WORLD INTELLECTUAL PROPERTY ORGANIZATION

世界知识产权组织

ORGANIZACION MUNDIAL DE LA PROPIEDAD INTELECTUAL

ORGANISATION MONDIALE DE LA PROPRIÉTÉ INTELLECTUELLE

المنظمة العالمية للملكية الفكرية

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

C. PCT 990
– 04

The International Bureau of the World Intellectual Property Organization (WIPO) presents its compliments and has the honor to transmit herewith documents PCT/R/WG/6/5 Add.2, 10 and 11, prepared for the sixth session of the *Working Group on Reform of the Patent Cooperation Treaty (PCT)*, which was held in Geneva from May 3 to 7, 2004.

./.

The working documents are also available on WIPO's Website (see http://www.wipo.int/pct/en/meetings).

For

June 7, 2004

Enclosures: documents PCT/R/WG/6/5 Add.2, 10 and 11

34, chemin des Colombettes, 1211 GENÈVE 20 (SUISSE); ✆ (022) 338 9111; Fac-similé (41-22) 733 5428; Télex CH - 412 912
Internet: http://www.wipo.int e-mail: wipo.mail@wipo.int Banque: Crédit Suisse, Genève, compte OMPI N° 48 7080-81
www.ompi.int Chèques postaux: OMPI N° 12-5000-8, Genève

E

WIPO

PCT/R/WG/6/5 Add.2
ORIGINAL: English
DATE: April 27, 2004

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT)

Sixth Session
Geneva, May 3 to 7, 2004

FURTHER CORRIGENDA AND CONSEQUENTIAL AMENDMENTS

Document prepared by the International Bureau

1. The Annex to this document contains proposals to further amend Rules 43*bis*.1, 44.1 and 69.1 as adopted by the PCT Assembly on October 1, 2002, with effect from January 1, 2004 (see document PCT/A/31/10, Annex V).[1] These proposed amendments are in the nature of corrigenda or consequential amendments based on the amendments already adopted. Explanations are set out in the Annex in comments relating to the provisions concerned.

2. The Working Group is invited to consider the proposals contained in the Annex to this document.

[Annex follows]

[1] References in this document to "Articles" and "Rules" are to those of the Patent Cooperation Treaty (PCT) and the Regulations under the PCT ("the Regulations"), or to such provisions as proposed to be amended or added, as the case may be.

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:[2]

FURTHER CORRIGENDA AND CONSEQUENTIAL AMENDMENTS

TABLE OF CONTENTS

Rule 43*bis* Written Opinion of the International Searching Authority 2
43*bis*.1 *Written Opinion* 2
Rule 44 Transmittal of the International Search Report, Written Opinion, Etc. 4
44.1 *Copies of Report or Declaration and Written Opinion* 4
44.2 and 44.3 [No change] 4
Rule 69 Start of and Time Limit for International Preliminary Examination 5
69.1 *Start of International Preliminary Examination* 5
69.2 [No change] 6

[2] Proposed additions and deletions are indicated, respectively, by underlining and striking through the text concerned.

Rule 43*bis*

Written Opinion of the International Searching Authority

43*bis*.1 *Written Opinion*

(a) Subject to Rule 69.1(b-*bis*), the International Searching Authority shall, at the same time as it establishes the international search report or the declaration referred to in Article 17(2)(a), establish a written opinion as to:

(i) and (ii) [No change]

The written opinion shall also be accompanied by such other observations as these Regulations provide for.

[COMMENT: It is proposed to amend Rule 43*bis*.1(a) so as to clarify that a written opinion under Rule 43*bis*.1 is to be established by the International Searching Authority even in the case that no international search report is established in accordance with Article 17(2)(a) (see paragraph (b), below, which refers to Article 35(3)). Since there has been no international search, the scope of the report will necessarily be very limited. Usually the only substantive content will be an explanation under Rules 43*bis*.1(b) and 66.2(a)(i) or (vi) of why no opinion is given on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable. This procedure is already envisaged in the PCT International Search and Preliminary Examination Guidelines (see paragraph 9.40 of document PCT/GL/ISPE/1). It is also equivalent to the procedure which has long existed under Chapter II where, if any of the situations referred to in Article 34(4) exists or if no international search report has been established, a similarly limited written opinion or international preliminary examination report is established (see Box No. III of Forms PCT/IPEA/408 and 409 and paragraph 17.29 of document PCT/GL/ISPE/1).]

[Rule 43bis.1, continued]

(b) [No change] For the purposes of establishing the written opinion, Articles 33(2) to (6), 35(2) and 35(3) and Rules 43.4, 64, 65, 66.1(e), 66.7, 67, 70.2(b) and (d), 70.3, 70.4(ii), 70.5(a), 70.6 to 70.10, 70.12, 70.14 and 70.15(a) shall apply *mutatis mutandis*.

(c) [No change]

Rule 44

Transmittal of the International Search Report, Written Opinion, Etc.

44.1 *Copies of Report or Declaration and Written Opinion*

The International Searching Authority shall, on the same day, transmit one copy of the international search report or of the declaration referred to in Article 17(2)(a), and one copy of the written opinion established under Rule 43*bis*.1~~, or of the declaration referred to in Article 17(2)(a),~~ to the International Bureau and one copy to the applicant.

