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BENEFIT-SHARING

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

Note by the Executive Secretary

1. At the request of the Government of Switzerland, the Executive Secretary is pleased to circulate herewith, for the information of participants in the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, a paper containing proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications.
2. The proposals are being circulated in the form and the language in which they were received by the Convention Secretariat.

* UNEP/CBD/WG-ABS/3/1.

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

I. Overview

The seventh Conference of the Parties (COP-7) of the Convention on Biological Diversity (CBD), held in February 2004, mandated the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing (Working Group on ABS) “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.”¹ The Terms of Reference for the Working Group on ABS list as one element to be considered for inclusion in the international regime the “disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights.”²

In this regard, Switzerland submitted proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications to the Working Group on Reform of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO) in May 2003.³ More specifically, 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. In order to further advance the discussions on its proposals, Switzerland presented two further submissions to the Working Group on PCT Reform in May 2004 and October 2004.⁴ These submissions 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 wrongful declaration of the source, the formal nature of the requirement to declare the source, and its optional vs. mandatory introduction at the national level. For information purposes, Switzerland also presented the three submissions on its proposals to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO), and to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO.

In the view of Switzerland, the proposed amendments to the PCT Regulations present one simple and practical solution to the issues arising in the context of access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization. These amendments could be introduced in a timely manner and would not require extensive changes to the provisions of relevant international agreements.

II. Proposals by Switzerland

Summary of the proposals: Switzerland proposes to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. More specifically, 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

¹ Decision VII/19, Section D, para. 1.

² Decision VII/19, Section D, Annex, subpara. (d)(xiv).

³ See WIPO-document PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev.

⁴ See WIPO-documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.

By reference, the proposed amendment to the PCT would also apply to WIPO's Patent Law Treaty (PLT). Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications.

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.

The 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 primary sources, including in particular Contracting Parties providing genetic resources, the Multilateral System of FAO's International Treaty, indigenous and local communities, and 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. A secondary source may only be declared if patent applicants have no information at hand about the primary source.

The 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 (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) 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.

Optional vs. mandatory introduction of the requirement at the national level: In view of the clear divergence of opinions among the Contracting Parties of the PCT with regard to the introduction of a requirement to declare the source, Switzerland proposed to make it optional for the national legislator to introduce such a requirement. If a Contracting Party of the PCT introduces the requirement in its national legislation, patent applicants would be required to declare the source of genetic resources and traditional knowledge in their patent applications. Failure to declare this source or wrongful declaration of the source would carry the sanctions described below. Accordingly, in this regard the requirement is of a mandatory and not of an optional nature.

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

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, 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 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 (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.

III. Documents by Switzerland on Its Proposals

With regard to its proposals, Switzerland submitted the following three documents:⁵

1. **English:** *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev.

<http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_5_11_rev.pdf>

Français: *Propositions de la Suisse en ce qui concerne la déclaration de la source des ressources génétiques et des savoirs traditionnels dans les demandes de brevet*, OMPI document PCT/R/WG/5/11

<http://www.wipo.int/pct/fr/meetings/reform_wg/pdf/pct_r_wg_5_11.pdf>

Español: *Propuestas de suiza relativas a la declaración de la fuente de los recursos genéticos y los conocimientos tradicionales en las solicitudes de patentes*, anexo al documento OMC IP/C/W/400/Rev.1 (pagina 16ff)

<<http://docsonline.wto.org/DDFDocuments/v/IP/C/W400R1.doc>>

⁵ Switzerland presented the three submissions on its proposals to the Working Group on PCT Reform. For information purposes, it also presented these submissions to the WTO's TRIPS Council and WIPO's IGC. Documents of the Working Group on PCT Reform are available in English and French only, whereas documents of the TRIPS Council are additionally available in Spanish. Accordingly, the list of documents to follow refers to documents of WIPO and the WTO in order to provide access to the submissions in English, French and Spanish. All documents referred to, however, have identical contents.

2. **English:** *Additional Comments by Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO document PCT/R/WG/6/11

<http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_6_11.pdf>

Français: *Observations supplémentaires de la Suisse portant sur les propositions concernant la déclaration de la source des ressources génétiques et des savoirs traditionnels dans les demandes de brevet*, document OMPI PCT/R/WG/6/11

<http://www.wipo.int/pct/fr/meetings/reform_wg/pdf/pct_r_wg_6_11.pdf>

Español: *Observaciones adicionales de Suiza sobre sus propuestas presentadas a la OMPI en relación con la declaración de la fuente de los recursos genéticos y los conocimientos tradicionales en las solicitudes de patentes*, documento OMC IP/C/W/423

<<http://docsonline.wto.org/DDFDocuments/v/IP/C/W423.doc>>

3. **English:** *Further Observations by Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO document PCT/R/WG/7 Paper No. 7

<http://www.wipo.int/pct/reform/en/draftdocs/wg7/pct_r_wg_7_paper_7.pdf>

Français: *Observations supplémentaires de la Suisse portant sur les propositions concernant la déclaration de la source des ressources génétiques et des savoirs traditionnels dans les demandes de brevet*, document OMC IP/C/W433

<<http://docsonline.wto.org/DDFDocuments/u/IP/C/W433.doc>>

Español: *Nuevas observaciones de Suiza sobre sus propuestas relativas a la declaración de la fuente de los recursos genéticos y los conocimientos tradicionales en las solicitudes de patentes*, documento OMC IP/C/W/433

<<http://docsonline.wto.org/DDFDocuments/v/IP/C/W433.doc>>
