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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

C. PCT 918
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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/4/4 Add.3, 4 Add.4, 8 Add.1, 10, 11, 12 and 13, prepared for the fourth session of the *Working Group on Reform of the Patent Cooperation Treaty (PCT)*, which will be held in Geneva from May 19 to 23, 2003.

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

May 7, 2003

Enclosures: documents PCT/R/WG/4/4 Add.3, 4 Add.4, 8 Add.1, 10, 11, 12 and 13

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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

FURTHER STREAMLINING AND SIMPLIFICATION OF PCT PROCEDURES:

FURTHER CORRIGENDA AND CONSEQUENTIAL AMENDMENTS

*Document prepared by the International Bureau*

1. The Annex to this document contains proposals to further amend Rules 16*bis*.2, 32.1, 44*bis*, 60.1 and 90.2 as adopted by the PCT Assembly on October 1, 2002, and due to enter into force on January 1, 2004 (see document PCT/A/31/10, Annex V), and to further amend Rule 90.5. These proposed amendments are in the nature of corrigenda or consequential amendments based on the amendments already adopted. Explanations are set out in the Annex in Comments relating to the provisions concerned.

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

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:

FURTHER CORRIGENDA AND CONSEQUENTIAL AMENDMENTS

TABLE OF CONTENTS

**Rule 16*bis***

**Extension of Time Limits for Payment of Fees**

16*bis*.1 [No change]

16*bis*.2 *Late Payment Fee*

(a) [No change] The payment of fees in response to an invitation under Rule 16*bis*.1(a) may be subjected by the receiving Office to the payment to it, for its own benefit, of a late payment fee. The amount of that fee shall be:

(i) 50% of the amount of unpaid fees which is specified in the invitation, or,

(ii) if the amount calculated under item (i) is less than the transmittal fee, an amount equal to the transmittal fee.

[COMMENT: No change is proposed to present paragraph (a); the text is reproduced above for convenient reference.]

(b) The amount of the late payment fee shall not, however, exceed the amount of 50% ~~25%~~ of the international filing fee referred to in item 1 of the Schedule of Fees, not taking into account any fee for each sheet of the international application in excess of 30 sheets.

[COMMENT: Without prejudice to the determination of the amount of the international filing fee (see document PCT/R/WG/4/8, paragraph 5), upon further reflection, the maximum amount of the late payment fee under Rule 16*bis*.2(b) as adopted by the Assembly on October 1, 2002, with effect from January 1, 2004, (25% of the international filing fee)

*[Rule 16bis.2.(b), continued]*

appears to be too low and would result in a maximum amount of the late payment fee which would be much lower than the maximum amount of the late payment fee under present Rule 16*bis*.2(b) (under present Rule 16*bis*.2(b), the amount of the late payment fee must not exceed the amount of the basic fee which, at present, is fixed at 650 Swiss francs). In respect of certain receiving Offices, a maximum amount of the late payment fixed at 25% of the international filing fee would even have the result that the minimum amount of the late payment fee fixed in accordance with Rule 16*bis*.2(a)(ii) would be higher than the maximum amount of that fee fixed in accordance with Rule 16*bis*.2(b) It is thus proposed to fix the maximum amount of the late payment fee under Rule 16*bis*.2(b) at 50% of the international filing fee.]

## Rule 32

## Extension of Effects of International Application to Certain Successor States

32.1 ~~*Request for*~~ *Extension of International Application to Successor State*

[COMMENT: Proposed amendment of the title of Rule 32.1 is consequential on the amendment of Rule 32.1 as adopted by the PCT Assembly on October 1, 2002, with effect from January 1, 2004. In line with the new approach with regard to designations, a request for extension by the applicant is no longer needed; the effects of an international application are automatically extended to a successor State which has deposited a declaration of continuation under Rule 32.1(a).]

(a) to (c) [No change]

(d) *[Remains deleted]*

32.2 [No change]

**Rule 44*bis***

**International Preliminary Report on Patentability by**

**the International Searching Authority**

44*bis*.1 *Issuance of Report; Transmittal to the Applicant*

(a) [No change] Unless an international preliminary examination report has been or is to be established, the International Bureau shall issue a report on behalf of the International Searching Authority (in this Rule referred to as "the report") as to the matters referred to in Rule 43*bis*.1(a). The report shall have the same contents as the written opinion established under Rule 43*bis*.1.

(b) [No change] The report shall bear the title "international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)" together with an indication that it is issued under this Rule by the International Bureau on behalf of the International Searching Authority.

[COMMENT: No change is proposed to paragraphs (a) and (b) as adopted by the PCT Assembly on October 1, 2002, with effect from January 1, 2004; the text is reproduced above for convenient reference.]

(c) The International Bureau shall promptly transmit one copy of the report issued under paragraph (a) to the applicant.

[COMMENT: It is proposed to add a new paragraph (c) so as to require the International Bureau to send one copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty) to the applicant as soon as it has been issued.]

44*bis*.2 to 44*bis*.4 [No change]

## Rule 60

## Certain Defects in the Demand

60.1 *Defects in the Demand*

(a) and (a-*bis*) [No change]

(a-*ter*) [No change] For the purposes of Rule 53.8, if there are two or more applicants, it shall be sufficient that the demand be signed by one of them.

[COMMENT: No change is proposed to paragraph (a-*ter*) as adopted by the PCT Assembly on October 1, 2002, with effect from January 1, 2004; the text is reproduced above for convenient reference.]

(b) and (c) [No change]

(d) [Deleted] ~~Where, after the expiration of the time limit under paragraph (a), a signature required under Rule 53.8 or a prescribed indication is lacking in respect of an applicant for a certain elected State, the election of that State shall be considered as if it had not been made~~.

[COMMENT: Proposed deletion of paragraph (d) is consequential on the addition of new Rule 60.1(a-*ter*) (see above) as adopted by the PCT Assembly on October 1, 2002, with effect from January 1, 2004.]

(e) to (g) [No change]

60.2 *[Remains deleted]*

## Rule 90

## Agents and Common Representatives

90.1 [No change]

90.2 *Common Representative*

(a) Where there are two or more applicants and the applicants have not appointed an agent representing all of them (a "common agent") under Rule 90.1(a), one of the applicants who is entitled to file an international application according to Article 9 [and in respect of whomthe indication ~~all indications~~ required under Rule 4.5(a)(ii) has ~~have~~ been provided] may be appointed by the other applicants as their common representative.

[COMMENT: Although the words "and in respect of whom all indications required under Rule 4.5(a) have been provided" were only added to paragraph (a) by way of an amendment adopted by the Assembly on October 1, 2002, with effect from January 1, 2004, it is proposed to further amend paragraph (a) so as to no longer require that only an applicant in respect of whom*all* indications required under Rule 4.5(a) (name, address, nationality *and* residence) have been provided can be appointed as the common representative. Upon further consideration, it would appear sufficient that the name, the nationality *or* residence, and the address of the applicant be furnished to be appointed as common representative. Note that the indication of the name and of the nationality *or* residence of the applicant is already required for the determination whether the applicant is entitled to file the international application according to Article 9, so that there would appear to be no need to specifically refer to the furnishing of the indications required under Rule 4.5(a)(i) and (iii). The requirement as such ("and in respect of whom the indication required under Rule 4.5(a)(ii) has been provided") is presented in square brackets for consideration by the Working Group whether the furnishing of the address should be made a condition for the appointment of an applicant as the common representative or whether it should not, as at present, be left to the practice of the receiving Office to decide how to deal with the case of a missing address of the applicant to be appointed as a common representative.]

