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

Document submitted by the Delegation of Switzerland

1. In a communication to the World Intellectual Property Organization (WIPO) dated May 19, 2005, the Government of Switzerland submitted a document entitled "Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications". The communication requested that the document be issued as an information document for the *Ad hoc* Intergovernmental Meeting on Genetic Resources and Disclosure Requirements.

2. The document is reproduced in the form received and published in the Annex to this document.

[Annex follows]

ANNEX

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

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I. Overview

Switzerland submitted its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications to the WIPO-Working Group on Reform of the Patent Cooperation Treaty (PCT) in May 2003.[1]

In summary, Switzerland proposes to amend the Regulations under the PCT (PCT Regulations) to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if the invention is directly based on such resources or knowledge (see the proposed new Rule 51*bis*.1[g]). Furthermore, Switzerland proposes to afford patent applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase (see the proposed new Rule 4.17[vi]), and to include the declaration of the source in the international publication of the patent application containing such a declaration (see the proposed new Rule 48.2[a]).

In order to advance the discussions on its proposals, Switzerland presented two further submissions to the WIPO-Working Group on PCT Reform in May 2004 and October 2004, respectively, containing more detailed explanations on its proposals.[2] These submissions

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1 See WIPO-document PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11/Rev. (available at <http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_5_11_rev.pdf>)

2 See WIPO-documents PCT/R/WG/6/11 (available at <http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_6_11.pdf>) and PCT/R/WG/7 Paper No. 7 (available at <http://www.wipo.int/pct/reform/en/draftdocs/wg7/pct_r_wg_7_paper_7.pdf>).

address the use of terms, the concept of the „source“ of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, the possible legal sanctions for failure to declare the source or for wrongful declaration of the source, and its optional *vs.* mandatory introduction at the national level.

Switzerland, not a demandeur with regard to the issue of the disclosure of the source in patent applications, submitted its proposals to be supportive of the process and because it is interested in a balanced patent protection for biotechnological inventions.

For information purposes, Switzerland also presented its proposals to the WIPO-Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC),[3] to the WTO-TRIPS Council,[4] and to the 3rd session of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing of the Convention on Biological Diversity (CBD).[5]

II. The Proposals by Switzerland

1) Policy objectives

In the view of Switzerland, the proposed disclosure of the source allows to achieve four policy objectives: These concern **t**ransparency, **t**raceability, **t**echnical prior art and mutual **t**rust (or, in short, “the four T’s”):

1. Transparency: With a requirement to disclose the source in national and international patent applications for inventions which are directly based on genetic resources or traditional knowledge, the patent system would increase transparency in access and benefit sharing with regard to genetic resources and traditional knowledge.
2. Traceability: Disclosing the source in patent applications would allow the providers of genetic resources and traditional knowledge to keep track of the use of their resources or knowledge in research and development resulting in patentable inventions.
3. Technical prior art: Disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges in the establishment of prior art with regard to inventions that somehow relate to these resources or this knowledge. In particular, it may facilitate the establishment of prior public use as well as the finding of lack of novelty or inventive step. This applies in particular to prior art regarding traditional knowledge, as disclosing the source would simplify searching the databases on traditional knowledge that are increasingly being established at the local, regional and national level.
4. Mutual Trust: The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing, including among developing and developed countries, indigenous and local communities, private companies, and public and private research institutions. All of these stakeholders may

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3 See WIPO-document WIPO/GRTKF/IC/7/INF/5 (available at <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_inf_5.pdf>).

4 See WTO-documents IP/C/W/400/Rev.1 (available at <http://www.ige.ch/E/jurinfo/documents/IP-C-W-400.pdf>), IP/C/W/423 (available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W423.doc>), and IP/C/W/433 (available at <http://www.ige.ch/E/jurinfo/documents/j110114e.pdf>).

5 See CBD-document UNEP/CBD/WG-ABS/3/INF/7 (available at <http://www.biodiv.org/doc/meetings/abs/abswg-03/information/abswg-03-inf-07-en.pdf>).

be providers and/or users of genetic resources and traditional knowledge. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the patent system.

2) Amendment of the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT)

Switzerland proposes to amend the PCT Regulations to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. To further strengthen the transparency-increasingfunction of the requirement to disclose the source, Switzerland proposes to include such declarations in the international publication of the relevant patent applications. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.

