E

WIPO

WIPO/GRTKF/IC/11/10
ORIGINAL: English
DATE: June 6, 2007

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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

Eleventh Session
Geneva, July 3 to 12, 2007

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

Document submitted by Switzerland

1. Regarding the agenda item on genetic resources, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') requested the Secretariat at its tenth session (November 30 to December 8, 2006), "to prepare for its consideration at its eleventh session: (i) a document listing options for continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts; and (ii) a factual update of international developments relevant to the genetic resources agenda item."

2. Switzerland submits the present document to contribute to the discussions of the Committee on genetic resources at its eleventh session. This document outlines the proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. These proposals were submitted to the WIPO Working Group on Reform of the Patent Cooperation Treaty (PCT) in May 2003.

3. In a letter dated June 5, 2007, the Swiss Federal Institute of Intellectual Property (IPI) requested that the annexed submission be circulated to the Committee.

4. The text of the document as received is published in the Annex to this document.

5. The Intergovernmental Committee is invited to take note of the contents of the Annex.

[Annex follows]

ANNEX

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

I. OVERVIEW

1. 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].

2. 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)). Under present Rule 48.2(a)(x), such declaration of the source would be included in the international publication of the international application concerned.

3. In order to advance the discussions on its proposals, Switzerland presented two further submissions to the WIPO Working Group on PCT Reform in April 2004 and April 2005, 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 for wrongful declaration of the source, and its optional *vs.* mandatory introduction at the national level.

4. For information purposes, Switzerland presented its proposals to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)[3], to the WIPO Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements held June 3, 2005[4], to the WTO TRIPS Council[5], and

---

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/edocs/mdocs/pct/en/pct_r_wg_5/pct_r_wg_5_11_rev.doc>)

2 See WIPO documents PCT/R/WG/6/11 (available at <http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_6/pct_r_wg_6_11.doc>) and PCT/R/WG/7/9 (available at <http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_7/pct_r_wg_7_9.doc>).

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

4 See WIPO document WIPO/IP/GR/05/INF/4 (available at <www.wipo.int/edocs/mdocs/tk/en/wipo_ip_gr_05/wipo_ip_gr_05_inf_4.doc>).

5 See WTO documents IP/C/W/400/Rev.1 (available at <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 <www.ige.ch/E/jurinfo/documents/j110114e.pdf>).

to the 3rd and 4th sessions of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing of the Convention on Biological Diversity (CBD)[6].

5. The present document summarizes the proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. The document contains in Appendix 1 the proposed amendments of the PCT Regulations, and in Appendix 2 the documents submitted by Switzerland on its proposals. The contents of the present document are identical to the contents of document PCT/R/WG/9/5 and PCT/R/WG/8/7.

II. BACKGROUND

5. In the context of access to genetic resources and the related traditional knowledge and the sharing of the commercial and other benefits arising from their use, numerous issues arise. Several international instruments have been concluded to date addressing these issues, including, in particular, the Convention on Biological Diversity (CBD), the Bonn Guidelines, and the International Treaty of the Food and Agriculture Organization (FAO). Moreover, in the context of the CBD, it was decided to elaborate and negotiate an International Regime on Access and Benefit Sharing.

6. In the context of access and benefit sharing, measures under patent law are also being discussed at the international and national level, including in particular requirements for patent applicants to disclose certain information in patent applications. These measures are, among others, seen as increasing transparency in access and benefit sharing, intended to prevent “bad” patents, ensuring the sharing of the benefits arising from the use of genetic resources and the related traditional knowledge, and as allowing the providers of genetic resources and traditional knowledge, in particular developing countries and indigenous and local communities, to more fully benefit from the patent system.

7. Switzerland, not a demandeur with regard to such measures, submitted its proposals on the disclosure of the source to be supportive of the process and because it is interested in a balanced patent protection for biotechnological inventions. The proposed disclosure requirement is intended as a measure under patent law which will increase transparency in access and benefit sharing.

8. In the view of Switzerland, it is crucial to keep in mind that patent-related measures by themselves will not be sufficient to resolve all issues arising in the context of access and benefit sharing. They are only one element, among others, that are to be integrated in a more global approach that would fully address the issues related to access and benefit sharing. Additional measures are to be introduced outside of the patent system in other fields of law. Moreover, it is important to implement the CBD, the Bonn Guidelines and the International Treaty at the national level, and to introduce the necessary administrative procedures relative to access and benefit sharing, and to designate the competent national authorities.