*[Rule 90.2, continued]*

(b) Where there are two or more applicants and all the applicants have not appointed a common agent under Rule 90.1(a) or a common representative under paragraph (a), the applicant first named in the request who is entitled according to Rule 19.1 to file an international application with the receiving Office ~~and in respect of whom all indications required under Rule 4.5(a) have been provided~~ shall be considered to be the common representative of all the applicants.

[COMMENT: Although the words "and in respect of whom all indications required under Rule 4.5(a) have been provided" were only added to paragraph (b) by way of an amendment adopted by the Assembly on October 1, 2002, with effect from January 1, 2004, it is proposed to further amend paragraph (b) so as to no longer require that only an applicant in respect of whom*all* indications required under Rule 4.5(a) (name, address, nationality *and* residence) have been provided can be considered to be the common representative. Upon further consideration, it would appear sufficient that, as at present, the name and the nationality *or* residence of the applicant be furnished to be considered to be common representative. Note that the indication of the name and of the nationality *or* residence of the applicant is already required for the determination whether the applicant is entitled according to Rule 19.1 to file the international application with the receiving Office, so that there would appear to be no need to specifically refer to the furnishing of the indications required under Rule 4.5(a)(i) and (iii). With regard to the address of the applicant to be considered as the common representative, rather than making the furnishing of the address a condition for considering the applicant to be the common representative, it is proposed to continue, as at present, to leave it to the practice of the receiving Office to decide how to deal with the case of a missing address. Otherwise, that is, if the furnishing of the address would be a condition for considering an applicant to be the common representative, it would appear possible that, in certain cases, none of the applicants could be considered to be the common representative (example: the applicant who is first named in the request is an applicant from a non-PCT Contracting State; the applicants named second and third in the request are applicants from a PCT Contracting State but not all indications required under Rule 4.5(a) have been provided for either of them).]

90.3 and 90.4 [No change]

90.5 *General Power of Attorney*

(a) [No change] Appointment of an agent in relation to a particular international application may be effected by referring in the request, the demand or a separate notice to an existing separate power of attorney appointing that agent to represent the applicant in relation to any international application which may be filed by that applicant (i.e., a "general power of attorney"), provided that:

(i) the general power of attorney has been deposited in accordance with paragraph (b), and

(ii) a copy of it is attached to the request, the demand or the separate notice, as the case may be; that copy need not be signed.

(b) [No change] The general power of attorney shall be deposited with the receiving Office, provided that, where it appoints an agent under Rule 90.1(b), (c) or (d)(ii), it shall be deposited with the International Searching Authority or the International Preliminary Examining Authority, as the case may be.

[COMMENT: No change is proposed to present paragraphs (a) and (b); the text is reproduced above for convenient reference.]

(c) Subject to paragraph (d), any receiving Office, any International Searching Authority and any International Preliminary Examining Authority may waive the requirement under paragraph (a)(ii) that a copy of the general power of attorney is attached to the request, the demand or the separate notice, as the case may be.

*[Rule 90.5, continued]*

(d) Where the agent submits any notice of withdrawal referred to in Rules 90*bis*.1 to 90*bis*.4, the requirement under paragraph (a)(ii) for the attachment of a copy of the general power of attorney to the request, the demand or the separate notice, as the case may be, shall not be waived under paragraph (c).

[COMMENT: During its second session, the Committee on Reform of the PCT agreed that there was no need to amend Rule 90.5 to permit a receiving Office or an International Authority to waive the requirement under Rule 90.5(a)(ii) for a copy of a general power of attorney to be attached to the request, demand or separate notice (see document PCT/R/2, paragraph 71). Upon further reflection, however, it would appear inconsistent to permit an Office to waive the requirement that a separate power of attorney is furnished while still insisting on the furnishing of a copy of such deposited general power of attorney. It is thus proposed to add new paragraphs (c) and (d) so as to permit (but not oblige) any receiving Office and any International Searching and Preliminary Examining Authority to waive the requirement that a copy of a deposited general power of attorney be submitted to it.]

90.6 [No change]

[End of Annex and of document]

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PCT/R/WG/4/4 Add.4
ORIGINAL: English
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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

FURTHER STREAMLINING AND SIMPLIFICATION OF PCT PROCEDURES:

ANNEXES TO THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

*Document prepared by the International Bureau*

BACKGROUND

1. Present Rule 70.16 of the Regulations under the PCT[1] provides for amendments to the international application that have been made in the course of the international preliminary examination procedure to be annexed to the international preliminary examination report. However, a replacement sheet which has been superseded by later replacement sheets or amendments resulting in the cancellation of entire sheets under Rule 66.8(b) is not to be annexed.

2. In a case where the International Preliminary Examining Authority considers that the relevant superseding replacement sheet or sheets or amendments contain an amendment that goes beyond the disclosure in the international application as filed, the report will contain an

[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.

indication accordingly under Rule 70.2(c). In order to make the report clear in this respect, it would be preferable for the superseded replacement sheet, suitably marked, also to be annexed to the report. The Annex to this document contains a proposal to amend Rule 70.16 accordingly.

*3. The Working Group is invited to consider the proposals contained in the Annex.*

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:

ANNEXES TO THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**Rule 70**

**International Preliminary Report on Patentability by**

**the International Preliminary Examining Authority**

**(International Preliminary Examination Report)**

70.1 to 70.15 [No change]

70.16 *Annexes to the Report*

(a) Each replacement sheet under Rule 66.8(a) or (b), each replacement sheet containing amendments under Article 19 and each replacement sheet containing rectifications of a mistake ~~obvious errors~~ authorized under Rule 91.1(b)(iii) ~~91.1(e)(iii)~~ shall, unless superseded by later replacement sheets or amendments resulting in the cancellation of entire sheets under Rule 66.8(b), be annexed to the report. Amendments under Article 19 which have been considered as reversed by an amendment under Article 34 and letters under Rule 66.8 shall not be annexed.[2]

(b) Notwithstanding paragraph (a), a superseded replacement sheet shall also be annexed to the report where the International Preliminary Examining Authority considers that the relevant superseding replacement sheet or sheets or amendments contain an amendment that goes beyond the disclosure in the international application as filed and the report contains an indication referred to in Rule 70.2(c). In such a case, the superseded replacement sheet shall be marked as provided by the Administrative Instructions.

70.17 [No change]

[End of Annex and of document]

[2] The proposed amendments shown in paragraph (a) simply reproduce those proposed for Rule 70.16 in document PCT/R/WG/4/4 Add.2.

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WIPO

PCT/R/WG/4/8 Add.1
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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

AMENDMENT OF THE SCHEDULE OF FEES
ANNEXED TO THE REGULATIONS UNDER THE PCT

*Proposal submitted by the United States of America*

INTRODUCTION

1. This document contains a proposal for an amendment of the Schedule of Fees annexed to the Regulations under the Patent Cooperation Treaty (PCT). The proposal concerns the concept of the "flat" international filing fee for the automatic indication of all designations possible under the PCT that was approved by the PCT Assembly in September 2002 with effect from January 1, 2004 (see paragraph 45 and Annex V of PCT/A/31/10).

2. It is proposed that the international filing fee be fixed at 1,210 Swiss francs and that the handling fee of 233 Swiss francs remain a separate fee applied only to applications in which a demand is filed. This is proposed in order to reflect the reduction in fees previously envisioned by the PCT Assembly in 2001, as explained below, and to ensure that applicants who, under the present system and fee structure, only use the Chapter I procedure will not be disadvantaged by having to pay considerably higher fees than is presently the case under Chapter I.