Based on the reference to the PCT contained in Article 6.1 of WIPO's Patent Law Treaty (PLT), the proposed amendment to the PCT would also apply to the PLT. Accordingly, it would be clarified that in the context of the PLT, the Contracting Parties may foresee in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications.

3) Use of terms

The Swiss proposals use the terms "genetic resources" and "traditional knowledge related to genetic resources" to ensure consistency with the CBD, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Bonn Guidelines), and the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) of the Food and Agriculture Organization (FAO). As a measure under patent law, the focus is on traditional knowledge that can give rise to a technical invention.

4) Concept of 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 international instrument referred to above, 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.

Depending on the genetic resource or traditional knowledge in question, one can distinguish:

1. Primary sources, including in particular Contracting Parties providing genetic resources,[6] the Multilateral System of FAO's International Treaty,[7] indigenous and local communities;[8] and
2. secondary sources, including in particular *ex situ* collections and scientific literature.

Accordingly, there is a "cascade" of possible primary and secondary sources: Patent applicants must declare the primary source to fulfil the requirement, if they have information about this primary source at hand, whereas a secondary source may only be declared if patent applicants have no information at hand about the primary source. Accordingly, if, for example, the patent applicant knows that the source of a genetic resource is the Contracting Party providing this resource, this Contracting Party must be disclosed as the source; in contrast, if the patent applicant received the genetic resource from a botanical garden, but does not know the Contracting Party providing the genetic resource, the botanical garden must be disclosed as the source.

5) Scope of the obligation to declare the source

With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) of the PCT Regulations makes clear that

1. the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource; and
2. 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) of the PCT Regulations makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

6) Optional *vs.* mandatory introduction of the requirement at the national level

Switzerland proposes to amend the PCT-Regulations to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. The proposals thus leave it up to the national legislator to decide whether such a requirement is to be introduced in the national patent legislation.

The optional approach by Switzerland intends to offer four main advantages:

1. At present, greatly divergent views exist on transparency measures, and the ongoing discussions have not brought any final results. Much faster progress, however, can be expected from an optional approach as is proposed by Switzerland, than can be expected from any mandatory approach.
2. An optional introduction of the disclosure requirement would explicitly enable those States interested in introducing such a requirement to do so. Additionally, it would allow the national governments and the international community to gain experience with the disclosure requirement, without prejudice to further international efforts.

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6 See Articles 15, 16 and 19 of the CBD.
7 See Articles 10-13 of FAO's International Treaty.
8 See Article 8(j) of the CBD.

3. The proposed establishment of the list of competent government agencies just described, and the inclusion of the declaration of the source in the publication of the patent application, would bring almost identical results as a mandatory approach. It is important to note that Switzerland[9] and most other European countries envisage to introduce a disclosure requirement in their national patent laws. This would create the critical mass to render the proposed disclosure of the source an effective measure internationally.
4. The approach proposed by Switzerland would not oblige developing countries, especially the least developed countries, to introduce the disclosure requirement in their national laws. Introducing such a requirement would generally bring little advantage to these countries. In contrast, a mandatory approach would oblige all countries to introduce such a requirement in their national patent laws.

It is crucial to keep in mind that once the disclosure requirement as proposed by Switzerland is implemented at the national level, it is mandatory for patent applicants to disclose the source in patent applications. Failure to disclose or wrongful disclosure would carry the severe sanctions outlined above. In this regard, the Swiss proposals are of a mandatory and not of a voluntary nature.

7) Sanctions

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

Accordingly, if the national law applicable by the designated Office requires the declaration of the source of genetic resources and traditional knowledge, the proposed amended 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 this 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, the designated Office must according to the proposed new Rule 51*bis*.2(d) 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.

Furthermore, if it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, such failure to comply with the requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention, if such sanction is provided for in the relevant national patent law (Article 10 PLT).

In addition, other sanctions provided for in national law, including criminal sanctions such as fines, as well as the publication of the judges' rulings may be imposed.

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[9] For more information on the draft for a revised Swiss Patent Law with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications, see <http://www.ige.ch/E/jurinfo/documents/j10017e.pdf>.

8) Establishment of a list of government agencies competent to receive information on declaration of source

The proposed transparency measure could be further strengthened by establishing a list of government agencies competent to receive information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge. For easy reference, this list should be made accessible on the internet. Patent offices receiving patent applications containing such declaration could inform the competent government agency that the respective State is declared as the source. This information could be provided in a standardized letter sent to the competent government agency. Switzerland invites WIPO, in close collaboration with the CBD, to further consider the possible establishment of such a list of competent government agencies.