[COMMENT: It is proposed to amend Rule 44.1 so as to clarify that the International Searching Authority will transmit to the International Bureau and to the applicant either a copy of the international search report or of the declaration referred to Article 17(2)(a) (that no international search report will be established) and, in any case, a copy of the written opinion under Rule 43*bis*.1, noting that a written opinion under Rule 43*bis*.1 is to be established by the International Searching Authority even in the case that no international search report is established in accordance with Article 17(2)(a).]

44.2 and 44.3 [No change]

Rule 69

Start of and Time Limit for International Preliminary Examination

69.1 *Start of International Preliminary Examination*

(a) Subject to paragraphs (b) to (e), the International Preliminary Examining Authority shall start the international preliminary examination when it is in possession of all of the following:

(i) [No change] the demand;

(ii) [No change] the amount due (in full) for the handling fee and the preliminary examination fee, including, where applicable, the late payment fee under Rule 58*bis*.2; and

(iii) either the international search report or the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established, and the written opinion established under Rule 43*bis*.1 ~~or a notice of the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established~~;

provided that the International Preliminary Examining Authority shall not start the international preliminary examination before the expiration of the applicable time limit under Rule 54*bis*.1(a) unless the applicant expressly requests an earlier start.

[Rule 69.1(a), continued]

[COMMENT: It is proposed to amend Rule 69.1 so as to clarify that the International Preliminary Examining Authority will receive either the international search report or a notice of the declaration referred to Article 17(2)(a) (that no international search report will be established) and, in any case, the written opinion established by the International Searching Authority under Rule 43*bis*.1, noting that a written opinion under Rule 43*bis*.1 is to be established by the International Searching Authority even in the case that no international search report is established in accordance with Article 17(2)(a).]

(b) to (e) [No change]

69.2 [No change]

[End of Annex and of document]

E

WIPO

PCT/R/WG/6/10
ORIGINAL: English
DATE: April 15, 2004

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT)

Sixth Session
Geneva, May 3 to 7, 2004

SINGLE REQUEST FOR THE RECORDING OF CHANGES DURING THE NATIONAL PHASE

Document prepared by the International Bureau

BACKGROUND

1. At its fifth session, the Working Group agreed that the International Bureau should study the possibility of providing for a request, to be made in a single document submitted to the International Bureau, to record certain changes concerning the applicant, inventor, licensees or security interests in respect of two or more designated or elected Offices in which the international application had entered the national phase, similar to the procedure under Article 14(1)(b) and Rules 15, 16 and 17 of the Patent Law Treaty (PLT) (see the summary by the Chair of the fifth session of the Working Group, document PCT/R/WG/5/13, paragraph 105).[1]

[1] References in this document to "Articles" and "Rules" are to those of the Patent Cooperation Treaty (PCT) and the Regulations under the PCT ("the Regulations"), or to such provisions as proposed to be amended or added, as the case may be. References to "national laws," "national applications," "the national phase," etc., include reference to regional laws, regional applications, the regional phase, etc. References to "PLT Articles" and "PLT Rules" are to those of the Patent Law Treaty (PLT) and the Regulations under the PLT.

2. This document considers proposals for setting up a system, under the PCT, which would facilitate, for both applicants and Offices, the recording of certain changes in respect of an international application which has entered the national phase before several designated or elected Offices, or of a patent granted on the basis of such an international application.

DISADVANTAGES OF THE CURRENT SYSTEM

3. In general, the recording of changes in the area of patents, for example, a change in ownership or a change in name of an owner, is currently made independently by each national or regional Office before which a patent application is filed or which has granted a patent, or in which a regional patent has effect. The only exception to this general rule concerns international applications during the international phase of processing, during which the International Bureau centrally records certain changes (in the person, name, residence, nationality or address of the applicant, and in the person, name or address of the agent, common representative or inventor) with effect for all designated and elected Offices (see Rule 92*bis*).

4. Recording of certain matters is mandatory in some States to ensure effects vis-à-vis third parties. In other States, the recording is made for information purposes only; in yet others, no such recording is provided for. Where recording is possible or even required, the request for recording generally must comply with a number of formal requirements. These requirements differ from State to State; with regard to harmonization of formal requirements under the PLT, see paragraphs 5 and 6, below. They often mandate, in the case of a change in ownership, an attestation or notarization of signatures by a notary public or legalization by a consulate. Some States also require a verified translation of the documents.

HARMONIZATION OF FORMAL REQUIREMENTS UNDER THE PATENT LAW TREATY

5. The Patent Law Treaty (PLT), concluded in 2000 and yet to enter into force, provides for a certain degree of harmonization between PLT Contracting States with regard to the formal requirements related to the filing of requests for the recording of certain changes relating to patents or patent applications. PLT Article 14(1)(b) and PLT Rules 15, 16 and 17 specify the formal requirements which a PLT Contracting Party is permitted to apply in respect of requests for the recordation:

(i) of a change in the name or address of an applicant for a patent or an owner of a patent, of any change in the name or address of the applicant's or owner's representative, and of any change relating to the address for correspondence or address for legal service (PLT Rule 15);

(ii) of a change in the person of an applicant for a patent or in the person of an owner of a patent (PLT Rule 16); and

(iii) of a license in respect of an application for a patent or a patent, of a security interest in respect of an application for a patent or a patent, and the cancellation of the recordation of a license or a security interest in respect of an application for a patent or a patent (PLT Rule 17).