BACKGROUND

3. The current fee structure of the PCT system includes a basic fee, a designation fee and, for international applications in which a demand is filed under PCT Chapter II, a handling fee. In addition, the maximum number of payable designation fees is currently five. For the year 2003, the fees are fixed at a basic fee of 650 Swiss francs, a designation fee of 140 Swiss francs and a handling fee of 233 Swiss francs. Because most PCT applicants indicate five or more designations per application, the great majority of applicants pay the maximum fee for designations of 700 Swiss francs. Under the current fee structure, therefore, most applicants using only Chapter I of the PCT pay a maximum fee of 1,350 Swiss francs, and those utilizing Chapter II of PCT pay a maximum fee of 1,583 Swiss francs.

4. A fee reduction was envisioned for the PCT that would have reduced the maximum number of payable designations to four with effect from January 1, 2003 (see paragraph 347 of WO/PBC/4/2 and paragraph 60 of PCT/A/31/6) in the 2001 meeting of the PCT Assembly. Assuming other existing fee levels had remained the same, this would have resulted in a basic fee of 650 Swiss francs, a maximum designation fee of 560 Swiss francs, or a total of 1,210 Swiss francs, plus a handling fee for international applications in which a demand had been filed of 233 Swiss francs. In other words, the envisaged fee reduction, which was not approved, would have resulted in maximum fees under Chapter I of the PCT of 1,210 Swiss francs, and maximum fees under both Chapters I and II of the PCT of 1,443 Swiss francs as from January 1, 2003.

PCT REFORM AND FEES

5. The PCT Assembly, in September 2002, unanimously adopted new regulations (see PCT/A/31/10), that provide for a combined search and examination system, as well as automatic designation of all Contracting States, among other changes. In light of these changes, the designation-based fee system will no longer be continued as from January 1, 2004. Instead, the Assembly agreed to a single “flat” international filing fee as part of the amendment package (see paragraph 45 and Annex V of PCT/A/31/10). The new fee would combine the current basic and designation fees. At current levels, this fee would be 650 +700 or 1,350 Swiss francs, while the fees envisioned by the reduction in paragraph 4, above, would be 650 + 560 or 1,210 Swiss francs.

6. Rather than attempting to implement the envisaged fee reduction, the International Bureau proposed that, in light of the significant revisions to the Regulations of the PCT, a review of the fee structure and the possible reduction of fees should be undertaken, in the context of the necessary determination of the new “international filing fee” (paragraph 27 of PCT/A/31/10). Although certain delegations at the 2002 PCT Assembly expressed concerns about this approach and doubts about the prospects for a fee reduction via this approach**,** the rationale of the International Bureau was eventually adopted.

7. The International Bureau now has produced a new proposal with respect to PCT fees for consideration at the May 2003 meeting of the Working Group on Reform of the PCT in document PCT/R/WG/4/8. In light of the fact that all applications will now require some type of report (International Preliminary Report on Patentability (Chapter I) and International Preliminary Report on Patentability (Chapter II)), the International Bureau proposes rolling the handling fee into the international filing fee, thereby applying a handling fee to all international applications. This is in contradistinction to the current system in which only those applications where the applicant files a demand are charged handling fee.

8. The International Bureau proposes an amount of 1,530 Swiss francs for the new fee. This represents a fee of 1,297 Swiss francs in addition to the current level of 233 Swiss francs for a handling fee. This is 87 Swiss francs higher than the reduction originally envisioned for January 1, 2003, as noted above, and additionally would provide that each and every international application be subject to a handling fee. That is, in addition to the issue of the handling fee, the International Bureau's proposal does not provide the previously promised 8% reduction in fees or any reduction to compensate for the delay in implementing that reduction. Rather, the International Bureau proposes a substantial increase in PCT international fees. The International Bureau has indicated that the specific figures are based on the calculation of estimated income in the context of WIPO's proposed program and budget for 2004-2005 presented in document WO/PBC/6/2 (paragraph 5 of PCT/R/WG/4/8). The current PCT fees in effect in 2003, the original reduction plan described in paragraph 4, above, WIPO's fee proposal in PCT/R/WG/4/8 and WO/PBC/6/2, and the fees under this proposal are compared in Annex II of this document.

PROPOSAL

9. It is proposed instead that the international filing fee be fixed at 1,210 Swiss francs and the handling fee remain a separate fee applied only to applications in which a demand is filed, in order to reflect the reduction in fees previously envisioned. With particular regard to the handling fee, while we recognize the existence of the new report, the International Bureau does not appear to have justified the need for the entire handling fee to be applied to all PCT cases. Therefore we propose to leave that fee as is.

*10. The Working Group on PCT Reform is invited to recommend adoption by the Assembly of the PCT Union of the proposed amendment to the Schedule of Fees annexed to the Regulations under the PCT as appearing in Annex I of this document and to decide that it will enter into force on January 1, 2004, and that it will apply only in respect of international applications filed on or after that date.*

[Annex I follows]

ANNEX I

PROPOSED AMENDMENT OF
THE REGULATIONS UNDER THE PCT

SCHEDULE OF FEES[1]
*(as proposed to be amended with effect from January 1, 2004)*

| **Fees** | | **Amounts** |
|---|---|---|
| 1. | International Filing Fee:<br>(Rule 15.2) | 1,210 ~~650~~ Swiss francs plus 15 Swiss francs for each sheet of the international application in excess of 30 sheets |
| 2. | Handling Fee:<br>(Rule 57.2) | 233 Swiss francs |

**Reductions**

3. The international filing fee is reduced by 200 Swiss francs if the international application is, in accordance with and to the extent provided for in the Administrative Instructions, filed:

(a) on paper together with a copy thereof in electronic form; or

(b) in electronic form.

4. All fees payable (where applicable, as reduced under item 3) are reduced by 75% for international applications filed by any applicant who is a natural person and who is a national of and resides in a State whose per capita national income is below US$3,000 (according to the average per capita national income figures used by the United Nations for determining its scale of assessments for the contributions payable for the years 1995, 1996 and 1997); if there are several applicants, each must satisfy those criteria.

[Annex II follows]

[1] The "present" text shown is that of the Schedule of Fees as amended by the Assembly on October 1, 2002 (see document PCT/A/31/10) and due to enter into force on January 1, 2004.

ANNEX II

COMPARISON OF PCT FEES
*(all fees shown in Swiss francs)*

| | *Basic Fee* | *Designation Fee* | *Maximum Designations* | *Maximum Combined Fee* | *Maximum Combined Fee with Handling Fee (plus 233 Sfr)* |
|---|---|---|---|---|---|
| *Current PCT Fees* | 650 | 140 | 5 (700 Sfr) | 1,350 | 1,583 |
| *Original Reduction Plan* | 650 | 140 | 4 (560 Sfr) | 1,210 | 1,443 |
| *WIPO Proposal (in PCT/R/4/8)* | | | | | 1,530 flat fee for all cases |
| *Proposal in this Document* | | | | 1,210 flat fee | Plus 233 Sfr for ONLY those cases in which a demand is made |

Note that the WIPO Proposal in PCT/R/4/8 of a flat fee of 1,530 Swiss francs in ALL cases represents a Maximum Combined Fee of 1,297 Swiss francs (1,530-233 handling fee), which is 87 Swiss francs higher than the estimated fee under the original reduction plan of 1,210 Sfr.

With respect to rationales for charging a PCT handling fee in all cases, it must also be borne in mind that PCT fees have no direct relation to services provided or work required under the PCT. Note that in the proposed 2004-2005 Program and Budget, PCT fee income is expected to fund 80% of the entirety of WIPO's budget, while Main Program 3 (Patents and the PCT System) accounts for only 21.5% of WIPO's total budget (see Table 7, p. 24). Hence, there is no relation between the PCT fees and PCT work undertaken by the International Bureau of WIPO, and no justification for charging a handling fee in all PCT cases.

