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

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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.

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[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

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*:

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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.

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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.

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[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."

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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.

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[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]

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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.

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[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]

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[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[.]"