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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

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The International Bureau of the World Intellectual Property Organization (WIPO) presents its compliments and has the honor to transmit herewith
./. documents PCT/R/WG/8/6 and 7, prepared for the eighth session of the *Working Group on Reform of the Patent Cooperation Treaty (PCT)*, which will be held in Geneva from May 8 to 12, 2006.

The working documents are also available on WIPO's Web site (*see http://www.wipo.int/pct/en/meetings*).

April 27, 2006

Enclosures: documents PCT/R/WG/8/6 and 7

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERNATIONAL PATENT COOPERATION UNION (PCT UNION)

WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT)

Eighth Session
Geneva, May 8 to 12, 2006

PHYSICAL REQUIREMENTS OF THE INTERNATIONAL APPLICATION: TEXT SIZE REQUIREMENTS; PROCEDURE FOR MAKING CORRECTIONS; DRAWING REQUIREMENTS

Proposals submitted by the United States of America

1. The current PCT standards relating to text size, the procedure for making corrections, and the requirements for drawings were established in the context of a paper based application filing and processing system and in view of technologies which have advanced significantly in the past 25 years. As technologies have advanced, with respect to both application processing and application subject matter, the need has arisen to reevaluate the current standards set forth in the Regulations with respect to these matters.

TEXT SIZE REQUIREMENTS

2. Currently, PCT Rule 11.9(d)[1] requires that "text matter shall be in characters the capital letters of which are not less than 0.21 cm high". Such a measurement corresponds to approximately a Times New Roman 9 point font.

[1] References in this document to "Articles" and "Rules" are to those of the Patent Cooperation Treaty (PCT) and the Regulations under the PCT ("the Regulations"), or to such provisions as proposed to be amended or added, as the case may be. References to "national laws", "the national phase", etc., include reference to regional laws, the regional phase, etc.

3. In an effort to increase efficiency and decrease processing delays, Offices and Authorities are increasingly transitioning from paper based application processing to electronic processing. Such electronic processing often involves scanning the application papers and converting them from image files to text files through Optical Character Recognition (OCR).

4. The accuracy of an OCR conversion is inversely proportional to the size of the text being scanned, and it has been found that the OCR scans of applications filed using the current minimum text size result in electronic files which contain numerous errors. Such errors in the text files are becoming an increasing source of wasted time and resources on the part of the Offices and Authorities as the files must then be corrected before they can be properly searched, examined, and published.

5. In contrast to scans of applications filed using the current minimum text size, it has been found that scans of applications using a font size having a capital letter height of no less than 0.28 cm (equivalent to approximately a Times New Roman 12 point font) result in an acceptable level of OCR accuracy.

6. Additionally, there are physiological reasons to consider a change to the present text size requirement. Specifically, scientific studies have shown that readability for humans generally only starts at a 9 point font. In other words, a 9 point font is approximately the smallest size that is comfortable for most humans to read (and for many people the studies have shown that even a 9 point font is too small to be comfortably read). Readability improves at 10 point and is better still at an 11 to 12 point range. Readability then begins to fall off sharply above that.

7. Therefore, it is proposed that Rule 11.9(d) be amended to require that text matter shall be in characters the capital letters of which are not less than 0.28 cm high.

PROCEDURE FOR MAKING CORRECTIONS

8. Currently, Rule 26.4 provides that, in situations where it will not adversely affect the clarity and the direct reproducibility of the sheet on which it is to be entered, a correction can be entered by hand directly onto the record copy. This procedure also applies, via *mutatis mutandis* provisions, to corrections to sequence listings under Rule 13*ter*.1(f) and to the rectification of obvious errors under Rule 91.1(d) (effective 01 April 2007, the rectification of obvious mistakes under Rule 91.2).

9. OCR scanners often have difficulty in recognizing handwritten characters. As a result, similar to the scanning problems encountered when an application having small size text is filed, scans of application papers containing handwritten entries also result in electronic files having numerous errors.

10. Therefore, in an effort to increase the ability of the Offices and Authorities to efficiently process applications electronically, it is proposed to amend the Regulations so as to remove the provision for handwritten entries in the application.

DRAWING REQUIREMENTS

11. Rule 11.13 requires that all drawings be "executed in durable, black, sufficiently dense and dark, uniformly thick and well-defined, lines and strokes without colorings". Such a requirement was certainly sufficient for most technologies when the Treaty was first drafted.

12. However, as technology has advanced, black and white line drawings have become insufficient in many technologies to adequately disclose the subject matter for which patent protection is being sought, and increasingly applicants require the use of photographs (both in color and in black and white) and color drawings in order to provide an adequate disclosure.

13. In fact, while not specifically provided for in the Rules, it has already been recognized that the use of photographs is necessary in certain situations as evidenced by paragraph 174 of Volume I/A of the Applicant's Guide, which sets forth an informal provision for accepting black and white photographs which is administered by the International Bureau. The paragraph states:

> "174. *May a photograph be presented instead of a drawing?* The PCT makes no provision for photographs. Nevertheless, they are allowed where it is impossible to present in a drawing what is to be shown (for instance, crystalline structures). Where, exceptionally, photographs are submitted, they must be black and white, must be on sheets of A4 size, and must respect the minimum margins (see paragraph 148) and admit of direct reproduction. Color photographs are not accepted, nor are color drawings. Photographs are retained by the International Bureau as part of the record copy."

14. Providing for the filing of photographs and color drawings in international applications would be a simple matter of amending Rule 11.13. However, it is recognized that there are numerous related issues which must first be addressed before any such amendment to Rule 11 is proposed.

15. Some examples of such issues are:

(a) Should Offices, Authorities and the International Bureau be allowed to charge additional fees in applications with photographs and/or color drawings?