[End of Annex II and of document]

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WIPO

PCT/R/WG/4/10
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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

COMPUTATION OF TIME LIMITS:

*Proposals submitted by Australia, Canada and the European Patent Office*

BACKGROUND

1. As reported in paragraphs 65 and 66 of the Summary of the third session of the Working Group on Reform of the Patent Cooperation Treaty (see document PCT/R/WG/3/5), changes were proposed to be made, *inter alia*, to Rule 80.5 so as to take into account the fact that, in particular in geographically large countries, an Office may have different branch Offices in different parts of the country in different time zones and with different local holidays. It was agreed that the Representative of the EPO and the Delegations of Australia, Canada and the United Kingdom, which had proposed further Rule changes, should present written proposals for consideration by the Working Group.

2. Taking into account the above, Australia, Canada and the European Patent Office propose that PCT Rule 80.5 be amended to read as shown in the Annex.

*3. The Working Group is invited to consider the proposals contained in the Annex to this document.*

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS

COMPUTATION OF TIME LIMITS

**Rule 80**

**Computation of Time Limits**

80.1 to 80.4 [No change]

80.5 *Expiration on a Non-Working Day*

If the expiration of any period during which any document or fee must reach a national Office or intergovernmental organization falls on a day:

(i) on which such Office or organization is not open to the public for the purposes of the transaction of official business;~~, or~~

(ii) on which ordinary mail is not delivered in the locality in which such Office or organization is situated;~~,~~

(iii) which, where such Office or organization is situated in more than one locality, is an official holiday in at least one of the localities in which such Office or organization is situated, and in circumstances where the national law applicable by that Office or organization provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day; or

*[Rule 80.5, continued]*

(iv) which, where such Office is the government authority of a Contracting State entrusted with the granting of patents, is an official holiday in part of that Contracting State, and in circumstances where the national law applicable by that Office provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day;

the period shall expire on the next subsequent day on which neither of the said four ~~two~~ circumstances exists.

80.6 and 80.7 [No change]

[End of Annex and of document]

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WIPO

PCT/R/WG/4/11
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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

PERIOD FOR PERFORMING THE INTERNATIONAL SEARCH

*Proposal submitted by the United States of America*

BACKGROUND

1. In earlier proposals for integration of the search and examination stages of PCT processing, the United States has urged that the period for establishment of the International Search Report (ISR) and the Written Opinion of the International Searching Authority (WO/ISA) should be relaxed (see PCT/R/WG/1/3 and PCT/R/WG/2/9). Relaxation of the time limit is warranted due to the extension of the Article 22 time period for national stage entry from 20 to 30 months and the desire to more effectively utilize the entire time period now provided for Chapter I processing. The time limit for establishment of the ISR and the WO/ISA should be relaxed if the revised PCT system is to function as envisioned. Three areas of concern that have arisen are: (1) issues with regard to priority claim processing, (2) issues regarding unity of invention, and (3) issues concerning the processing of sequence listings.

PRIORITY CLAIM ISSUES

2. There is currently a conflict between the time limit for establishment of the search and the time limits pertaining to the priority claim. This conflict first came to light as the result of comments by the delegation of Japan in the second meeting of the Committee in July of last year. The comments of the Japanese delegation dealt with the conflict between the time limit under Rule 17.1 for providing a copy of the priority document and the time limit under

Rule 42.1 for establishment of the WO/ISA, and the fact that applicant may have difficulty providing a copy of the priority document in time for the ISA to take it into account in establishing the WO/ISA. Rather than shorten the period during which applicant could submit a copy of the priority document, a move that was viewed as being detrimental to applicants' rights, the Committee chose to resolve this conflict by making Rule 66.7 apply *mutatis mutandis* to the establishment of the WO/ISA (see document PCT/R/2/9, paragraphs 113-115).

3. However, it has come to light that there may be an even greater conflict between the Rule 42.1 time limit and the time limit under Rule 26*bis* for correction or addition of a priority claim. Specifically, under Rule 42.1 the ISR and WO/ISA must be established by the later of three months from receipt of the search copy by the ISA or nine months from the priority date, or between nine and 16 months from the priority date (the 16 month date being based on an assumed average search copy processing time on the part of the receiving Office of 1 month). However, under Rule 26*bis*, applicants have until 16 months from the priority date to submit any corrections or additions to the receiving Office. Assuming an average processing time of one month by the RO of any request under Rule 26*bis*, the ISA is required to begin the international search and establish the WO/ISA during a period that can range from 1 to 8 months prior to the ISA becoming aware that a priority claim exists. In that, under Rules 43*bis*.1(b) and 64.1, the ISA must take into account any priority claim in establishing the WO/ISA, a relaxation of the Rule 42.1 time limit would appear to be necessary in order to protect applicants' right to have all priority claims permissible under the Treaty taken into account when the WO/ISA is established.

UNITY OF INVENTION ISSUES

4. During the last meeting of the Working Group, discussions were held on several proposals concerning unity of invention, and specifically to either simplify or eliminate altogether the protest mechanism. Comments were made by the delegation of the EPO, and supported by other delegations, that the protest procedure was quite time consuming and when invoked by an applicant often led to problems in meeting the time limit under Rule 42.1. The United States would urge that a relaxing of the Rule 42.1 time limit would, in most instances, eliminate this problem by allowing ample time for protests to be properly resolved. Such a relaxation would be advantageous to applicants in that it would allow for sufficient time, prior to the deadline for establishment of the ISR and WO/ISA, for any protests to be properly and thoroughly considered.

SEQUENCE LISTING ISSUES

5. Similarly, during the last meeting of the Working Group discussions were also held on the topic of sequence listings. During these discussions the delegation of the EPO pointed out that as many as 50% of international applications containing disclosure of nucleotide and/or amino acid sequences were not accompanied by an acceptable computer readable form sequence listing. It was further pointed out that in many cases multiple invitations to provide such a sequence listing are required before an acceptable listing is submitted. Therefore, in a large number of applications requiring a sequence listing it is difficult, if not impossible, for the searching authority to carry out a meaningful international search within the Rule 42.1 time limit as a result of these delays in obtaining an acceptable listing. The United States, as with unity of invention protests discussed above, believes that a relaxation of the Rule 42.1 time limit would, in most instances, eliminate this problem by allowing ample time for proper sequence listings to be filed. The relaxation of this time limit would be beneficial to

applicants in that it would provide the necessary time for the filing of an acceptable computer readable form sequence listing thus allowing the ISA to establish a search which is as complete and accurate as possible.

PROPOSAL

6. There are various processing conflicts that arise as the result of the current limited time period for establishment of the international search under Rule 42.1. Given that the Article 22 time period for entering the national stage has been extended to 30 months from the priority date, it would be reasonable to also extend the Rule 42.1 time limit for establishment of the ISR and WO/ISA. This would allow the Authorities to take full advantage of the complete time period available for international stage processing in order to properly address these conflicts.

7. Therefore, it is the proposal of the United States that Rule 42.1 be amended as follows:

(i) to extend the time limit by which the ISA is supposed to have established the ISR and WO/ISA to 22 months from the priority date thus providing sufficient time for the resolution of all issues that must be addressed prior to the international search; and

(ii) to include a minimum period in which the ISR and WO/ISA may be established of 17 months from the priority date so as to ensure that applicants have the full time period afforded them under Rule 26*bis* to make changes or additions to the priority claim and have those changes or additions taken into account by the searching authority as required by Rules 43*bis*.1(b) and 64.1.