6. Pursuant to PLT Article 3, PLT Article 14(1)(b) and PLT Rules 15, 16 and 17 apply to national and regional applications for patents, as well as international applications on or after

the date on which national processing or examination of an international application may start under PCT Article 24 or 40, that is, after that application has entered the national phase before the designated or elected Office concerned.

SHORTCOMINGS OF THE CURRENT SYSTEM, DESPITE HARMONIZATION OF FORMAL REQUIREMENTS UNDER THE PLT

7. The fact that the PLT provides for a maximum list of formal requirements which national and regional Offices are permitted to apply will, once the PLT has entered into force, facilitate the life of applicants and Offices, reduce costs, and streamline and simplify procedures related to the recording, in PLT Contracting States, of the kind of changes outlined above (hereinafter referred to as "changes"). However, despite the achieved harmonization of formal requirements, in the absence of at least a central system for the filing of requests for such changes, the disadvantages of the current system as outlined in paragraphs 3 and 4, above, remain. In particular, it remains the case that, where a change (say, in the address of an applicant) concerns several national or regional applications, or several granted patents, the applicant will have to perform the same administrative task several times over, before each national or regional Office concerned.

8. As far as the PCT is concerned, while Rule 92*bis* provides, as indicated above, for the central recording, with the International Bureau, of certain changes during the international phase, with effect for all designated and elected Offices, there is no such central recording of changes with regard to international applications which have entered the national phase before several designated or elected Offices. Again, the applicant will have to perform the same administrative task several times over, before each designated or elected Office concerned.

9. It would thus appear to be in the interest of applicants and owners, licensees and licensors, as well as third parties, if, at least in the context of the PCT with regard to international applications, in line with the objectives of the PCT as set out in the Preamble to the Treaty, a system could be set up which, based on the principles embodied in the PLT, would facilitate, for both applicants and Offices, the recording of certain changes in respect of an international application which has entered the national phase before several designated or elected Offices, or of a patent granted on the basis of such an international application. Possible features of such a system are discussed in the following paragraphs.

INTERNATIONAL REQUEST FOR THE RECORDING OF CERTAIN CHANGES DURING THE INTERNATIONAL PHASE AND THE NATIONAL PHASE OF PROCESSING

International Phase

10. As at present, for as long as the international application is in the *international* phase of processing (in other words, prior to the expiration of the time limit under Article 22(1) (Chapter I) or Article 39(1)(a) (Chapter II), that is, 30 months from the priority date), the International Bureau would centrally record certain changes (in the person, name, residence, nationality or address of the applicant, and in the person, name or address of the agent, common representative or inventor) with effect for all designated and elected Offices (see present Rule 92*bis*). Rule 92*bis* would be aligned to the corresponding PLT provisions (PLT Article 14(1)(b) and PLT Rules 15 and 16) with regard to the formal requirements to be complied with.

11. As at present, the International Bureau would make any changes recorded by it during the international phase available to the general public, be it in the form of access to the (paper) file held by the International Bureau (as at present) or, eventually, in electronic form, as part of an online PCT public file inspection service. The establishment of such an online PCT public file inspection service, designed to provide access to the file and up-to-date status information on international applications during both the international and the national phase, is currently being studied by the International Bureau, as part of its ongoing efforts to move from paper files and paper-based procedures to electronic dossiers and electronic processing of data.

National Phase

12. In addition to the opportunity to file a request for the recording of certain changes during the international phase (see above), the PCT Regulations would be amended so as to allow the applicant to centrally file, with the International Bureau, a request for the recording of certain changes in respect of an international application which has entered the *national* phase before one or more designated or elected Offices, or in respect of patents based on such international applications. Such a request could be made instead of filing multiple requests directly with the designated or elected Offices concerned, and could be made using an international form made available in both English and French, or in a bilingual English/French version (see present Rule 92.2(d) and (e)), preferably in electronic form.

13. An international request for the recording of certain changes could be made with respect to any designated and elected Office (subject to the usual transitional reservation provision). No designated or elected Office would be required or expected to stop receiving requests for the recording of changes concerning international applications which have entered the national phase before the Office concerned; the system of filing an international request for the recording of changes would exist in addition to, and in no way replace, the possibility for filing multiple national requests directly with the designated or elected Offices concerned.

14. So as to avoid adding further complexity and to enable a relatively quick establishment of the new system for the recording of changes, it is proposed to limit the possibility of filing an international request for the recording of changes in relation to international applications which have entered the *national* phase, at least at the outset, to those changes in respect of which, under the PLT, no further documentation, evidence, certifications or translations may be required by the Office which is requested to record the change—that is, to changes in the *name or address* of the applicant or owner of a patent, the agent or the inventor, and to changes relating to the address for correspondence (see PLT Rule 15).

15. It would thus not be possible under the new system (or at least not at the outset) to file a request for the recording of changes in respect of which the Office requested to record the change could, under the PLT, require further documentation, evidence, certifications or translations to be furnished to it—that is, any requests for the recording of a change in the *person* of an applicant for a patent or in the person of an owner of a patent (see PLT Rule 16), or any requests for the recording of a license in respect of an application for a patent or a patent, of a security interest in respect of an application for a patent or a patent, and the cancellation of the recordation of a license or a security interest in respect of an application for a patent or a patent (see PLT Rule 17). The possibility of filing such requests could, however, be added to the system at a later stage, provided agreement can be reached on the remaining optional requirements permitted under PLT Rules 16 and 17 (relating to

certifications, furnishing of further documentation and translations) and thus on a uniform set of requirements which would be acceptable to all designated or elected Offices.

