

WIPO



PCT/R/WG/7/9
ORIGINAL:English
DATE:April5,2005

E

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)

WORKING GROUP ON REF ORM OF THE PATENT
COOPERATION TREATY (PCT)

Seventh Session
Geneva, Ma y 25 to 31, 2005

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

Document prepared by the International Bureau

BACKGROUND

1. The further observations by Switzerland on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications appearing on the following pages were made by Switzerland in a submission to the International Bureau received on October 26, 2004.

2. *The Working Group is invited to consider the further observations contained in the Annex to this document.*

[Annex follows]

ANNEX

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

TABLE OF CONTENTS

I.	OVERVIEW	1
II.	FORMAL VS. SUBSTANTIVE DISCLOSURE REQUIREMENT	2
III.	OPTIONAL VS. MANDATORY INTRODUCTION OF DISCLOSURE REQUIREMENT	3
IV.	THE CONCEPT OF THE SOURCE	4
V.	CONCLUSIONS	5

APPENDIX: PROPOSED AMENDMENTS OF THE PCT REGULATIONS

I. OVERVIEW

3. At the fourth session of the Working Group on Reform of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO) held in May 2003, Switzerland submitted proposals regarding transparency measures under patent law in the area of genetic resources and traditional knowledge.¹ More specifically, Switzerland proposed to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if an invention is directly based on such resources or knowledge.

4. In order to further advance the discussions of the Working Group on PCT -Reform, Switzerland submitted additional comments on its proposal to the sixth session of this Working Group held in May 2004.² These comments concern 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, and the possible legal sanctions for failure to disclose or the wrongful disclosure of the source.

5. In the discussions on the Swiss proposal held at the sixth session of the Working Group on PCT -Reform³, a number of issues were raised requiring further clarification. The present submission, which complements the two previous submissions by Switzerland to this Working Group, addresses (1) the formal vs. substantive nature of the disclosure requirement, (2) the optional vs. the mandatory introduction of the disclosure requirement, and (3) the concept of the source.

¹ These proposals are contained in PCT/R/WG/5/11 Rev.

² These additional comments are contained in PCT/R/WG/6/11.

³ See PCT/R/WG/6/12, paras. 82 -107, in particular paras. 105 -107.

II. FORMAL VS. SUBSTANTIVE DISCLOSURE REQUIREMENT

6. When considering the introduction of the disclosure requirement in patent law, its legal nature (formal vs. substantive) needs to be determined. This is decisive not only for the identification of the competent international forum to address and implement the requirement, but also with regard to the sanctions imposed for failure to disclose or wrongful disclosure of the source.

7. Generally, the requirements with regard to patent applications can be categorized as follows:⁴

- *formal requirements* which are examined for the purposes of determining if a complete application has been filed;
- *formal requirements strongly linked to substance* concerning the various parts of the patent application for the purposes of search, examination and grant, that is, requirements which could affect the scope of a search or result in the rejection of the claims during the substantive examination of the patent application; and
- *substantive requirements*, under which the claims are evaluated for patentability, namely, definition of prior art, disclosure of the claimed invention, patentable subject matter, novelty, inventive step and industrial utility.

8. The policy objective of the disclosure requirement proposed by Switzerland 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, in particular with regard to the obligations of the users of genetic resources and traditional knowledge.⁵ Increased transparency will allow the providers of genetic resources and traditional knowledge to verify whether the inventor and/or patent applicant complied with the applicable rules and procedures on access to these resources or this knowledge, and whether provision for benefit sharing has been made. This transparency measure will enhance the mutual supportiveness of the relevant international agreements, namely the treaties administered by WIPO, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Convention on Biological Diversity (CBD) and 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).

9. Due to its policy objective outlined above, the disclosure requirement is examined for the purposes of determining if a complete patent application has been filed. The disclosure requirement is in the view of Switzerland linked neither to the search, examination or grant of patents, nor to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement, not a formal requirement strongly linked to substance or even as a substantive requirement.

⁴ See generally SCP/5/6, para. 51.

⁵ See PCT/R/WG/5/11 Rev., para. 7.