8. The upper limit period of 22 months has been chosen as a date that would allow sufficient time for resolution of the search related issues as well as for any response by applicants and issuance of the International Preliminary Examination Report by 28 months. The lower limit of 17 months is based on the 16 months allowed by the Rule 26*bis* plus an additional one month to allow for RO processing and transmission to the ISAs of any such requests. Finally, the current provision that the ISR and WO/ISA be due 3 months from the date of receipt of the search copy has been retained to protect the ISAs from being accountable for any delays on the part of the RO which would prevent the timely establishment of the search.

9. A review of both the existing Rules and those which are scheduled to take effect 01 January 2004 indicates that the only Rules that would need to be amended in this regard are Rules 42.1, 46.1 and 69.2.

*10. The Working Group is invited to consider the proposals contained in the Annex to this document.*

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS

PERIOD FOR PERFORMING THE INTERNATIONAL SEARCH

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**Rule 42**

**Time Limit for International Search**

42.1 *Time Limit for International Search*

The time limit for establishing the international search report or the declaration referred to in Article 17(2)(a) shall be:

(i) not more than the later of three months from the receipt of the search copy by the International Searching Authority, or 22 ~~nine~~ months from the priority date ~~whichever time limit expires later~~; and

(ii) not less than 17 months from the priority date.

## Rule 46

## Amendment of Claims Before the International Bureau

46.1 *Time Limit*

The time limit referred to in Article 19 shall be two months from the date of transmittal of the international search report to the International Bureau and to the applicant by the International Searching Authority ~~or 16 months from the priority date, whichever time limit expires later~~, provided that any amendment made under Article 19 which is received by the International Bureau after the expiration of the applicable time limit shall be considered to have been received by that Bureau on the last day of that time limit if it reaches it before the technical preparations for international publication have been completed.

46.2 to 46.5 [No change]

**Rule 69**

**Start of and Time Limit for International Preliminary Examination**

69.1 [No change]

69.2 *Time Limit for International Preliminary Examination*

The time limit for establishing the international preliminary examination report shall be whichever of the following periods expires last:

(i) 28 months from the priority date; or

(ii) three ~~six~~ months from the time provided under Rule 69.1 for the start of the international preliminary examination; or

(iii) three ~~six~~ months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under Rule 55.2.

[End of Annex and of document]

E

WIPO

PCT/R/WG/4/12
ORIGINAL: English
DATE: April 28, 2003

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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

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

## Fourth Session
## Geneva, May 19 to 23, 2003

A COMMON FRAMEWORK FOR
INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION

*Initial Task Force Report prepared by the United Kingdom*

INTRODUCTION

1. At the third session of the Working Group on Reform of the PCT, held in Geneva from November 18 to 22, 2002, it was decided to establish a "virtual" task force to consider the proposals put forward by the United Kingdom for a common quality framework (PCT/R/WG/3/4) and other points raised during the discussion on those proposals. The United Kingdom was asked to coordinate the work of the task force and submit an initial report to the Working Group and to the Meeting of the International Authorities (MIA) by the end of April 2003.

2. To facilitate discussion the United Kingdom prepared a discussion document which was posted for comment on the electronic forum website the International Bureau had created for the task force. All the responses received on that discussion paper can be viewed on the e-forum site (http://www.wipo.int/pct/reform/qualityframework).

3. The present document constitutes the initial report of the task force. It contains a synopsis of the comments received on the discussion document together with brief analysis by the United Kingdom. Attached in Annex I is a framework document which takes into account the comments received on the discussion document and sets out the key components of a quality framework the aim of which is to provide a model on which each Authority can base

its own detailed quality system. Reproduced in Annex II are the comments on the other points raised when document PCT/R/WG/3/4 was discussed. The United Kingdom is very grateful for the detailed and constructive comments received and thanks all those who made comments.

4. It should be stated at the outset that in light of the strong opposition expressed by the Authorities to the idea of an independent review mechanism, as proposed in the discussion document, that feature has now been replaced in the framework document by an internal review system for self assessment.

QUALITY MANAGEMENT SYSTEM (QMS)

5. This part of the framework document sets out the basic features of a management system considered necessary to support the international search and preliminary examination process.

6. A proposal by the Netherlands to restructure this part of the framework by grouping the requirement criteria into two broad categories, namely: (a) technical competences of searchers and examiners, and (b) management and administration systems, has not been adopted at this stage but the document can be reformatted along these lines if others consider it appropriate. Moreover, the additional requirement criteria listed in Annex 3 of the Netherlands' submission may be too prescriptive for a document the aim of which is to provide a set of broad requirement criteria on which each Authorities can base its QMS. However, these can be added if others consider them appropriate.

7. On a general point, the United States of America felt that there should be flexibility in the requirements to meet the time limits for issuing search and examination reports and that those time limits should be re-evaluated. However, we would suggest that this is not a matter which falls within the remit of the task force.

8. Japan asked who would judge the effectiveness and appropriateness of the measures taken by Authorities to meet the requirements criteria while the United States of America indicated that it should be for each Authority to decide what is appropriate. To take account of these comments it is made clear in the framework document that it is for individual Authorities to make these judgements.

*Resources*

9. Singapore stated that the resources specified in this section were an essential element in achieving and maintaining quality. Austria, in expressing support for this item, mentioned that it already has the listed resources in place. However, Japan wondered whether some of the resources mentioned were appropriate while Spain, Sweden and the European Patent Office (EPO) indicated that an Authority should not be tied to a standard list. To address these concerns the resources listed are presented as "examples" of the kind of resources an Authority should consider establishing to support the search and examination process.

10. Canada and the United States of America, while agreeing that each Authority should acquire and maintain sufficient resources, believes that it should be left to the individual Authorities rather than an outside body to determine what constituted sufficient staffing and

appropriate equipment and facilities. This point has been taken into account by the replacement of the idea of an independent review mechanism with internal review systems in each Authority.

11. Sweden asked if there was any thought of establishing ISAs with responsibility for less than all technical fields. The International Federation of Intellectual Property Attorneys (FICPI) proposed that the complementary resources and competences of the Authorities could be pooled so that different Authorities could conduct parallel, supplementary, non-overlapping searches the results of which could be drawn together in a final composite international search report. The United Kingdom considers that this is more appropriate for discussion by the Working Group as part of the general discussions on PCT reform.

12. The Russian Federation suggested the creation of a centralised distance learning and training course for all staff involved in the search and examination process, analogues to WIPO World Academy's "General Course in Intellectual Property."

*Administration*

13. Canada, Spain, Sweden and the EPO, in referring to control mechanisms postulated under this item, indicated that it is not possible to guarantee that search and examination reports will always be issued on time and that backlogs will be kept to a minimum. They therefore preferred a less rigid approach. Japan also questioned the feasibility of imposing a strict requirement for the control mechanism with regard to backlogs. These concerns have been taken into account in the framework document by proposing more flexible administration criteria.

14. Australia suggested that the administration arrangements should also provide for preventative action and continuous improvement. These suggestions have been reflected in the attached document.

15. Singapore, in supporting the concept of a control mechanism, suggested that each Authority should including a report on backlogs to the proposed external review panel. Although it is now proposed to drop the idea of an external panel, reporting on backlogs should form part of the internal reporting mechanism within each Authority. This is taken into account in the framework document.

16. The United States of America supported the concept of each Authority establishing a control mechanism but felt that the Authorities themselves should determine how to deal with backlogs. This will be possible under the proposed internal review arrangement.

17. Canada also felt it may be of limited value to establish procedures for measuring user perception.

*Quality Assurance*

18. The EPO said that it should be left to each Authority to decide what quality assurance procedures to implement rather than be subject to a standard set of procedures. Canada, Spain and Sweden also felt that the proposals were too rigid and needed to be more flexible. To address these concerns the attached framework document sets out what aspects a quality

assurance system should cover, for example verification, validation and monitoring of search and examination work, and leaves it to individual Authorities to set up appropriate arrangements.

