

**SWITZERLAND'S PROPOSALS REGARDING THE DECLARATION OF THE SOURCE
OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT
APPLICATIONS AND
SWITZERLAND'S VIEWS ON THE DECLARATION OF EVIDENCE OF PRIOR
INFORMED CONSENT AND BENEFIT SHARING IN PATENT APPLICATIONS**

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), in particular, to include a new Rule 51*bis*.1(g) in 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, 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 WIPO-Working Group on PCT Reform in May 2004 and October 2004, respectively, containing more detailed explanations on its proposals.² 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, and its optional vs. mandatory introduction at the national level.

Switzerland is not a demandeur with regard to the disclosure of the source in patent applications; Switzerland 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 the three submissions on its proposals to the WTO / TRIPS Council,³ and to the WIPO-Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).⁴ Furthermore, Switzerland presented a submission summarizing its proposals to the 3rd session of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing of the Convention on Biological Diversity (CBD) in February 2005.⁵

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 transparency, traceability, technical prior art and mutual trust (in short, “the four T’s”):

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>).

³ 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>>).

⁴ 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>).

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>>).

1. **Transparency:** With a requirement in national and international patent applications to disclose the source, 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, as was the case with regard to the so-called "neem tree oil" patent (European Patent 0 436 257). 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 research institutions. All of these stakeholders may 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 and the Patent Law Treaty

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, and to include the declaration of the source in the international publication of the patent application containing such a declaration. 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, 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.

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 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.
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 Switzerland⁹ and most European countries plan 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.
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

⁶ See Articles 15, 16 and 19 CBD.

⁷ See Articles 10-13 FAO International Treaty.

⁸ See Article 8(j) CBD.

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>>.

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

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. Evidence of Prior Informed Consent (PIC) and Benefit Sharing in Patent Applications

In the discussions on transparency measures for access and benefit sharing in the patent system, it has been proposed to require patent applicants to provide evidence of prior informed consent and of fair and equitable benefit sharing in patent applications. Under some of these proposals, providing this evidence would be a condition for acquiring patent rights¹⁰.

When assessing these proposals, it is as a first step important to take into consideration the relevant international law: According to Article 15 of the CBD, access to genetic resources and the sharing of the benefits arising out of their utilization shall be on mutually agreed terms. Article 15 furthermore requires that “[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.” The International Treaty of FAO establishes a Multilateral System of Access and Benefit Sharing. Under this system, prior informed consent is not required for access to genetic resources. Furthermore, Article 13 of the FAO-Treaty contains a closed list of the possible forms of benefit sharing. Moreover, both The CBD and the FAO-Treaty foresee a multitude of entities to be involved in access and benefit sharing.

¹⁰ See explicitly document IP/C/W//438 para. 8 re. prior informed consent (PIC). Unclear remains document IP/C/W/442 regarding fair and equitable benefit sharing.

In the view of Switzerland, a number of legal and technical problems arise. This applies in particular if the patent granting authorities would have to determine the veracity of the provided evidence. These problems include the following:

1. According to a recent survey,¹¹ only a small number of CBD-Contracting Parties have implemented a national system of access and benefit sharing and have designated the relevant national authorities. Furthermore, the few existing national systems on PIC differ considerably. Some national laws provide that PIC is not necessary at all or only in certain cases, whereas other national laws may spell out in detail the elements and modalities of PIC. Such differences can also be expected from future national systems of PIC.
2. Patent granting authorities would need to have access to the various national legislations on PIC in a language familiar to them and would have to familiarize themselves with each of the national systems of PIC each time a patent application is submitted containing such evidence. Patent granting authorities, however, are neither designed to carry out nor do they have the necessary legal and technical competence to determine the veracity of the provided evidence.
3. The International Treaty of FAO does not foresee that PIC must be obtained when accessing genetic resources. Thus, since any requirement to provide evidence of PIC would not apply to the genetic resources access under FAO's International Treaty, burdensome distinctions would have to be made.
4. How would the patent granting authorities determine whether the sharing of the benefits in each individual case at hand is "fair and equitable"? Moreover, at the time of submitting a patent application, the commercial success of the invention is generally unknown and no monetary benefits will have arisen yet. Not all patents that are applied for will be granted, and a large part of the granted patents will never be commercialized. In most instances, the patent applicant will thus not be able to provide evidence that benefits have actually been shared in a fair and equitable way at the point in time when submitting a patent application.

