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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL
PROPERTY AND GENETIC RESOURCES: SUBMISSION BY SWITZERLAND

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

“invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee.” [...]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the decision above, the Delegation of Switzerland submitted a document entitled “Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Provisions of the Swiss Patent Act” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

DECLARATION OF THE SOURCE OF GENETIC RESOURCES
AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS:
PROVISIONS OF THE SWISS PATENT ACT

I. INTRODUCTION

1. At the international and national level, measures under patent law are being discussed to address access and benefit-sharing issues, including in particular requirements for patent applicants to disclose certain information in patent applications (“disclosure requirements”).
2. Switzerland submitted proposals to WIPO on the disclosure of the source of genetic resources and traditional knowledge in patent applications.¹ The proposed amendment of the Regulations of the Patent Cooperation Treaty (PCT) would explicitly enable the national legislator to introduce such a disclosure requirement.²
3. To further strengthen the effectiveness of the proposed disclosure of source requirement, Switzerland proposed to establish an online list of government agencies competent to receive information about patent applications containing a declaration of the source. Patent offices receiving such patent applications would inform the competent government agency in a standardized letter about the respective declaration of the source.³
4. Moreover, Switzerland proposed the establishment of an international gateway for traditional knowledge. This gateway, to be administered by WIPO, would electronically link existing databases and thus facilitate access to their contents by patent authorities.⁴
5. Switzerland submitted the mentioned proposals to WIPO in order to contribute in a constructive manner to the international discussions. These proposals were submitted a number of years ago; however, only limited substantial discussions have taken place so far. Switzerland remains committed to discuss its proposals in the Intergovernmental Committee, provided there is the political will to resolve the intellectual property-related issues arising in the context of access and benefit-sharing. Taking into account the introduction of disclosure requirements in various national patent laws, and bearing in mind the growing importance attached to genetic resources and traditional knowledge in recent years, time might now be ripe to address these issues at the international level.
6. It is crucial to keep in mind that the disclosure of source requirement will by itself not be sufficient to resolve all issues arising in the context of access and benefit-sharing. It is

¹ Switzerland is also part of a coalition of approximately 110 Members of the World Trade Organization (WTO) supporting proposals for modalities on three issues concerning the TRIPS Agreement, including the disclosure requirement. See document TN/C/W/52.

² See document WIPO/GRTKF/IC/11/10 for a summary of these proposals.

³ See document PCT/R/WG/5/11, paragraphs 33-35.

⁴ See documents IP/C/W/284, paragraphs 16-19, and IP/C/W/400/Rev.1, paragraphs 30-32.

only one element that is to be integrated in a more global approach that would fully address the issues related to access and benefit-sharing. In the view of Switzerland, additional measures have to be taken outside of the patent system in other fields of law. Such measures need to be in harmony with and mutually supportive of the relevant international instruments and fora, including the decisions adopted by the CBD.

7. On a more general note, the Intergovernmental Committee has so far not been able to resolve several fundamental and basic issues, above all determining the policy objectives of its activities and clarifying terminology. In the view of Switzerland, these issues need to be clarified in due course in order for meaningful progress to be made in the Committee. In this regard, Committee participants, particularly the demandeurs, should become active.

II. THE PROVISIONS OF THE SWISS PATENT ACT

8. A number of countries have implemented disclosure requirements at the national level. This includes Switzerland, which revised its Federal Act on Patents for Inventions (Patent Act, PatA) in accordance with its proposals for the amendment of the PCT Regulations. The following describes the relevant provisions of this Act in more detail.

Overview

9. The revised Patent Act, including the new provisions on the disclosure of the source (Articles 49a, 81a and 138 subpara. b PatA), entered into force July 1, 2008. These provisions require patent applicants to disclose the source of genetic resources and traditional knowledge in patent applications, if the invention concerned is directly based on these resources or this knowledge.

The Concept of "Source"

10. According to the relevant international instruments on access and benefit-sharing, namely the Convention on Biological Diversity (CBD), the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization, and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, a multitude of entities may be involved in access and benefit-sharing.

11. Article 49a PatA thus requires patent applicants to declare the *source* of genetic resources and traditional knowledge. The generic term "source" should be understood in its broadest sense, covering any type of provenance or origin: It includes national governments and their authorities, including the "country of origin of genetic resources" and the "country providing genetic resources" according to Article 2 of the CBD; the "geographic origin" according to recital 27 of the EU Biotech Directive⁵; the Multilateral System of the FAO International Treaty⁶; natural and legal persons; indigenous and local communities⁷; *ex situ* collections such as gene banks and botanical gardens; scientific publications and books; and databases.

⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions.

⁶ See Articles 10-13 of the International Treaty.

⁷ See Article 8(j) of the CBD.