19. Australia believes that the quality assurance procedures should also verify the action taken by an Authority to address deficiencies and prevent a recurrence. This suggestion has been taken on board in the framework document.

20. Japan expressed concern over the use of the terms “effective,” “suitable” and “reliable” which it felt were unclear. The words “suitable” and “reliable” have now been deleted and it is made clear in the framework document that it is for each Authority to determine whether the measures it takes to meet the QMS requirement criteria are effective and appropriate.

21. Japan also questioned the feasibility of providing “evidence” of conformity while the United States objected to such evidence being made available outside the Authority. To overcome these concerns no reference is made in the framework document to the provision of “evidence.”

22. Singapore expressed support for the quality assurance proposal which it viewed as a means of meeting and maintaining user expectations.

23. Austria said that more practical language should be used to clarify what needs to be accomplished with regard to measuring, recording monitoring and analyzing the performance of a quality management system. In this regard, as explained above, the framework document now simply sets out the basic requirement criteria of a QMS leaving it to individual Authorities to decide how to build those requirements into their individual QMSs.

*Feedback Arrangements*

24. In view of their opposition to an external review panel, Australia, Canada, Japan, Spain, Sweden, the the United States of America and the EPO could not support the proposal that each Authority establish arrangements to allow for feedback from such a body.

25. Canada did however say that it would support the sharing of best practice between Authorities and leave it to each Authority to react as appropriate. It also made the point that a well-functioning feedback mechanism is an essential element of the proposed quality framework which needed a means by which users could voice their opinion and their views could be assessed. EAPO felt that the feedback mechanism could include arrangement of meetings and seminars.

26. The Russian Federation suggested that it would be useful to establish a common central database containing information about applications filed under the PCT in order to provide quality assessment of international searches and examinations in comparison with the national phase. The information would allow examiners to assess the quality of their work and identify any mistakes they may have made.

27. Japan expressed concern about using subjective indexes, like user satisfaction and perception, because of the variations between countries in user characteristics and filing strategies. Singapore, on the other hand, said that two-way communication/feedback arrangements should help clarify doubts and reservation while FICPI felt that it was important to canvass users’ views.

28. The United Kingdom appreciates that there may be variations between countries but believes that the views of customers on the service they receive is a central plank of any quality system if the organisation providing the service is to be able to understand and meet its customer needs and expectations.

29. Japan questioned the meaning of “constructive feedback” and felt that feedback from national and regional Offices to Authorities should be flexible and voluntary. The word “constructive” has accordingly been deleted from the framework document while it is left open for each Authority to arrange how it might receive feedback from national and regional Offices.

30. Canada also expressed concern about the nature of comments from national and regional Offices and suggested the creation of a centralized feedback repository, controlled by the International Bureau.

31. Austria felt that the use of the word “mechanism” where used in respect to feedback from national and regional Offices should be replaced with something more precise. Accordingly, the word “mechanism” is not now used in the framework document and the passage in question has been revised.

*Communication and Guidance to Users*

32. Japan, Singapore, Spain and the EPO found the proposals under this item acceptable though the EPO expressed a preference for the use of the word “communication” in place of “dialogue.” Austria also said it preferred “communication.”

33. FICPI stressed that it was important for Authorities to warn applicants about proceeding without professional help.

INTERNAL REVIEW

34. Singapore supported the concept of a review mechanism, as proposed in the discussion document, which involved the use of an independent assessment panel, and made several recommendations. The Netherlands agreed that a common quality framework should be supported by a quality review panel acting initially as a forum for disseminating best practice, monitoring progress and providing advice and subsequently as an assessment body. Hungary suggests that, besides the use of an independent panel, the possibility of a uniform internal validation system should be explored. New Zealand said that, while it could understand the sensitivities in publishing the identity of an Authority that did not meet quality standards, it would be extremely useful for national Offices to know how much credibility to place on the search and examination reports from particular Authorities. FICPI supported the idea of an independent review and said that the findings should be made publicly available to ensure transparency.

35. Austria also felt that some outside control of the work of the Authority could be helpful in securing the quality of search and examination reports but, because of the practical and cost implications, questioned the feasibility of an independent review panel.

36. Canada, Spain and the EPO stated that they could not support the concept of an external review panel. Sweden also expressed scepticism and mentioned the difficulties in identifying and choosing suitable candidates for such a panel and the bureaucracy and costs implications. Japan also referred to the practical implications and the affect on an Authority's discretion to act and indicated that a review arrangement should be considered in the context of self-assessment.

37. The United States of America could see benefit in Authorities sharing information about how they achieved and monitored compliance with quality standards but could see little or no benefit in an Authority disclosing the results of its internal review to other bodies. The United States of America strongly opposed the concept of an independent review panel and took the view that each Authority must retain the right to determine how to allocate its resources. It also doubted the ability of an external panel to provide advice to an Authority without knowledge of that Authority's resource constraints and to define and evaluate quality beyond objective statistics. Like others, the United States of America also expressed concerns over the resources needed to maintain such a panel.

38. Australia put forward an alternative approach whereby the results of an internal performance audit and system audit should be made publicly available or at least available to other Offices using a standard reporting template. This it said would assure Offices that the QMS were operational and effective and provide a means of disseminating best practice.

39. In light of the reservations expressed by the Authorities to the concept of an independent review panel the original idea of a review mechanism has been replaced in the attached framework document with a scheme that recommends that each Authority establish its own internal review system for self assessment. The document sets out a model review arrangement on which individual Authorities should base their own in-house systems.

40. The framework document also proposes that each Authority present an annual report to MIA and that MIA in turn submit a general progress report to the PCT Assembly. This should help disseminate best practice between Authorities and promote confidence among national and regional Offices in the work undertaken by those Authorities and hopefully discourage the duplication of work in the national and regional phase. It is for future debate whether the specific results of each Authority's internal review are made available to other Authorities and national and regional Offices.

IMPLEMENTATION

41. If the quality framework set out in the attached document is acceptable, consideration will need to be given as to how it should be implemented. For instance, should it be incorporated in the agreements between the International Authorities and the International Bureau, the International Search and Preliminary Examination Guidelines, the PCT Administrative Guidelines, the PCT Regulations or should it be implemented by some other means? Australia believed it should form part of the agreements between an Authority and the International Bureau while the EPO were of the view that quality should remain an issue for each Authority and would not be appropriate for inclusion in such agreements. The Netherlands would like to see the framework incorporated in the PCT Guidelines initially but ultimately presented in a document of a more general nature.

COMMENTS BY TASK FORCE MEMBERS ON OTHER SUGGESTIONS MADE BY DELEGATIONS WHEN DOCUMENT PCT/R/WG/3/4 WAS DISCUSSED AT THE THIRD SESSION OF THE WORKING GROUP ON REFORM OF THE PCT

42. The detailed comments made by those who subscribed to the task force e-forum site on the other points made by the Working Group when PCT/R/WG/3/4 was discussed are reproduced in Annex II. The following is a summary of those comments.

*A common central database containing the entire PCT minimum documentation and accessible by all Authorities would help to ensure consistency*

43. Canada, Japan, the Russian Federation, Sweden, the United States of America and FICPI supported this proposal though the United States of America expressed concerns over funding and maintaining such a database. Australia and Sweden also questioned how it would help improve consistency of citation. Austria, Spain and the EPO and felt that the idea of a central database was more a matter for consideration by the PCT Committee on Technical Cooperation.