10. To clarify the legal situation and to provide for legal certainty, Switzerland proposes to amend the Regulations under the PCT to explicitly enable the national legislator to require patent applicants to disclose the source of genetic resources and traditional knowledge in patent applications. At the sixth session of the Working Group on the Reform of the PCT, the question was raised whether this Working Group is the competent forum to discuss these proposals. The Working Group can discuss only matters related to the PCT, that is, matters related to former contents of patent applications. Accordingly, since the disclosure requirement is in the nature of a formal requirement, the Working Group on the Reform of the PCT is the competent forum to address the proposals by Switzerland.

III. OPTIONAL VS. MANDATORY INTRODUCTION OF DISCLOSURE REQUIREMENT

11. 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 proposal thus leaves it up to the national legislator to decide whether such a requirement is to be introduced in the national patent legislation. This optional nature of the disclosure requirement was chosen because of the great divergence in the views on transparency measures, and because at the international level the discussion on disclosure requirements has not brought any final results. An optional introduction of the disclosure requirement would enable those States interested in introducing such a requirement to do so, but would not oblige States to take action. Additionally, it would allow the national governments and the international community to gain experience with the disclosure requirement, without prejudice to further international efforts.

12. In this context, the amendment proposed by Switzerland with regard to the international publication is of relevance: The proposed Rule 48.2(a)(xi) provides that the pamphlet of the international publications shall contain any declaration as referred to in the proposed Rule 4.17(vi). Accordingly, if one or several Contracting Parties of the PCT require in their national legislation patent applicants to declare the source of genetic resources and traditional knowledge as provided for in the proposed Rule 51 *bis*.1(g), this declaration, if already included in the international patent application, would form part of the international publication of this application. As a result, any declaration of the source of genetic resources or traditional knowledge contained in an international patent application would generally become accessible to the public after the expiration of 18 months from the priority date of these applications by being included in the international publication. Thus, even though it is optional for the Contracting Parties of the PCT to implement the proposals by Switzerland at the national level, the proposed Rule 48.2(a)(xi) would in practice bring effects which are very similar to those of a mandatory approach: By being included in the international publication, the declaration of the source would be publicly accessible, and would thus increase transparency in the context of access and benefit sharing at the global level, without it being necessary that it is mandatory for the Contracting Parties of the PCT to require patent applicants to declare the source. At the same time, the proposed Rule 48.2(a)(xi) combined with the optional approach as proposed by Switzerland would have the advantages described in the preceding paragraph.

IV. THE CONCEPT OF THE SOURCE

13. According to the CBD, the Bonn Guidelines and the International Treaty of FAO, a multitude of entities may be involved in access and benefit sharing. To take into account this multitude of entities, Switzerland proposes to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications, the term “source” being understood in its broadest sense possible.

14. Based on the mentioned international instruments, the entity competent (1) to grant access to genetic resources and traditional knowledge, and/or (2) to participate in the sharing of the benefits arising out of their utilization, is in the foreground to be declared as the source. Depending on the genetic resource or traditional knowledge in question, one can distinguish “primary” and “secondary” such sources: Primary sources are the Contracting Party providing genetic resources (see Arts. 15, 16 and 19 of the CBD), indigenous and local communities (see Art. 8(j) of the CBD), and the Multilateral System established by the International Treaty (see Arts. 10 -13), and secondary sources are *ex situ* collections such as gene banks and botanical gardens as well as databases on genetic resources and traditional knowledge, and scientific literature.

15. As a result, according to the proposals by Switzerland, there is a “cascade” of primary and secondary sources the patent applicant may be required to disclose in order to fulfill the disclosure requirement. If the patent applicant (or the inventor) has information at hand about:

- the primary source, this primary source must be disclosed; thus, for example, if 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;
- the primary and one or several secondary sources, the primary source must be disclosed, whereas the disclosure of these secondary sources is optional; thus, for example, if the patent applicant received the genetic resource from a botanical garden, but also knows the Contracting Party providing the genetic resource, this Contracting Party must be disclosed, whereas the disclosure of the botanical garden is optional.
- a secondary source, but not about a primary source, this secondary source must be disclosed; thus, for example, 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.
- several secondary sources, but not about the primary source, these secondary sources with the closest relationship to the primary source must be disclosed; the disclosure of the other secondary sources is optional; thus, for example, if the genetic resource was provided from one botanical garden to several others, the first botanical garden in this chain must be disclosed, whereas the disclosure of the other botanical gardens is optional.

16. Only if the patent applicant (or the inventor) has no information at hand about the primary or the secondary source, may he disclose that such source is unknown. Considering the broad understanding of the term “source,” cases where neither a primary nor a secondary source is known are likely to be rare.