---

[6] See CBD documents UNEP/CBD/WG-ABS/3/INF/7 (available at <www.biodiv.org/doc/meetings/abs/abswg-03/information/abswg-03-inf-07-en.pdf>), and UNEP/CBD/WG-ABS/4/INF/12 (available at <www.biodiv.org/doc/meetings/abs/abswg-04/information/abswg-04-inf-12-en.doc>).

9. In the view of Switzerland, retaining the high quality of patents requires, among others, the observance of the applicable patentability criteria and the proper examination of patent applications. In the past, several cases became public where patents were granted for inventions that were based on or used traditional knowledge and that did not meet the criteria of novelty and/or inventive step. Generally, the granting of such "bad" patents can be explained by the lack of the accessibility of prior art regarding this knowledge by patent authorities. Often, traditional knowledge is only transmitted orally and is therefore not documented in a written form; oral information, however, may not be accessible at all by these authorities. Or, if it is documented in writing, it may be so in languages that these authorities are not familiar with. Therefore, even if these authorities try their best, they may not be able to access prior art regarding traditional knowledge for reasons beyond their control.

10. One way to substantially improve this situation is the collection of traditional knowledge in databases. Patent authorities could search these databases when dealing with patent applications raising questions regarding traditional knowledge as an element of prior art. Various governments, indigenous and local communities and non-governmental organizations (NGOs) have become active in the establishment of such databases at the local, regional and national levels. The number of such databases can be expected to further increase in the future. These databases are likely to have differing structures and to store traditional knowledge in different forms and formats. Great variability of the structure and contents of these databases, however, will seriously hinder the efficient access of patent authorities to these databases and the effective search for prior art. To avoid these problems, at least a minimum harmonization of the structure and contents of these databases should be achieved. This would also allow to make the local, regional or national databases available through an international gateway for traditional knowledge to be administered by WIPO, as was proposed by Switzerland in the TRIPS Council[7].

11. 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.

III. SUMMARY OF THE PROPOSALS

Policy Objectives

12. 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"):

---

[7] See documents IP/C/W/284 (available at <www.ige.ch/E/jurinfo/documents/IP_C-W-284.pdf>), paragraphs 16-19, and IP/C/W/400/Rev.1 (available at <www.ige.ch/E/jurinfo/documents/IP-C-W-400.pdf>), paragraphs 30-32.

(a) *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.

(b) *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.

(c) *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. 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.

(d) *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.

Amendment of the Patent Cooperation Treaty and the Patent Law Treaty

13. 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. Under present Rule 48.2(a)(x), such declaration of the source would be included in the international publication of the international application concerned. 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.

14. 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 also explicitly be enabled 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

15. 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.

Concept of the "Source" of Genetic Resources and Traditional Knowledge

16. 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.

17. 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.

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

(a) *Primary* sources, including in particular Contracting Parties providing genetic resources[8], the Multilateral System of FAO's International Treaty[9], indigenous and local communities[10]; and

(b) *secondary* sources, including in particular *ex situ* collections and scientific literature.

19. Accordingly, there is a "cascade" of possible primary and secondary sources: Patent applicants must declare the primary source to fulfill 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.

Scope of the Obligation to Declare the Source

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

(a) the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource; and

(b) 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.

---

8 See Articles 15, 16 and 19 CBD.

9 See Articles 10-13 FAO International Treaty.

10 See Article 8(j) CBD.

21. 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

22. 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.

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

(a) 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.

(b) 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.

(c) The proposed establishment of the list of competent government agencies described below, 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[11] 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.

(d) The approach proposed by Switzerland would not oblige developing countries, especially the least developed countries, to introduce the disclosure requirement in their national laws. Indeed, these countries might face difficulties with such a requirement, since their authorities are likely to lack the necessary legal and technical capacities to apply such an obligation. Moreover, most biotechnology patents are applied for in developed countries. Introducing such a requirement would thus generally bring little advantages to these countries, but would burden them with an additional international obligation. In contrast, a mandatory approach would oblige all countries to introduce such a requirement in their national patent laws.

24. 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

---

[11] 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 generally <www.ige.ch/E/jurinfo/j100.shtm> and <www.ige.ch/E/jurinfo/documents/j10017e.pdf> in particular.

carry the severe sanctions outlined below. In this regard, the Swiss proposals are of a mandatory and not of a voluntary nature.

Sanctions

25. 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.

26. 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.

27. 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.

Establishment of a List of Government Agencies Competent to Receive Information on Declaration of Source

28. 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 therefore invited WIPO, in close collaboration with the CBD, to further consider the possible establishment of such a list of competent government agencies.

IV. CONCLUSIONS

29. In the view of Switzerland, the proposed amendments to the PCT 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.

30. 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.

31. 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.