*Mechanisms could usefully be provided for feedback from designated and elected Offices, as well as from applicants and their representatives who received searches carried out by different Offices on applications from the same patent family*

44. There was general support for this proposal though Australia, Austria and the EPO indicated that the feedback should be directed to the Authorities only. Sweden asked in what instances feedback would be given while the United States of America and Canada felt that it should be better defined.

*It may be useful for the International Bureau to arrange meetings or seminars at which Offices could exchange experience in quality control*

45. There was general support for this idea though Austria raised the question of cost while Sweden felt that bilateral visits would probably be more beneficial than meetings.

*An extensive examiner exchange program would encourage the development of consistent standards and practices*

46. There was general support for this proposal though reservations were expressed about an “extensive” exchange program in view of the resource implications for Authorities. The United States of America suggested that it might be worth exploring other ways of improving communication and cooperation among Authorities to achieve consistency. FICPI also suggested supplementing an exchange program with a common training program for examiners.

*ìTop -upî searches might be introduced into the PCT system, providing for additional search, late in the international phase, for potentially relevant material which had not yet been included in the relevant search databases at the time of the main international search*

47. Views were mixed on this proposal. Australia and Sweden were not in favor of a “top-up” search which the latter felt would result in duplication while Austria also expressed concerns and wondered whether it would result in a new fee and if the results would be

published. Canada also felt that the proposal was not feasible given current work pressures. The EPO also had reservations over “top-up” searches being carried out in the international phase while the United States of America said that such searches should only be performed as part of the international preliminary examination report (IPER). Singapore thought that “top-up” searches could be beneficial but that a detailed time/cost/benefit analysis should be undertaken. The Russian Federation also felt they could be beneficial but expressed concerns about the effect on time limits and suggested that they should be performed in conjunction with the preparation of an IPER. FICPI, expressed strong support for the proposal.

*In relation to the references to ìinventive concept(s)î in the suggested quality criteria in the Appendix, the search could consider the limitations of every claim, rather than a general inventive concept*

48. Spain and Sweden were opposed to this proposal while the EPO did not consider it feasible. Canada also felt that it would not add any value as the claims may change during the international and national phase. The United States of America in contrast supported the proposal on the grounds that it would increase the usefulness to national and regional Offices of the Preliminary Report on Patentability.

*The definition and monitoring of quality may be a matter to be dealt with in the agreement between the International Bureau and various Authorities*

49. Canada and the EPO did not consider quality to be appropriate for inclusion in the agreements between the Authorities and the International Bureau while Australia, in contrast felt that it should be part of those agreements. Canada felt that a quality framework should be incorporated in the Search and Examination Guidelines. Austria questioned the role of the International Bureau if quality was included in the agreements.

[Annex I follows]

ANNEX I

# A COMMON FRAMEWORK FOR INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION

## INTRODUCTION

1. This document sets out the main features of a quality framework for international search and preliminary examination. It describes a minimum set of criteria which each International Authority ("Authority") should use as a model for establishing their individual quality scheme.

## QUALITY MANAGEMENT SYSTEM

2. Each Authority should establish and maintain a quality management system (QMS) which sets out the basic requirements with regard to resources, administrative procedures, feedback and communication channels required to underpin the search and examination process. The QMS established by each Authority should also incorporate a quality assurance scheme for monitoring compliance with these basic requirements and the International Search and Preliminary Examination Guidelines.

3. Adoption by the Authorities of common QMS requirements, which are recognised by all Authorities and national and regional Offices, should help achieve a consistent approach. This, in turn, should help build confidence among national and regional Offices in the work done by the Authorities. It will be for each Authority to ensure that the measures they have taken to meet the requirements are effective and appropriate.

### *Resources*

4. An Authority should be able to accommodate changes in workload and should have an appropriate infrastructure to support the search and examination process and comply with the QMS requirements and Search and Examination Guidelines. The following are examples of the kind of resources and infrastructure an Authority should consider establishing:

(a) A complement of staff sufficient to deal with the inflow of work and which has the technical qualifications to search and examine in the required technical fields and the language facilities to understand at least those languages in which the minimum documentation referred to in PCT Rule 34 is written or is translated.

(b) Appropriately trained/skilled administrative staff, resources at a level to support the technically qualified staff and facilitate the search and examination process.

(c) Appropriate equipment and facilities, such as IT hardware and software, to support the search and examination process.

(d) Possession of, or access to, at least the minimum documentation referred to in PCT Rule 34, properly arranged for search and examination purposes, on paper, in microform or stored on electronic media.

(e) Comprehensive and up-to-date work manuals to help staff understand and adhere to the quality criteria and standards and follow work procedures accurately and consistently.

(f) An effective training and development programme for all staff involved in the search and examination process to ensure they acquire and maintain the necessary experience and skills and are fully aware of the importance of complying with the quality criteria and standards.

(g) A scheme for periodically testing all staff for knowledge of the requirements and standards of search and examination.

(h) A system for continuously monitoring and identifying the resources required to deal with demand and comply with the quality standards for search and examination.

*Administration*

5. An Authority should have in place the following minimum practices and procedures for handling search and examination requests and performing related functions, such as data-entry and classification:

(a) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard consistent with the Search and Examination Guidelines.

(b) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

(c) An appropriate system for handling complaints and taking corrective and preventative action where appropriate, and the application of monitoring procedures for measuring user satisfaction and perception and for ensuring their needs and legitimate expectations are met.

(d) An effective system for ensuring the continuous improvement of the established processes.

*Quality Assurance*

6. An Authority should have procedures regarding timely issue of search and examination reports of a quality standard in accordance with the Search and Examination Guidelines. Such procedures should include:

(a) An effective internal quality assurance system for self assessment, involving verification and validation and monitoring of searches and examination work for compliance with the Search and Examination Guidelines and channeling feedback to staff;

(b) A system for measuring, recording, monitoring and analysing the performance of the quality management system to allow assessment of conformity with the requirements; and

(c) A system for verifying the effectiveness of actions taken to address deficiencies and to prevent issues from recurring.

*Feedback Arrangements*

7. To help improve performance and foster continual improvement, each Authority should:

(a) Communicate the results of their internal quality assurance process to their staff to ensure that any necessary corrective action is taken and for the dissemination and adoption of best practice; and

(b) Provide for effective communication with WIPO and designated and elected Offices to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

*Communication and Guidance to Users*

8. An Authority should have in place the following arrangements for ensuring effective communication with users:

(a) Effective communication channels so that enquiries are dealt with promptly and that appropriate two-way communication is possible between applicants and examiners.

(b) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process which could be included on each Authority's website as well as in guidance literature.

INTERNAL REVIEW

9. In addition to establishing a quality assurance system for checking and ensuring compliance with the requirements set out in its QMS, each Authority should be required to establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent so as to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year.

10. It is open to each Authority to set up its own arrangements but the following is proposed as a guide to the basic components of an internal review mechanism and reporting system.

*Monitoring and Measuring*

11. The input to each review should include information on:

(a) conformity with the QMS requirements and Search and Examination Guidelines;

(b) any corrective and preventative action taken to eliminate the cause of non-compliance;

(c) any follow-up action from previous reviews;

(d) the effectiveness of the QMS itself and its processes;

(e) feedback from customer, including designated and elected Offices as well as applicants; and

(f) recommendations for improvement.

12. Suitable arrangements should be established for monitoring, recording and measuring compliance with the QMS requirements and Search and Examination Guidelines. Arrangements should also be made to measure customer satisfaction, which should include the views of designated and elected Offices as well as applicants and their representatives.

*Analysis*

13. The collected data should be analysed to determine to what extent the QMS requirements and Search and Examination Guidelines are being met. The results of the internal review should be presented to senior management within the Authority so that they can gain an objective appreciation of performance against the QMS requirements and Search and Examination Guidelines and identify opportunities for improvement and whether changes are needed.