V. CONCLUSIONS

17. *Formal vs. substantive disclosure requirement*: The policy objective of the disclosure requirement 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 disclosure 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 disclosure requirement is linked to the research, examination or grant of patents, or to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement. In the context of amendments to the Regulations under the PCT only formal requirements can be taken into consideration.

18. *Optional vs. mandatory introduction of disclosure requirement in the PCT*: In view of the clear divergence of opinions among the Contracting Parties of the PCT with regard to the introduction of a formal disclosure requirement, Switzerland has proposed to make it optional for the national legislator to introduce such a requirement.

The concept of “source”: The relevant international instruments foresee a multitude of entities to 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 traditional knowledge, and/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 disclose the primary source to fulfill the disclosure requirement, if they have information about this primary source at hand. A secondary source may only be disclosed if patent applicants have no information at hand about the primary source.

[Appendix follows]

APPENDIX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:

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

TABLE OF CONTENTS

INTRODUCTION	2
Rule 4 The Request (Contents)	3
4.1 to 4.16 [No change]	3
4.17 <i>Declarations Relating to National Requirements Referred to in Rule</i> <i>51bis.1(a)(i) to (v) <u>and Rule 51bis.1(g)</u></i>	3
4.11 to 4.18 [No change]	4
Rule 26 <i>ter</i> Correction or Addition of Declarations Under Rule 4.17	5
26 <i>ter</i> .1 <i>Correction or Addition of Declarations</i>	5
26 <i>ter</i> .2 <i>Processing of Declarations</i>	5
Rule 48 International Publication	7
48.1 [No change]	7
48.2 <i>Contents</i>	7
48.3 to 48.6 [No change]	8
Rule 51 <i>bis</i> Certain National Requirements Allowed Under Article 27	9
51 <i>bis</i> .1 <i>Certain National Requirements Allowed</i>	9
51 <i>bis</i> .2 <i>Circumstances in Which Documents or Evidence May Not Be Required</i>	10
51 <i>bis</i> .3 <i>Opportunity to Comply with National Requirements</i>	11

INTRODUCTION

This Annex contains the wording of the amendments of the PCT Regulations proposed by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. Proposed additions and deletions are indicated, respectively, by underlining and striking through of the text concerned. Amendments are proposed to Rule 4.17 (addition to chapeau and new subpara. vi), Rule 48.2(a) (new subpara. xi), Rule 51 *bis*.1 (new subpara. g), Rule 51 *bis*.2 (new subpara. d), and Rule 51 *bis*.3 (amendment of subpara. a). Rule 26 *ter* is not proposed to be amended, but is included in this Annex for ease of reference.

To take into account the discussions of the Working Group on the Reform of the PCT on the proposals by Switzerland, the wording of the amendments of the PCT Regulations originally proposed by Switzerland⁶ has been slightly adapted, without, however, modifying the substance of the proposals. This concerns, in particular, the use of the term “traditional knowledge related to genetic resources” instead of the term “knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.”

⁶ See PCT/R/WG/5/11 Rev., paras. 24 and 29.

Rule 4

The Request (Contents)

4.1 to 4.16 [No change]

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

[COMMENT: Rule 4.17 sets forth those matters relating to which applicants may include a declaration in the request pursuant to Rule 4.1(c)(iii). Such matters include those as to which designated Offices are entitled to require documents or evidence during the national phase of processing and which are expressly listed in Rule 51 bis. 1(a). The proposed new subparagraph (vi) would give patent applicants the possibility of satisfying the declaration requirement under national patent law in accordance with the proposed new Rule 51 bis. 1(g) at the time of filing an international patent application or later during the international phase.

[Rule 4.17, continued]

This would further simplify procedures related to the declaration of the source of genetic resources and/or traditional knowledge related to genetic resources, with regard to international patent applications. The Administrative Instructions will have to prescribe the standardized wording of such declarations which may be included in the request pursuant to the proposed Rule 4.17(vi).]

4.11 to 4.18 [No change]

Rule 26 *ter*

Correction or Addition of Declarations Under Rule 4.17

26ter.1 Correction or Addition of Declarations

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.