16. The International Bureau would check any international request for compliance with the formal requirements under the PCT (which would be identical to those under the PLT) and decide, with effect for all designated or elected Offices concerned, whether those requirements were met. The applicant or owner would be required to furnish further evidence only where the International Bureau may reasonably doubt the veracity of an indication contained in the request (see PLT Rule 15.4).

17. If all requirements were complied with, the International Bureau would notify each designated or elected Office concerned accordingly, preferably in electronic form. Any such Office would then be required to record the change in its national register, unless the Office may reasonably doubt that a requirement applied by the International Bureau under the PCT Regulations was complied with. In turn, each designated or elected Office would notify the International Bureau of the fact that the change had been recorded in its national registry (see paragraph 20, below).

18. The international request would have to be accompanied by the payment of a fee, which could consist either of a fee whose amount would be determined by the total amount of the national fees (if any) payable to each of the designated or elected Offices concerned and an additional amount for the benefit of the International Bureau, or of a flatinternational fee for the benefit of all designated or elected Offices concerned and the International Bureau. Any fees paid for the benefit of designated or elected Offices would be transferred by the International Bureau to the Offices concerned.

19. In order to facilitate the processing of international requests for the recording of changes, the International Bureau proposes to further study the possibility of introducing unique identifier numbers for applicants, enabling the International Bureau and all designated or elected Offices to quickly and accurately identify the applications or patents affected by a change, in particular in cases where a request for the recording of a change relates to multiple applications or patents by the same owner.

20. As in the case of changes recorded by the International Bureau during the international phase (see paragraph 11, above), the International Bureau would make any changes recorded by the designated or elected Offices under the new system available to the general public, based on the notifications received from the Offices, once the change has been recorded (see paragraph 16, above), be it in the form of access to the (paper) file held by the International Bureau or, eventually, in electronic form, as part of an online PCT public file inspection service.

Advantages

21. Clearly, such a system of centralized filing of international requests for the recording of certain changes in respect of international applications which have entered the national phase before several designated or elected Offices, building on the achievements of the PLT, would be in line with the objectives and the spirit of the PCT. It would allow applicants and patent owners to deal with one office, with one set of requirements, to make only one fee payment, and to file one request (or a limited number of requests) for the recording of changes in respect of all affected international applications filed by the same applicant, or patents owned by the same owner. Such a system would reduce administrative work for applicants and

patent owners, minimize the difficulties of working in various languages and of meeting different legal requirements, and reduce overall fees.

22. Any designated or elected Office could, for the recording of changes, rely on the checks carried out by the International Bureau, and would thus be relieved of at least a certain amount of work in relation to the recording of changes in international applications that have entered the national phase, or in patents based on such international applications.

How to Establish Such System

23. A system of centralized filing of international requests for the recording of certain changes as outlined above could be implemented by way of amendment of the PCT Regulations and modification of the PCT Administrative Instructions and thus could become operational relatively quickly. It is expected that the International Bureau could absorb the additional work related to the processing of requests for the recording of changes without the need for additional resources.

24. The Working Group is invited to consider the proposals contained in this document.

[End of document]

E

WIPO

PCT/R/WG/6/11
ORIGINAL: English
DATE: April 21, 2004

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT)

Sixth Session
Geneva, May 3 to 7, 2004

ADDITIONAL COMMENTS BY SWITZERLAND ON ITS PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

Document prepared by the International Bureau

BACKGROUND

1. The additional comments by Switzerland on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications appearing on the following pages were made by Switzerland in a submission to the International Bureau received on April 16, 2004.

2. The Working Group is invited to consider the additional comments contained in the Annex to this document.

[Annex follows]

ANNEX

ADDITIONAL COMMENTS BY SWITZERLAND ON ITS PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

SUMMARY

The present submission contains additional comments by Switzerland on its proposals submitted to the Working Group on Reform of the Patent Cooperation Treaty (PCT) in May 2003 with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications.[1] These comments concern the use of terms, 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 the wrongful disclosure of the source. By submitting these additional comments, Switzerland aims at enabling the Working Group on the PCT-Reform to have a more substantive discussion on its proposals.

Use of terms: The Swiss proposals use the terms "genetic resources" and "knowledge, innovations and practices" to ensure consistency with the CBD, the Bonn Guidelines and the International Treaty of FAO. The more elaborate and detailed term "knowledge, innovations and practices" is used in the understanding that it is synonymous with the term "traditional knowledge." Based on the mentioned international instruments, the relevant knowledge, innovations and practices must be related to or associated with genetic resources. Furthermore, as a measure under patent law, the focus is on knowledge, innovations and practices that can give rise to a technical invention.

The source of genetic resources and traditional knowledge: Switzerland proposes to require patent applicants to declare the "source" of genetic resources and traditional knowledge. The term "source" should be understood in its broadest sense possible. This is because according to the CBD, the Bonn Guidelines and the International Treaty of FAO, a multitude of entities may be involved in access and benefit sharing. In the foreground to be declared as the source is the entity competent (1) to grant access to genetic resources and/or traditional knowledge or (2) to participate in the sharing of the benefits arising out of their utilization.