Based on these considerations, the task of verifying whether the national systems of PIC have been adhered to on one hand, and whether fair and equitable benefit sharing has been mutually agreed to or has taken place on the other hand, can best be done by the providers of the genetic resources or the traditional knowledge in accordance with the relevant provisions of the CBD and FAO's International Treaty.

In the view of Switzerland, its proposals on the declaration of the source and the establishment of a list of government agencies competent to receive information about this declaration would allow the providers of genetic resources and traditional knowledge to verify whether the obligations regarding access and benefit sharing have been complied with. Should patent applicants additionally be required to provide evidence of fair and equitable benefit sharing in patent applications, they would be required to submit information they do not have at hand, or, if they do, they would have to submit double and triple information that would be of little advantage to the providers of genetic resources and traditional knowledge.

IV. The Role of the TRIPS Agreement

In the discussions on the disclosure requirement, reference is made to Articles 27.1, 29.1 and 62.1 of the TRIPS Agreement. In the view of Switzerland, these provisions can be interpreted as follows: Article 27.1 does not preclude Members from introducing additional formal requirements in their national patent laws. Such requirements, however, must be in line with Article 62.1; this provision allows Members to require, as a condition of the acquisition or maintenance of patents, compliance with procedures and formalities, as long as these procedures and formalities are "reasonable." Article 29.1 states that inventions must be disclosed in the patent application "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." The disclosure of the invention as required by Article 29.1 is thus of a different nature than the disclosure of the source of genetic resources and traditional knowledge as proposed by Switzerland. Consequently, it can be said that Article 29.1 does not affect the introduction of the requirement to disclose the source. In the view of Switzerland, the provisions of the TRIPS Agreement provide for adequate flexibility with regard to a formal requirement to disclose the source. Accordingly, Switzerland does not consider it to be necessary to amend the TRIPS Agreement.

¹¹ See VALERIE NORMAND, "National Implementation," paper presented to the International Expert Workshop on Access to Genetic Resources and Benefit Sharing (Mexico, Oct. 04), available at: <<http://www.canmexworkshop.com/documents/papers/I.1.pdf>>.

These legal considerations notwithstanding, the approach proposed by Switzerland to amend the PCT and the PLT has two considerable advantages over any TRIPS-based approach: One, the simple amendment of the Regulations under the PCT could be carried out in a very short period of time. In contrast, any amendment of the TRIPS Agreement would probably require considerable time in order to achieve consensus on a respective negotiation. And two, an amendment of the PCT can be decided by a three-quarters majority of the PCT's Contracting Parties, whereas an amendment of the TRIPS Agreement requires consensus among the WTO's Members.

V. Conclusions

The proposals submitted by Switzerland to WIPO aim 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, that is, the PCT and the PLT. As the proposed transparency measures do not require modifications of the TRIPS Agreement, they are further evidence of the flexibility that this agreement provides for. The proposals are also intended to enhance the cooperation between the competent international fora and the mutual supportiveness of the relevant international agreements.

Disclosing the source can be seen as the "entering point" of the access and benefit sharing in the patent system. In this way, disclosing the source would help to 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.

The proposed declaration of the source of genetic resources and traditional knowledge in patent applications would allow States that are party 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 not only assist in and simplify the enforcement of these obligations, but would also allow to verify whether prior informed consent (PIC) of the country providing the genetic resources has been obtained and whether provisions have been made for fair and equitable benefit sharing.

The proposals made by Switzerland would thus enable the Contracting Parties of relevant international agreements, including the TRIPS Agreement, the PCT, the PLT, the CBD and the FAO-IT, to fulfill their respective obligations. This applies in particular to the Articles 27.1 and 62.1 of the TRIPS Agreement as well as Articles 8(j), 15.4, 15.5, 15.7 and 16.5 of the CBD. 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 several of the 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 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: Switzerland's Proposals for Amendments to PCT-Regulations¹²

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 51bis.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 26ter.1, which was received by the International Bureau before the expiration of the time limit under Rule 26ter.1.

Rule 51bis: Certain National Requirements Allowed Under Article 27

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

(g) Subject to Rule 51bis.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 51bis.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 51bis.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 51bis.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;

(ii) relating to the source of traditional knowledge related to genetic resources, (Rule 51bis.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 51bis.3: *Opportunity to Comply with National Requirements*

(a) Where any of the requirements referred to in Rule 51bis.1(a)(i) to (iv), and (c) to (e), and (g), [...] is not already fulfilled during the same period within which the requirements under Article 22 must be complied with, the designated Office, in the 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. [...].

¹² Wording of the proposed amendments is underlined.