(b) Should photographs and/or color drawings be allowed only in those applications where the use of such is the only means for adequate disclosure of the invention? If so, what type of showing should be required and who should make the determination?

(c) What technical requirements (e.g., formats, resolution, color depth, etc.) should be placed on applicants in the filing of, and on Offices and Authorities in the processing of, photographs and/or color drawings?

(d) With respect to photographs in particular, what non-technical requirements should be placed on them (e.g., background/foreground limitations, etc.)?

(e) What constitutes a photograph (e.g., a computer screenshot)?

(f) How should applications filed in Offices not prepared to accept photographs and/or color drawings (if any) be handled?

16. Therefore, it is proposed that a task force be established to examine issues relevant to the acceptance of photographs and color drawings in international applications. The work of the task force will be conducted primarily through the use of the PCT Reform electronic forum. The objective of the task force would be to provide a recommendation at an upcoming meeting of the Working Group as to how to proceed with respect to photographs and color drawings.

17. The Working Group is invited:

(i) to consider the proposals contained in the Annex; and

(ii) to consider the establishment of a task force to provide recommendations with regard to providing for photographs and color drawings.

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:[2]

PHYSICAL REQUIREMENTS OF THE INTERNATIONAL APPLICATION: TEXT SIZE REQUIREMENTS; PROCEDURE FOR MAKING CORRECTIONS; DRAWING REQUIREMENTS

TABLE OF CONTENTS

[2] Proposed additions and deletions are indicated, respectively, by underlining and striking through the text concerned.

Rule 11

Physical Requirements of the International Application

11.1 to 11.8 [No change]

11.9 *Writing of Text Matter*

(a) to (c) [No change]

(d) All text matter shall be in characters the capital letters of which are not less than 0.28 ~~0.21~~ cm high, and shall be in a dark, indelible color, satisfying the requirements specified in Rule 11.2.

[COMMENT: It is proposed to amend paragraph (d) to Rule 20.8 so as to establish a minimum text size which will allow for acceptable electronic processing of the international application.]

(e) [No change]

11.10 to 11.14 [No change]

Rule 26

Checking by, and Correcting Before, the Receiving Office of Certain Elements of the International Application

26.1 to 26.3*ter* [No change]

26.4 *Procedure*

Any correction offered to the receiving Office ~~may be stated in a letter addressed to that Office if the correction is of such a nature that it can be transferred from the letter to the record copy without adversely affecting the clarity and the direct reproducibility of the sheet on to which the correction is to be transferred; otherwise, the applicant~~ shall be submitted on ~~required to submit~~ a replacement sheet embodying the correction and ~~the letter accompanying the replacement sheet~~ shall be accompanied by a letter which draws ~~draw~~ attention to the differences between the replaced sheet and the replacement sheet.

[COMMENT: It is proposed to amend Rule 26.4 so as to increase the ability of the Offices and Authorities to efficiently process applications electronically by eliminating the provision for handwritten corrections in the application.]

26.5 and 26.6 [No change]

[End of Annex and of document]

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT)

Eighth Session
Geneva, May 8 to 12, 2006

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

Proposals submitted by Switzerland

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.

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[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>)

3. In order to 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 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 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 thirty-fourth Session of the Assembly of the International Patent Cooperation Union (September 26 to October 5, 2005) "unanimously approved the proposals concerning the work program in connection with reform of the PCT to be undertaken between the September 2005 and September 2006 sessions of the Assembly"[7]. This includes the proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. The present document is intended to serve as the basis for the discussions of the 8th session of the Working Group on Reform of the PCT, to be held May 8 to 12, 2006, on the proposals by Switzerland.

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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 Paper No. 7 (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>).

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>).

7 See paragraph 8(ii) of document PCT/A/34/6.

BACKGROUND

6. 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.

7. 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.

8. 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.

9. 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.

10. In November 2005, the Swiss Federal Council submitted to Parliament the draft for a revised patent law. This draft contains a requirement to disclose the source of genetic resources and traditional knowledge in patent applications to be implemented at the national level. It remains to be seen whether Parliament will retain this obligation in the revised law without harmonized international rules on this issue.

11. 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.

12. 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[8].

13. 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.

SUMMARY OF THE PROPOSALS

Policy Objectives

14. 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”):

(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.

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

(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

15. 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.

16. 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

17. 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

18. 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.

19. 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.

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

(a) *Primary* sources, including in particular Contracting Parties providing genetic resources[9], the Multilateral System of FAO's International Treaty[10], indigenous and local communities[11]; and

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

21. 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

22. 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.

23. 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

24. 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.

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9 See Articles 15, 16 and 19 CBD.

10 See Articles 10-13 FAO International Treaty.

11 See Article 8(j) CBD.

25. 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[12] 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.

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

Sanctions

27. 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.

28. 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

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[12] 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 <www.ige.ch/E/jurinfo/j100.shtm> and <www.ige.ch/E/jurinfo/documents/j10017e.pdf>.

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.

29. 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

30. 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.

CONCLUSIONS

31. 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.

32. 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.

33. 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.

34. 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 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.

35. The Working Group is invited to consider the proposals contained in Annex I.

[Annexes follow]

ANNEX I

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:[1]

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

TABLE OF CONTENTS

[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[2]

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]

[2] The proposed amendments are shown relative to the text of Rule 4 as adopted by the Assembly on October 5, 2005, with effect from April 1, 2007.

Rule 48[3]

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]

[3] The text of Rule 48 is as adopted by the Assembly on October 5, 2005, with effect from April 1, 2007.

Rule 51*bis*[4]

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.

[4] The proposed amendments are shown relative to the text of Rule 51*bis* as adopted by the Assembly on October 5, 2005, with effect from April 1, 2007.

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]

[Annex II follows]

ANNEX 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 Annex II and of document]