III. Conclusions

The proposals submitted by Switzerland to WIPO intend to present a simple and practical way forward. These proposals could be introduced in a timely manner and would not require extensive changes to the provisions of the relevant international agreements.

Disclosing the source of genetic resources and traditional knowledge in patent applications for inventions which are directly based on such resources or knowledge can be seen as the "entering point" of the access and benefit sharing in the patent system. In this way, disclosing the source would strengthen the mutual supportiveness of the access and benefit sharing system and the patent system. Moreover, disclosing the source would help to build mutual trust in the North – South – relationship.

The proposed declaration of the source of genetic resources and traditional knowledge in patent applications would allow the parties to a contract on access and benefit sharing to verify whether the other contracting party is complying with its obligations arising under that contract. This transparency measure would assist in and simplify the enforcement of these obligations, including in particular the verification of whether prior informed consent (PIC) of the country providing the genetic resources has been obtained and whether provision have been made for fair and equitable benefit sharing.

The proposals by Switzerland would thus enable the Contracting Parties of relevant international agreements, including the PCT, the PLT, the TRIPS Agreement, the CBD and the International Treaty of FAO, to fulfil their respective obligations. These proposals aim to provide the means to ensure that the international agreements on intellectual property and the CBD can be implemented in a mutually supportive way. Furthermore, the Swiss proposals would enable the Contracting Parties of the CBD to implement the provisions of the Bonn Guidelines, in particular their paragraph 16(d), as well as the relevant decisions adopted by the CBD's COP6 and COP7. And finally, the possibility to require the declaration of the source would also support the determination of prior art, in particular with regard to traditional knowledge, as it would simplify searching the databases on traditional knowledge that are increasingly being established at the local, regional and national level.

[Appendix follows]

APPENDIX (of ANNEX)

Appendix: Switzerland's Proposals for Amendments to PCT-Regulations[10]

Rule 4: The Request (Contents)

Rule 4.17: *Declarations Relating to National Requirements Referred to in Rule 51bis.1(a)(i) to (v) and Rule 51bis.1(g)*

The request may, for the purposes of the national law applicable in one or more designated States, contain one or more of the following declarations, worded as prescribed by the Administrative Instructions:

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

Rule 48: International Publication

Rule 48.2: *Contents*

(a) The pamphlet shall contain:

(xi) any declaration referred to in Rule 4.17(vi), and any correction under Rule 26*ter*.1, which was received by the International Bureau before the expiration of the time limit under Rule 26*ter*.1.

Rule 51*bis*: Certain National Requirements Allowed Under Article 27

Rule 51*bis*.1: *Certain National Requirements Allowed*

(g) Subject to Rule 51*bis*.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish:

(i) a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource;

(ii) a declaration as to the source of traditional knowledge related to genetic resources, if the inventor knows that the invention is directly based on such knowledge;

(iii) a declaration that the source referred to in (i) or (ii) is unknown to the inventor or applicant, if this is the case.

Rule 51*bis*.2: *Circumstances in Which Documents or Evidence May Not Be Required*

(d) Where the applicable national law requires the applicant to furnish a declaration as to the source (Rule 51*bis*.1(g)), the designated Office shall not, unless it may reasonably doubt the veracity of the declaration concerned, require any document or evidence:

(i) relating to the source of a specific genetic resource (Rule 51*bis*.1(g)(i) and (iii)) if, in accordance with Rule 4.17(vi), such declaration is contained in the request or is submitted directly to the designated Office;

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10 The wording of the proposed amendments is underlined.

(ii) relating to the source of traditional knowledge related to genetic resources, (Rule 51*bis*.1(g)(ii) and (iii)) if, in accordance with Rule 4.17(vi), such declaration is contained in the request or is submitted directly to the designated Office.

Rule 51*bis*.3: *Opportunity to Comply with National Requirements*

(a) Where any of the requirements referred to in Rule 51*bis*.1(a)(i) to (iv), ~~and~~ (c) to (e), and (g), […] is not already fulfilled during the same period within which the requirements under if Article 22 must be complied with, the designated Office circumstances, shall invite the applicant to comply with the requirement within a time limit which shall not be less than two months from the date of the invitation. […].

[End of Appendix
and of document]