The scope of the obligation to declare the source: With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) 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 or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51*bis*.1(g)(ii) 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.

Sanctions: 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.

---

[1] These proposals are contained in WIPO-document PCT/R/WG/5/11.

ADDITIONAL COMMENTS BY SWITZERLAND ON ITS PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

TABLE OF CONTENTS

I. OVERVIEW 3

II. THE PROPOSALS BY SWITZERLAND 4

III. TRANSPARENCY MEASURES IN THE CURRENT PATENT SYSTEM 5

IV. GENETIC RESOURCES AND KNOWLEDGE, INNOVATIONS AND PRACTICES 5

(1) Genetic Resources 5
(2) Knowledge, Innovations and Practices / Traditional Knowledge 6

V. THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE 7

(1) Policy Objective of the Declaration of the Source 7
(2) The CBD and the Bonn Guidelines 8
(3) The FAO-IT 9
(4) The Proposals by Switzerland 10

VI. THE POSSIBLE LEGAL SANCTIONS FOR FAILURE TO DISCLOSE OR WRONGFUL DISCLOSURE OF THE SOURCE 11

VII. THE SCOPE OF THE OBLIGATION 12

VIII. CONCLUSIONS 12

I. OVERVIEW

1. At the fourth session of the Working Group on Reform of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO) held on 19-23 May 2003, Switzerland submitted proposals regarding transparency measures under patent law in the area of genetic resources and traditional knowledge.[2] More specifically, Switzerland proposed to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if the invention is directly based on such resources or knowledge. Switzerland also presented its proposals to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO; the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO); and the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing and the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD). Many delegations welcomed the initiative by Switzerland and expressed support for the proposed measures.

2. Other delegations also submitted proposals with regard to transparency measures under patent law.[3] These proposals may differ with regard to the information to be disclosed, the legal nature of the proposed measures, the effects of non-compliance, or the international forum competent for the realization of the measures. This notwithstanding, they all share the common policy objective of increasing transparency in the context of access to genetic resources and traditional knowledge, and the sharing of the benefits arising out of their commercial utilization.

3. In the international discussions on transparency measures related to intellectual property rights (IPRs), several issues were raised which require further analysis. Most recently, para. 8 of Section E of the Decision on "access and benefit sharing as related to genetic resources (Article 15)" adopted by the seventh COP of the CBD (held in Kuala Lumpur, Malaysia, 9-20 February 2004) invites WIPO "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*:

---

2 These proposals are contained in WIPO-document PCT/R/WG/5/11.

3 See WTO-document IP/C/W/383, Communication from the European Communities and Their Member States: Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore, "A Concept Paper" (17 October 2002); WTO-document IP/C/W/403, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, and Venezuela: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge (24 June 2003); and WTO-document IP/C/W/404, Joint Communication from the African Group: Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement (26 June 2003).

(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[.]"

4. In order to further advance the discussions of the Working Group on Reform of the PCT, Switzerland submits these additional comments on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. These comments concern the definition of the terms "genetic resources" and "traditional knowledge," the concept of the "source," and the scope of the obligation to declare this source in patent applications.

II. THE PROPOSALS BY SWITZERLAND

5. Switzerland proposes to introduce two new subparagraphs in Rules 51*bis*.1 and 4.17, respectively, of the Regulations Under the PCT (PCT-Regulations). They read as follows:

- New subpara. (g) of Rule 51*bis*.1:

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

(i) to declare the source of a specific genetic resource to which the inventor has had access, if an invention is directly based on such a resource; if such source is unknown, this shall be declared accordingly;

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

- New subpara. (vi) of Rule 4.17:

> "(vi) a declaration as to the source of a specific genetic resource and/or knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity, as referred to in Rule 51*bis*.1(g)."

III. TRANSPARENCY MEASURES IN THE CURRENT PATENT SYSTEM

6. The current patent system foresees a number of transparency measures. These may vary according to national law, and include the disclosure of "the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art" (Art. 29.1 of the TRIPS Agreement), the indication of "the best mode for carrying out the invention known to the inventor" (Art. 29.1 of the TRIPS Agreement), the declaration as to the identity of the inventor (Rules 4.17(i) and 51*bis*.1(a)(i) of the PCT-Regulations), the publication of international patent applications (Art. 21 of the PCT and Rule 48 of the PCT-Regulations), the reference to deposited biological materials (Rule 13*bis* of the PCT-Regulations), and the listing of nucleotide and/or amino acid sequences (Rule 13*ter* of the PCT-Regulations). Some of these transparency measures, such as the disclosure of the invention in the patent application, are substantive requirements of patentability, whereas other measures, such as the listing of nucleotide and/or amino acid sequences, have a formal character and first and foremost aim at facilitating access to certain information.

7. Requiring the patent applicant to declare the source of genetic resources and/or traditional knowledge in patent applications presents an additional transparency measure under patent law.

