more precision on what Members are trying to achieve in this area, review the past experiences and situations that have prompted various concerns and consider any appropriately tailored solutions. As many of the broad objectives are widely shared, we are confident that appropriate solutions can surely be reached to address the concerns of all Members.

THE NETHERLANDS AND THE
PERMANENT REPRESENTATIVE OF THE EUROPEAN COMMISSION ON BEHALF OF THE EUROPEAN COMMUNITY AND ITS MEMBER STATES

Received December 16, 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

Introduction

1. 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.

2. 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.[47] 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.[48] 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.

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

3. 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.

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[47] 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).

[48] See document WIPO/GRTKF/IC/6/13.

4. 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.

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

5. 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.[49]

6. 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 excluded[50], and this exclusion should be carried over to the proposed system.

7. 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.

8. 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.[51]

9. 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

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49 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.

50 As clarified by the CBD COP Decision II/11, paragraph 2.

51 Article 2.

the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden.[52]

10. 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.[53]

Disclosure of associated traditional knowledge

11. 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.[54]

12. 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.

13. 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.

A standardised and formal requirement

14. In order to become effective, the way that the relevant information will be submitted from the patent applicant to the patent offices must be standardised. This should be organised

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[52] 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 commercialisation.

[53] 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.

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

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.

15. 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.

16. The EC and its Member States propose that the disclosure of the information be organised 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 fulfil 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.

17. 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.

<u>What should happen in cases of incorrect or incomplete information?</u>

18. 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.

19. 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.

Exchange of information

20. 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.

21. 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.

22. 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.

Summary

23. 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.

EGYPT on behalf of the AFRICAN GROUP
Received December 15, 2004

1. With reference to the invitation by the Director General of WIPO to all Member States to submit proposals and suggestions concerning the invitation of the Conference of the Parties of the Convention on Biological Diversity for WIPO to "examine, and where appropriate, taking into account the need to ensure that this work is supportive and does not run counter the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications" before December 15, 2004, the African Group wishes to make the following remarks and suggestions:

2. At the outset, the African Group wishes to emphasize the importance it attaches in the wording of the invitation of the Conference of the Parties of the CBD for WIPO, to the reference that "the work is supportive and does not run counter to the objectives and principles of the CBD". This must be a fundamental guiding principle in WIPO's work when examining, and where appropriate addressing, the interrelation of access to genetic resources and disclosure requirements in intellectual property rights. In this connection, the African Group wishes to highlight the objectives and principles enshrined in articles 3, 15 and 16 of the CBD.

3. The African Group wishes also to point to the fact that the interrelation between access to genetic resources and disclosure requirements in intellectual property rights, particularly patent applications, is a matter which has been the subject of discussions and deliberations at a number of different international fora and bodies, both within WIPO and outside of it, in recent years. Different views and opinions have been made by countries on how to approach this matter and specific proposals have been presented, in particular by developing countries.

4. In this connection, the African Group is of the view that WIPO's response to the CBD invitation should fully take into account these opinions and proposals and be without prejudice to any position taken by its Member States on these matters. Given the ongoing debates in this area, it would not be appropriate for WIPO to advocate any specific approach to the detriment of others. The Group wishes to recall that this consideration was already stated when the 30th Session of the General Assembly decided to forward to the CBD the technical study prepared by WIPO on disclosure.

5. The African Group's views on the interrelation between access to genetic resources and disclosure requirements in intellectual property rights are well known, as the Group has repeatedly argued in many WIPO bodies that only internationally legally binding measures could effectively contribute to combating the misappropriation of genetic resources and the traditional knowledge associated with these resources.

6. The African Group has expressed this view in the context of the Working Group on the Reform of the PCT, the Standing Committee on the Law of Patents and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Since the First session of the IGC, the African Group has advocated the establishment of an internationally legally binding instrument for the protection of genetic resources, traditional knowledge and folklore. At the Sixth session of the IGC, the African Group submitted a document containing possible objectives, principles and elements of such an instrument (WIPO/GRTKF/IC/6/12). This document mentioned among the principles

"introducing a disclosure requirement in patent laws as well as evidence of compliance with national access and benefit sharing laws of the country of origin of the genetic resource in claimed invention and of the associated traditional knowledge use in the invention".

7. The African Group has also expressed its support for the introduction of an internationally legally binding disclosure requirement as well as evidence of compliance with national access and benefit sharing laws of the country of origin of the genetic resource, through the amendment of international patent law related legal instruments such as the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), at the World Trade Organization. The African Group wishes to make reference in this regard to the proposals it has presented to the TRIPS council on this matter; the latest being the one contained in document IP/C/W/404. These could be of particular relevance in WIPO's response to the CBD invitation.

8. In light of the above, the African Group considers that it is not appropriate for WIPO to examine in point a) of the CBD invitation, options for model provisions on proposed disclosure requirements, as model provisions would not constitute an effective measure for combating the misappropriation of genetic resources, taking into consideration, its previously stated opinion that the effective solution to this global problem should be a mandatory universal disclosure requirement implemented in all countries. WIPO's response to the CBD invitation should take this opinion into account.

9. In conclusion, the African Group wishes to underline the importance it attaches to the mutual supportiveness mentioned in the invitation between CBD and WIPO. This mutual supportiveness entails making the intellectual property system, and in particular the patent system, supportive of the protection bio-diversity, through the introduction of legally binding measures such as the disclosure of the source and country of origin of the biological resources and associated traditional knowledge used in the invention and evidence of compliance with national access and benefit sharing laws of the country of origin of the genetic resources, as requirements for the granting of patents.