26ter.2 Processing of Declarations

(a) Where the receiving Office or the International Bureau finds that any declaration referred to in 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) Where the International Bureau receives any correction or addition of a declaration 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 26ter, continued]

[COMMENT: Rule 26 *ter* is unchanged. It is included in this Annex for ease of reference only. Rule 26 *ter* provides procedures for the addition or correction of declarations in the request which are referred to in Rule 4.17. It also applies in the context of the proposed new Rules 4.17(vi) and 51 *bis*.1(g). Rule 26 *ter* provides the applicant with a mechanism for providing or correcting a declaration of the source of genetic resources and/or traditional knowledge related to genetic resources pursuant to the proposed Rule 4.17(vi) during the international phase.]

Rule 48

International Publication

48.1 [No change]

48.2 *Contents*

(a) The pamphlet shall contain:

(i) to (ix) [No change]

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

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

[COMMENT: The proposed Rule 48.2(a)(xi) provides that the pamphlet shall contain any declaration contained in the request that is referred to in the proposed Rule 4.17(vi), that is, a declaration regarding the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in the proposed Rule 51 *bis.1*(g). With the proposed subpara. (xi), the declaration of the source of such a resource or such knowledge in a patent application would generally become accessible to the public after the expiration of 18 months from the priority date of that application. Accordingly, the proposed Rule 48.2(a)(xi) would further support the policy objective of the declaration of the source, that is, increasing transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization.]

[Rule 48.2, continued]

(b)to(i) [Nochange]

48.3to48.6 [Nochange]

Rule 51 bis

Certain National Requirements Allowed Under Article 27

51bis.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.

[COMMENT: The proposed Rule 51 bis.1(g) provides that the national law applicable by the designated Office may require patent applicants to furnish either a declaration as to the source of a specific genetic resource and/or traditional knowledge related to genetic resources, or a declaration that this source is unknown to the inventor or applicant. The proposed Rule 51bis.1(g) takes into account the discussions held in the Working Group on PCT on the proposals by Switzerland. Accordingly, the wording of the proposed Rule 51 contains minor adaptations compared with the wording of the proposals originally submitted -Reform bis.1(g) submitted

[Rule 51 bis.1(g), continued]

by Switzerland to the Working Group on Reform of the PCT in May 2003.⁷ These adaptations concern the structure and the use of terms, but do not alter the substance of the proposed Rule 51 bis.1(g). These adaptations are: First, the proposed Rule 51 bis.1(g) uses the term “traditional knowledge related to genetic resources” instead of the term “knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.” In the view of Switzerland, both terms are fully synonymous,⁸ the term “traditional knowledge related to genetic resources” being used for reasons of simplicity and brevity. Second, a subpara. (iii) is added to the proposed Rule 51 bis.1(g), containing the provision of the last part of the originally proposed subparas. (i) and (ii), respectively, with regard to the case where the source is unknown to the inventor or applicant. And third, the proposed subpara. (iii) clarifies that the source must be unknown to the inventor or patent applicant.]

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;

⁷ See PCT/R/WG/5/11 Rev., paras. 24 and 29.

⁸ See PCT/R/WG/6/11, para. 11.

[Rule 51 bis.2(d), continued]

(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.

[COMMENT: The proposed Rule 51 bis.2(d) is intended to limit the circumstances in which designated Offices are entitled to require documents or evidence from applicants in the national phase in relation to certain matters referred to in the proposed Rule 51 bis.1(g). The limitation is consistent with draft PLT Article 6(6). Accordingly, if the request, in accordance with Rule 4.17(vi), contains a declaration as to the source of a genetic resource or traditional knowledge, or a declaration that this source is unknown to the inventor or applicant (Rule 51 bis.1(g)), or if such a declaration is submitted directly to the designated Office, the Office would not be entitled to require documents or evidence relating to this declaration, unless the Office has reasonable doubts as to the veracity of the declaration.]

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 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. Each designated Office may require that the applicant pay a fee for complying with national requirements in response to the invitation.

[Rule 51 bis.3(a), continued]

[COMMENT: Rule 51 *bis*.3(a) provides that designated Offices shall invite the applicant to comply with those requirements of national law which designated Offices may apply under Rule 51 *bis*.1(a) and (c) to (e) and Article 27(1) and (2), respectively, which have not already been fulfilled by the time of entry of the application into the national phase. It is proposed to apply this Rule also with regard to requirements of national law which designated Offices may apply under Rule 51 *bis* .1(g).]

(b) and (c) [No change]

[End of Appendix, Annex and document]