IV. GENETIC RESOURCES AND KNOWLEDGE, INNOVATIONS AND PRACTICES

8. According to the Swiss proposals, the patent applicant should declare the source of "genetic resources" and "knowledge, innovations and practices." These terms ensure consistency with the three international instruments which are primarily relevant in this regard, that is, (1) the CBD, (2) the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Bonn Guidelines), and (3) the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization (FAO-IT). These instruments use the following terminology and definitions:

(1) Genetic Resources

9. Genetic resources are defined in Art. 2 of the CBD as meaning genetic material – that is, any material of plant, animal, microbial or other origin containing functional units of heredity – of actual or potential value.[4] Based on para. 8 of the Bonn Guidelines, this instrument uses the same definition.

---

[4] Para. 2 of CBD-COP Decision II/11 "[r]eaffirms that human genetic resources are not included within the framework of the [CBD]." The same is stated in para. 9 of the Bonn Guidelines.

10. Plant genetic resources for food and agriculture (PGRFA), a special category of plant genetic resources, are defined in Art. 2 of the FAO-IT as meaning any genetic material of plant origin – that is, any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity – of actual or potential value for food and agriculture.

(2) Knowledge, Innovations and Practices / Traditional Knowledge

11. The terminology used in the above-mentioned international instruments is not uniform: Art. 8(j) of the CBD uses the term "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"; para. 9 of the Bonn Guidelines refers to "traditional knowledge, innovations and practices associated with genetic resources"; and Art. 9.2(a) of the FAO-IT uses the term "traditional knowledge relevant to PGRFA."[5] Neither of these instruments, however, defines the terms used; nevertheless, it can be concluded from the relevant international discussions that these terms are generally understood to be synonymous.[6]

12. The proposed new provisions in Rules 51*bis*.1 and 4.17, respectively, of the PCT-Regulations use the term "knowledge, innovations and practices" instead of the term "traditional knowledge." The term "knowledge, innovations and practices" is chosen because it is more elaborate and detailed, but in the understanding that it is synonymous with the term "traditional knowledge."[7] Based on the terminology used in the mentioned international instruments and their scope of application, the "knowledge, innovations and practices" in question must be related to or associated with genetic resources.

---

5 This term is generally also used in WIPO and the WTO.

6 Article 8(j) of the CBD and para. 44(g) of the Bonn Guidelines use the term „knowledge, innovations and practices." This term is also used in several of the decisions adopted by the Conference of the Parties of the CBD (CBD-COP), including para. 8 C of Decision VI/10. Para. 16(c)(i) of the Bonn Guidelines and some decisions of the CBD-COP use the term "traditional knowledge" instead. This applies, for example, to paras. 10 and 11 of Section C of Decision VI/24. Furthermore, para. 9 of the Bonn Guidelines and para. 4 of Section C of Decision VI/24 use the term "associated traditional knowledge, innovations and practices." And finally, para. 31 of the Bonn Guidelines uses both the terms "traditional knowledge associated with genetic resources" and "traditional knowledge, innovations and practices." Thus, in the context of the CBD, the term "knowledge, innovations and practices" is used interchangeably with the term "traditional knowledge."

7 For reasons of simplicity and conciseness, this submission uses the term "traditional knowledge" instead of "knowledge, innovations and practices."

13. The proposed declaration of the source is a measure to be taken under patent law. Thus, it clearly focuses on traditional knowledge that can give rise to a technical invention, whereas other forms of this knowledge are beyond the scope of application of this measure.[8]

V. THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

(1) Policy Objective of the Declaration of the Source

14. The policy objective of the declaration of the source of genetic resources and traditional knowledge in patent applications is to increase transparency in the context of access to such resources and knowledge, and the sharing of the benefits arising out of their commercial utilization. This is of particular relevance with regard to the obligations of the users of genetic resources and traditional knowledge.

---

[8] The following definition of the term traditional knowledge would thus seem much too broad for the purposes of the proposed new subparas. (g) of Rule 51bis.1 and (vi) of Rule 4.17 of the PCT-Regulations: It defines traditional knowledge as referring "to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. "Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge; "expressions of folklore" in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of [traditional knowledge] would be items not resulting from intellectual activity in the industrial, scientific, literary or artistic fields, such as human remains, languages in general, and other similar elements of "heritage" in the broad sense." (WIPO-document WIPO/GRTKF/IC/3/9, Traditional Knowledge – Operational Terms and Definitions (20 May 2002), paragraph 25).

In contrast, the following definition of the term traditional knowledge would seem much more appropriate for the purposes of the proposed new subparas. (g) of Rule 51*bis*.1 and (vi) of Rule 4.17 of the PCT-Regulations: Traditional knowledge is defined "as knowledge which is:

- *generated, preserved and transmitted in a traditional context;*
- *distinctively associated with the traditional or Indigenous culture or community which preserves and transmits it between generations;*
- *linked to a local or Indigenous community or other group of persons identifying with a traditional culture through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive, a relationship that may be expressed formally or informally by customary law;*
- *knowledge in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and*
- *identified by the community or other group as being traditional knowledge."*

(WIPO-document WIPO/GRTKF/IC/5/12, Overview of Activities and Outcomes of the Intergovernmental Committee (3 April 2003), paragraph 45).

15. Increased transparency will allow the providers of genetic resources and traditional knowledge to verify whether the inventor and/or patent applicant complied with the applicable rules and procedures on access to these resources or this knowledge, including particularly prior informed consent (PIC), and whether provision for benefit sharing has been made.