12. In the foreground to be declared as the source is the entity competent either to grant access to genetic resources and/or traditional knowledge, or to participate in the sharing of the benefits arising from their use. Depending on the genetic resource or traditional knowledge in question, one can distinguish:

(a) *primary* sources, in particular the country providing genetic resources, the Multilateral System of the FAO International Treaty, and indigenous and local communities; and

(b) *secondary* sources, in particular *ex situ* collections, databases and scientific publications.

13. Accordingly, there is a “cascade” of sources: Patent applicants must declare the primary source, if they have information at hand about this primary source, whereas a secondary source may only be declared if patent applicants have no information at hand about the primary source, or where this primary source can only be determined with unjustifiable efforts. For example, if the patent applicant knows the country providing a genetic resource, this primary source must be disclosed; in contrast, if the patent applicant received the genetic resource from a botanical garden and has no information at hand about a primary source because over time there has been a chain of different recipients, the secondary source “botanical garden” must be disclosed. Thus, Article 49a PatA requires only the declaration of information readily available to the applicant.

14. In case the source of the relevant genetic resource or traditional knowledge is unknown to the inventor or the patent applicant, this must be confirmed in writing by the patent applicant. This is to avoid that the patent cannot be granted in those exceptional cases where the source is unknown to the inventor and the patent applicant.

Terminology – Genetic Resources and Traditional Knowledge

15. With regard to the definition of the term “genetic resources,” the dispatch of the Patent Act refers to Article 2 of the CBD, which defines genetic resources as genetic material – that is, any material of plant, animal, microbial or other origin containing functional units of heredity – of actual or potential value.

16. In contrast, there exists at present no internationally agreed definition of the term “traditional knowledge.” The dispatch of the Patent Act understands this term as referring to the knowledge, innovations and practices of indigenous and local communities in developing and developed countries, which over years have been created, improved and adapted to changing needs and environmental influences, and which have been handed down, often in oral form, to the next generation.

Scope of the Obligation to Declare the Source – The Trigger Mechanism

17. Article 49a PatA requires the declaration of source in cases where:

(a) the inventor has had access to the genetic resource or the related traditional knowledge, that is, their possession or at least contact which is sufficient enough to identify their specific properties relevant for the invention, and

(b) the invention is directly based on the genetic resource or traditional knowledge, that is, the invention must make immediate use of and depend on the identified specific properties.

International Patent Applications

18. According to Article 138 subpara. b PatA, the patent applicant must submit to the Swiss Federal Institute of Intellectual Property (Institute) within 30 months from the filing date or the priority date a declaration of the source as referred to in Article 49a PatA. This provision thus also takes effect with regard to international patent applications which designate Switzerland.

Lack of Disclosure

19. If the patent application does not contain a declaration of the source, Article 59 para. 2 and Article 59a para. 3 subpara b PatA apply: The Institute shall allow the applicant a period of time for the correction of the defect. If this period of time expires without correction, the Institute shall reject the application. Thus, the absence of a declaration of the source can eventually prevent the patent from being granted.

Sanctions for Wrongful Declaration

20. According to Article 81a PatA, the intentional wrongful declaration of the source is liable to a fine of up to 100,000 Swiss Francs, and the judge may order the publication of the ruling.

21. Article 81a PatA applies if patent applicants intentionally declare (1) a source different to the one known to them, or (2) that the source is unknown to them, even though they have the necessary information at hand.

22. Wrongful declaration of the source is an offense to be prosecuted *ex officio*.

APPENDIX

**PROVISIONS OF THE SWISS PATENT ACT
ON THE DISCLOSURE OF THE SOURCE
(Unofficial translation)**

Art. 49a

II. Declaration of the source of genetic resources and traditional knowledge

1 The patent application shall contain information on the source of:

- a. a genetic resource, to which the inventor or the patent applicant has had access, insofar as the invention is directly based on this resource;
- b. traditional knowledge of indigenous or local communities related to genetic resources, to which the inventor or the applicant has had access, insofar as the invention is directly based on this knowledge.

2 In case the source is neither known to the inventor nor the patent applicant, the patent applicant shall confirm this in writing.

Art. 59

A. Subject of the examination

2 If the patent application does not meet the other requirements of this Act or the Ordinance, the Institute shall set a time limit for the patent applicant by which the defects must be corrected.

Art. 59a

B. Completion of the examination

3 The Institute shall reject the patent application if

[...]

- b. the defects mentioned in Article 59 paragraph 2 have not been corrected.

Art. 81a

II. Wrongful declaration of the source

1 Whoever intentionally makes a wrongful declaration according to Article 49a shall be liable to a fine of up to 100,000 Swiss Francs.

2 The judge may order the publication of the ruling.

Art. 138

C. Formal conditions

The applicant shall be required to carry out within a period of 30 months as from the filing date or the priority date, with respect to the Federal Institute of Intellectual Property, the following acts:

[...]

- b. provide information on the source (Art. 49a)[.]

[End of Annex and of document]