32. The proposals made by Switzerland would thus enable the Contracting Parties of relevant international agreements, including the CBD, the International Treaty of FAO, the PCT, the PLT and the TRIPS Agreement, to fulfill their respective obligations. This applies in particular to Articles 8(j), 15.4, 15.5, 15.7 and 16.5 of the CBD. 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 Conference of the Parties of the CBD. 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 follow]

APPENDIX I

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:[1]

DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

TABLE OF CONTENTS

Rule 4 The Request (Contents) 2
4.1 to 4.16 [No change] 2
4.17 *Declarations Relating to National Requirements Referred to in Rule 51bis.1(a)(i) to (v) and Rule 51bis.1(g)* 2
4.18 and 4.19 [No change] 2
Rule 26*ter* Correction or Addition of Declarations under Rule 4.17 3
26*ter*.1 *Correction or Addition of Declarations* 3
26*ter*.2 *Processing of Declarations* 3
Rule 48 International Publication 4
48.1 [No change] 4
48.2 [No change] *Contents* 4
48.3 to 48.6 [No change] 4
Rule 51*bis* Certain National Requirements Allowed Under Article 27 5
51*bis*.1 *Certain National Requirements Allowed* 5
51*bis*.2 *Circumstances in Which Documents or Evidence May Not Be Required* 6
51*bis*.3 *Opportunity to Comply with National Requirements* 7

[1] Proposed additions and deletions are indicated, respectively, by underlining and striking through the text concerned. Certain provisions that are not proposed to be amended may be included for ease of reference.

Rule 4

The Request (Contents)

4.1 to 4.16 [No change]

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:

(i) to (iv) [No change]

(v) a declaration as to non-prejudicial disclosures or exceptions to lack of novelty, as referred to in Rule 51*bis*.1(a)(v);

(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).

4.18 and 4.19 [No change]

Rule 26*ter*

Correction or Addition of Declarations under Rule 4.17

26*ter*.1 *Correction or Addition of Declarations*

[No change] The applicant may correct or add to the request any declaration referred to in Rule 4.17 by a notice submitted to the International Bureau within a time limit of 16 months from the priority date, provided that any notice which is received by the International Bureau after the expiration of that time limit shall be considered to have been received on the last day of that time limit if it reaches it before the technical preparations for international publication have been completed.

26*ter*.2 *Processing of Declarations*

(a) Where the receiving Office or the International Bureau finds that any declaration referred to in Rule 4.17(i) to (v) ~~Rule 4.17~~ is not worded as required or, in the case of the declaration of inventorship referred to in Rule 4.17(iv), is not signed as required, the receiving Office or the International Bureau, as the case may be, may invite the applicant to correct the declaration within a time limit of 16 months from the priority date.

(b) [No change] Where the International Bureau receives any declaration or correction under Rule 26*ter*.1 after the expiration of the time limit under Rule 26*ter*.1, the International Bureau shall notify the applicant accordingly and shall proceed as provided for in the Administrative Instructions.

Rule 48

International Publication

48.1 [No change]

48.2 [No change] *Contents*

(a) [No change] The publication of the international application shall contain:

(i) to (ix) [No change]

(x) [No change] any declaration referred to in Rule 4.17, and any correction thereof under Rule 26*ter*.1, which was received by the International Bureau before the expiration of the time limit under Rule 26*ter*.1;

(xi) [No change]

(b) to (k) [No change]

48.3 to 48.6 [No change]

Rule 51*bis*

Certain National Requirements Allowed Under Article 27

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

(a) to (f) [No change]

(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.

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

(a) to (c) [No change]

(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;

(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.

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), or any other requirement of the national law applicable by the designated Office which that Office may apply in accordance with Article 27(1) or (2), is not already fulfilled during the same period within which the requirements under if Article 22 must be complied with, the designated Office 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. Each designated Office may require that the applicant pay a fee for complying with national requirements in response to the invitation.

(b) and (c) [No change]

[Appendix II follows]

APPENDIX II

DOCUMENTS BY SWITZERLAND ON ITS PROPOSALS

With regard to its proposals, Switzerland submitted the following documents to WIPO:[1]

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/edocs/mdocs/pct/en/pct_r_wg_5/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/edocs/mdocs/pct/fr/pct_r_wg_5/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>

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/edocs/mdocs/pct/en/pct_r_wg_6/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/edocs/mdocs/pct/fr/pct_r_wg_6/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>

[1] Switzerland presented the three submissions on its proposals to the Working Group on PCT Reform. For information purposes, it 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.

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/7/9 <http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_7/pct_r_wg_7_9.doc>

   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/7/9 <http://www.wipo.int/edocs/mdocs/pct/fr/pct_r_wg_7/pct_r_wg_7_9.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>

[End of Appendix II and of document]