16. In light of this policy objective, it is evident that in the foreground as the source to be declared should be the entity competent (1) to grant access to genetic resources and/or traditional knowledge, or (2) to participate in the sharing of the benefits arising out of their utilization. Depending on the genetic resource or traditional knowledge in question, the provisions of different international agreements apply, namely the CBD, the Bonn Guidelines and the FAO-IT.

(2) The CBD and the Bonn Guidelines

17. The CBD and the Bonn Guidelines cover genetic resources of plants, animals and microorganisms as well as "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"[9] or "traditional knowledge, innovations and practices associated with genetic resources,"[10] respectively.

- *Access to genetic resources*: According to Art. 15.5 of the CBD, "[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources,[11] unless otherwise determined by that Party." The same provisions are contained in para. 28 of the Bonn Guidelines, which states that "[p]rior informed consent for access to *in situ* genetic resources shall be obtained from the Contracting Party providing such resources,[12] through its competent national authority(ies), unless otherwise determined by that Party." In order to respect established legal rights of indigenous and local communities associated with the genetic resources being accessed, para. 31 of the Bonn Guidelines requires that the PIC of these communities "should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws." Furthermore, with regard to *ex situ* collections of genetic resources, para. 32 of the Bonn Guidelines requires that the PIC "should be obtained from the competent national authority(ies) and/or the body governing the *ex situ* collection concerned as appropriate."

---

9 Art. 8(j) of the CBD.

10 Para. 9 of the Bonn Guidelines.

11 Art. 2 of the CBD defines the term "country providing genetic resources" as meaning "the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country."

12 The Bonn Guidelines also use this term in paras. 16(d)(iii) and 24.

Benefit sharing: According to Art. 15.7 of the CBD, "[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." Para. 48 of the Bonn Guidelines, which is entitled "distribution of benefits," states that "[p]ursuant to mutually agreed terms established following prior informed consent, benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process. The latter may include governmental, non-governmental or academic institutions and indigenous and local communities. Benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity."

- *Access to traditional knowledge*: Art. 8(j) of the CBD requires each Contracting Party, as far as possible and as appropriate, and subject to its national legislation, to promote the wider application of traditional knowledge. This is to occur with the "approval and involvement of the holders of such knowledge[.]" The same is stated in para. 31 of the Bonn Guidelines, which requires that "the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws," in order to respect "established legal rights of indigenous and local communities […] where traditional knowledge associated with […] genetic resources is being accessed[.]"

  Benefit sharing: Art. 8(j) of the CBD requires each Contracting Party, as far as possible and as appropriate, and subject to its national legislation, to "encourage the equitable sharing of the benefits arising from the utilization of such knowledge[.]" Furthermore, according to para. 48 of the Bonn Guidelines, "the benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process[,]" including indigenous and local communities.

18. Thus, according to the CBD and the Bonn Guidelines, a multitude of entities may be involved in access and benefit sharing. This multitude of entities is explicitly reflected in para. 18 of the Bonn Guidelines, which states that "[r]elevant stakeholders should be consulted and their views taken into consideration in each step of the process, including: (a) When determining access, negotiating and implementing mutually agreed terms, and in the sharing of benefits[.]" Additionally, para. 17, entitled "participation of stakeholders", states that "[i]nvolvement of relevant stakeholders is essential to ensure the adequate development and implementation of access and benefit-sharing arrangements. However, due to the diversity of stakeholders and their diverging interests, their appropriate involvement can only be determined on a case-by-case basis."

(3) The FAO-IT

19. The FAO-IT covers plant genetic resources for food and agriculture (PGRFA)[13] and traditional knowledge relevant to PGRFA.

---

13 The PGRFA covered by the FAO-IT are listed in its Annex I.

- *PGRFA*: Arts. 10 to 13 of the FAO-IT establish a Multilateral System of access and benefit sharing. In this system, there is no "need to track individual accessions."[14] The monetary benefits of commercialization referred to in Art. 13.2(d)(ii) are to be paid into an appropriate mechanism, such as a trust account, to be established by the Governing Body of the FAO-IT.[15] The benefits arising from the use of PGRFA that are shared under the Multilateral System should, according to Art. 13.3, flow primarily to farmers in all countries. In the context of Farmers' Rights, Art. 9.2(b) of the FAO-IT refers to "the right to equitably participate in sharing benefits arising from the utilization of [PGRFA]" as one measure to protect and promote these rights.

- *Traditional knowledge*: The FAO-IT states in Art. 9.2(a) that the "protection of traditional knowledge relevant to [PGRFA]" is one measure to protect and promote Farmers' Rights.

20. Thus, parallel to the CBD and the Bonn Guidelines, the FAO-IT allows for a multitude of entities to be involved in access and benefit sharing. They include the Multilateral System; an appropriate mechanism, such as a trust account; and farmers in all countries.

(4) The Proposals by Switzerland

21. According to the CBD, the Bonn Guidelines and the FAO-IT, different entities may be involved in access to genetic resources and traditional knowledge, and the sharing of the benefits arising from their utilization. They include the Contracting Parties providing genetic resources and their competent national authorities, the Multilateral System and the "appropriate mechanism" according to the FAO-IT, indigenous and local communities, and the bodies governing ex situ collections of genetic resources.