PERU
on behalf of
the ANDEAN COMMUNITY

Received December 17, 2004

1. In its capacity as Andean coordinator and on behalf of the delegations of the countries forming the Andean Community – Bolivia, Colombia, Ecuador, Peru and Venezuela – the Delegation of Peru has the honor to address the Secretariat of the World Intellectual Property Organization (WIPO) in relation to the Decision on Item 10 "Invitation from the Conference of Parties of the Convention on Biological Diversity," taken at the General Assembly of WIPO Member States, held between September 27 and October 5, 2004.

2. In that connection, the delegations of the countries forming the Andean Community wish, as a preliminary, to express a number of important points which they consider should be taken into account at the time the response to the Convention on Biological Diversity (CBD) is prepared. The countries of the Andean Community consider that this is a process recently established and within which they hope to continue making new contributions both on an individual and group level.

3. The delegations of the countries of the Andean Community recognize the CBD as an independent forum of the greatest relevance.

4. Our countries possess an invaluable genetic and cultural heritage which we wish to protect; we share one of the most important mountain ranges in the world, the Andes, and form part of the longest river basin on the planet: the Amazon. The tropical Andes of the member countries of the Andean Community are at the global epicenter of biodiversity, since they contain approximately 25 per cent of the planet's biological diversity and are associated with valuable Andean cultural diversity. In similar vein, our territories are inhabited by indigenous communities whose traditional knowledge constitutes what is probably unequalled wealth in the world.

5. For that reason, the Andean Community attaches singular importance to all the tasks being carried out in different fora, with the aim of responding to a major global concern: the increase in the number of cases of biopiracy which have arisen, thereby preventing our countries from benefiting in a fair manner from the genetic wealth which we possess. This is also very closely related to the protection of the traditional knowledge of our communities, in many cases also linked to certain genetic resources[55]

[55] The countries of the Andean Community have community legislation relating to intellectual property, which takes into account the necessary complementarity and demonstrates the priority attached to the treatment of these subjects. In this regard, Article 3 of Decision 486 – which is the most important Andean intellectual property standard – is considered to be a principle which serves as a guide for all our legislation and which may give an idea of the importance attached to the subject. The standard states that "the Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African-American, or local communities. As a result, the granting of patents on

[Footnote continued on next page]

6. It is in this sense that the work of the CBD is vital, since it is an instrument designed to achieve the preservation of our biological diversity and also the sustainable use of its components, and the fair and equitable distribution of the benefits produced as a result of using our genetic resources.

7. The countries of the Andean Community consider that regulation of access to genetic resources and benefit sharing, and also the protection of traditional knowledge, are subjects which, although linked to intellectual property elements, are more important than such elements. In this regard, the efforts which WIPO will make in these areas should not prevent or limit the efforts undertaken within the CBD forum but, on the contrary, must be compatible with and complementary to the work done by the CBD.

8. In this context, the countries of the Andean Community place special emphasis on the view that an essential element, which allows such complementarity between the intellectual property system and that of the protection of biological diversity, is necessarily channelled through the incorporation of the requirement of disclosure or revelation of source in the patent system.

9. The requirement for disclosure or revelation of source allows the legal origin of the genetic resources to be proven, which also helps to provide a guarantee that the use or exploitation of said resources is carried out with the consent of the communities owning those resources, and subsequently ensures fair and equitable sharing of the benefits obtained from said use or exploitation.

10. The inclusion of the requirement of disclosure or revelation of origin constitutes a system which does not involve additional charges for intellectual property offices, is consistent with and complementary to the CBD, and represents a means of tracking which guarantees better evaluation of the criteria and requirements for the granting of patents. In that connection, it provides an opportunity for our countries to defend themselves, in a preventive manner, against possible cases of biopiracy.

11. Furthermore, the countries of the Andean Community consider that an initial way of responding to the request from the CBD should take into account the main positions and documents submitted to the various bodies which deal directly with the subject within WIPO, such as the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the Working Group on Reform of the Patent Cooperation Treaty (PCT) and the Standing Committee on the Law of Patents.

12. A systematic approach to the positions adopted within these WIPO bodies and the inclusion of proposals put forward in other fora – especially in the CBD and in the World

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[Footnote continued from previous page]

inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law". Similarly, our subregion has Decision 391 which contains the regime for access to genetic resources and Decision 345 on protection for breeders of new plant varieties.

Trade Organization (WTO)[56] - constitute a first step by means of which our countries may have a clear idea of the situation regarding these subjects, something which may be established as a basis for future analysis and submission of further comments by States and observers, in accordance with the mandate contained in the decision taken in October 2004. Similarly, this should be implemented without losing sight of the development dimension, in line with the views expressed at the Organization's last General Assembly.

13. The delegations of the member countries of the Andean Community hope to continue analyzing the points contained in Decision VII/19 of the Conference of the Parties (COP) VII of the CBD and reiterate their desire to contribute further, along with the WIPO Secretariat, to finding a response to the request made, as part of the process launched in October 2004.

[End of Annex and of document]

[56] Various developing countries – including certain countries from the Andean Community – have submitted different documents relating to the requirement for disclosure of the source for the granting of patents in the TRIPS Council (documents IP/C/W/356, IP/C/W/403, IP/C/W/420, IP/C/W/429 Rev. 1 and IP/C/W/438).