22. Because of this multitude of entities which may be involved in access and benefit sharing, Switzerland proposes to require patent applicants to declare the "source,"[16] and to understand this term in its broadest sense possible: The term source should thus not only include the just mentioned entities, but also other possible sources of genetic resources and traditional knowledge proposed in this context, namely "origin,"[17] "geographical origin,"[18] "country of origin of genetic resources,"[19] and any other source that may be relevant, such as databases on traditional knowledge as well as scientific and other publications.[20]

---

14 Art. 12.3(b) of the FAO-IT.

15 According to Art. 19.3(f) of the FAO-IT, this mechanism is foreseen to receive and utilize the "financial resources that will accrue to it for purposes of implementing this Treaty[.]"

16 This term is used in para. 4 of Section C of Decision VI/24.

17 This term is used in paras. 31 and 46 of COP-Decision VI/10 (entitled „Article 8(j) and related provisions").

18 This term is used in Recital 27 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (EU Biotech Directive).

19 This term is used in Art. 15.3 of the CBD, para. 16(d)(ii) of the Bonn Guidelines and para. 1 of Section C of Decision VI/24 adopted by the CBD-COP. It is defined in Art. 2 of the CBD as "the country which possesses those genetic resources in *in-situ* conditions."

20 This may, for example, be the case where traditional knowledge was found in a scientific journal.

23. A broad understanding of the term source allows for the declaration of a variety of sources. This has several advantages, including the following: First, the patent applicant is able to declare the source which is most appropriate with regard to the invention in question, as all entities which according to the CBD, the Bonn Guidelines and the FAO-IT may be involved in access and benefit sharing can be declared as source. Second, it enables "those who have been identified as having contributed to the resource management, scientific and/or commercial process"[21] to participate in the sharing of the benefits, as is explicitly foreseen in para. 48 of the Bonn Guidelines. Third, it allows scientists and industry to carry out research activities with regard to genetic resources and traditional knowledge of which one of these sources is known, without risking that the granting of patents for resulting inventions is jeopardized by the lacking knowledge about the source of the used genetic resource or traditional knowledge. Limiting the number of sources permitted to be declared could hinder these research activities and could thus prevent the development of innovations such as for example new and improved pharmaceuticals or seed. Fourth, patent applicants are not deterred from filing for patents and maintaining secrecy over their inventions instead. And fifth, with a multitude of sources which can be declared, patent applicants will generally be able to declare the source, whereas they should only in exceptional cases declare that the source is unknown to them or the inventor.

VI. THE POSSIBLE LEGAL SANCTIONS FOR FAILURE TO DISCLOSE OR WRONGFUL DISCLOSURE OF THE SOURCE

24. 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.

25. 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.

26. 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.

---

[21] Para. 48 of the Bonn Guidelines.

VII. THE SCOPE OF THE OBLIGATION

27. With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) 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 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.

28. With regard to traditional knowledge, the proposed new Rule 51*bis*.1(g)(ii) 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.

VIII. CONCLUSIONS

29. The present submission contains additional comments on the proposals submitted by Switzerland to the Working Group on Reform of the PCT in May 2003 with regard to the declaration of the source of genetic resources and/or traditional knowledge in patent applications. These comments concern the use of terms, the concept of the source of genetic resources and traditional knowledge, and the scope of the obligation to declare this source in patent applications.

30. The current patent system foresees a number of transparency measures. These include the disclosure of the invention and the indication of the best mode for its carrying out, the declaration the inventor's identity, the publication of international patent applications, the reference to deposited biological material, and the listing of nucleotide and/or amino acid sequences. Some of these transparency measures, such as the disclosure of the invention in the patent application, are substantive requirements of patentability, whereas other measures, such as the listing of nucleotide and/or amino acid sequences, have a formal character and first and foremost aim at facilitating access to certain information.

31. The proposed declaration of the source presents a patent-related measure to increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their commercial utilization. It complements other measures outside the patent system that have or will be taken to resolve the issues arising with regard to access and benefit sharing. Examples of the many possible other measures are the designation of competent national authorities, the introduction of administrative procedures on access to genetic resources and traditional knowledge, the establishment of local and national databases and of an international internet portal for traditional knowledge.[22]

---

[22] WTO-document IP/C/W/284, Communication by Switzerland: Review of Article 27.3(b), the View of Switzerland (15 June 2001), paras. 16-19.

32. The declaration of the source allows international agreements on intellectual property, including particularly the PCT, the Patent Law Treaty (PLT) once it enters into force, and the TRIPS Agreement, to be implemented in a mutually supportive way with the CBD, the Bonn Guidelines and the FAO-IT once it enters into force. Furthermore, amending the PCT-Regulations enabling the national legislator to require the declaration of the source in patent applications could be one of the elements of an international regime on access and benefit sharing foreseen to be negotiated.[23]

[End of Annex and of document]

[23] The World Summit on Sustainable Development (WSSD), held in August/September 2002, calls in paragraph 44(o) of the Plan of Implementation on States to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources." According to para. 1 of Section D of Decision VII/19 on "access and benefit sharing as related to genetic resources (Article 15)," the seventh COP of the CBD (held in Kuala Lumpur, Malaysia, 9-20 February 2004) "[d]ecides to mandate 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 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[.]"