*Improvement*

14. Each Authority should:

(a) have an established system to continually improve its performance against the QMS requirements and to review the effectiveness of its QMS; and

(b) identify and promptly take corrective action to eliminate the cause of any failure to comply with the QMS requirements and Search and Examination Guidelines.

REPORTING ARRANGEMENTS

15. There should be two stages in the reporting arrangements.

*Stage 1*

16. Each Authority should be required to submit an initial report to MIA describing what it has done to implement a QMS based on the broad requirements set out in the present document. This would help identify and disseminate best practice among Authorities. MIA should then submit a general initial report on progress to the PCT Assembly.

*Stage 2*

17. Following the initial reporting in stage 1, annual reports should be prepared by each Authority on the results of its internal review. The report should be submitted to MIA using a standard template. Without naming specific Authorities, MIA should, in turn, present a general progress report each year to the PCT Assembly.

[Annex II follows]

ANNEX II

# COMMENTS MADE BY MEMBERS OF THE TASK FORCE ON THE OTHER SUGGESTIONS MADE BY DELEGATIONS WHEN DOCUMENT PCT/R/WG/3/4 WAS DISCUSSED AT THE THIRD SESSION OF THE WORKING GROUP ON REFORM OF THE PCT

## (A) A COMMON CENTRAL DATABASE CONTAINING THE ENTIRE PCT MINIMUM DOCUMENTATION AND ACCESSIBLE BY ALL AUTHORITIES WOULD HELP TO ENSURE CONSISTENCY?

*Comment by Australia:* "We understand this has been driven by user dissatisfaction where potentially different citations have been raised by different Offices against the same invention. However we do not believe that the provision of a common central database will address this problem."

*Comment by Austria:* "This was already discussed in the last meeting and it was considered that this question should be discussed in the framework of the PCT CTC."

*Comment by Canada:* "CIPO fully supports the establishment of a common central database containing the entire PCT minimum documentation as a means of promoting consistency among International Authorities."

*Comment by the EPO*: "Should be referred to the PCT Committee on Technical Co-operation."

*Comment by Japan:* "We support."

*Comment by Russian Federation:* "Rospatent support the establishment of a common central database containing the entire PCT minimum documentation."

*Comment by Spain:* "This matter should be studied in the PCT/CTC."

*Comment by Sweden:* "We wonder in what way "common central database . . ." could help improve consistency and who will finance hosting of the database, updating it and the necessary high-speed-links."

*Comment by the United States of America:* "This proposal sets forth the establishment of a common central database. The United States supports this proposal in principle, but has concerns over funding and maintenance of such a database."

*Comment by the International Federation of Intellectual Property Attorneys (FICPI):* ". . . a common database is a *sine qua non* to the objective of achieving consistency. It is equally important that searchers/examiners should interrogate the database in a common way and should be provided with the same search tools and a common practice manual."

(B) MECHANISMS COULD USEFULLY BE PROVIDED FOR FEEDBACK FROM DESIGNATED AND ELECTED OFFICES, AS WELL AS FROM APPLICANTS AND THEIR REPRESENTATIVES WHO RECEIVED SEARCHES CARRIED OUT BY DIFFERENT OFFICES ON APPLICATIONS FROM THE SAME PATENT FAMILY

*Comment by Austria:* "This obviously covers only a feedback to the Authorities not to a QRP."

*Comment by Australia:* "We support this because feedback is an inherent part of a quality system. However we believe the feedback should be given directly to the International Authority."

*Comment by Canada:* "While, in general, CIPO supports a feedback mechanism, once again we would appreciate a more detailed description of the proposed mechanism."

*Comment by the EPO:* "Supported, however feedback should only be to the International Authorities themselves, not to any external body."

*Comment by Spain:* "We can support."

*Comment by Sweden:* "It is not clear to what instances the feedback will be given."

*Comment by the United States of America:* "The United States can support a proposal to implement a system that would allow the national and regional Offices the ability to provide feedback to the Authorities. However, the nature of the feedback must be better defined in line with our previous comments to paragraph 6(d)(ii) above."

(C) IT MAY BE USEFUL FOR THE INTERNATIONAL BUREAU TO ARRANGE MEETINGS OR SEMINARS AT WHICH OFFICES COULD EXCHANGE EXPERIENCE IN QUALITY CONTROL

*Comment by Australia:* "We believe this would foster understanding between Offices and enable all Offices to learn and contribute."

*Comment by Austria:* "The Austrian Patent Office can support this; however, also in this context we would like to raise the question of costs."

*Comment by Canada:* "CIPO fully supports a greater forum for the exchange of ideas concerning quality control."

*Comment by the EPO:* "Supported."

*Comment by Japan:* "We support."

*Comment by the Netherlands:* "Organisation of meetings and seminars to exchange experience will be very useful. It could also be worthwhile to organise presentations on key aspects of the quality system."

*Comment by Sweden:* "Bilateral visits would probably yield more than the proposal international meetings."

*Comment by Spain:* "We can support."

(D) AN EXTENSIVE EXAMINER EXCHANGE PROGRAM WOULD ENCOURAGE THE DEVELOPMENT OF CONSISTENT STANDARDS AND PRACTICES

*Comment by Australia:* "We support this but have reservations about an "extensive" program as the feasibility of such a program would be dependent on the available human and financial resources of individual International Authorities."

*Comment by Austria:* "In principle the Austrian patent Office can support this, however in the current workload situation we are not in favour that the exchange should be extensive."

*Comment by Canada:* "While the productivity and financial implications associated with an extensive exchange program raise some concern, on general CIPO is supportive of this type of initiative."

*Comment by the EPO:* "Supported, however the word extensive should be removed, as this would perhaps not be realistic in the current work environment."

*Comment by Japan:* "We support."

*Comment by Spain:* "We can support."

*Comment by Sweden:* "This proposal is very well worth pursuing, since it is an effective means to ensure harmonisation. However, for economical and production reasons we are not in favour of "extensive" examination exchange, but we have good experience of a more moderate exchange of examiners."

*Comment by the United States of America:* "This proposal calls for establishment of an extensive examiner exchange program. While we share the goal of encouraging development of consistent standards and practice, we have some reservations concerning the effectiveness of such a program in achieving this goal. While it is possible that a limited, voluntary exchange program might have some value, an extensive program as proposed would be very resource intensive and would likely yield little in the way of results for the amount of funds expended. It may be helpful to investigate other ways of improving communication and cooperation among offices to achieve the stated goal of consistency in a more effective manner."

*Comment by FICPI:* ". . . searchers should be given common training, preferably under central control . . . supplemented with systematic and extensive exchange of examiners between offices."

(E) "TOP-UP" SEARCHES MIGHT BE INTRODUCED INTO THE PCT SYSTEM, PROVIDING FOR ADDITIONAL SEARCH, LATE IN THE INTERNATIONAL PHASE, FOR POTENTIALLY RELEVANT MATERIAL WHICH HAD NOT YET BEEN INCLUDED IN THE RELEVANT SEARCH DATABASES AT THE TIME OF THE MAIN INTERNATIONAL SEARCH

*Comment by Australia:* "We would not support the concept of supplementary searches being carried out routinely because we believe this would largely result in duplication of work. However, we acknowledge that there may be limited occasions when a "top-up" search may be necessary."

*Comment by Austria:* "We have some concerns about this proposal. At this time there is no possibility for this in present PCT-Rules. In addition we are wondering if this would not result in a new fee for the applicants. How would the results of the "Top-up" search be published?"

*Comment by Canada:* "This proposal is not feasible in the current environment of unprecedented growth and escalating backlogs."

*Comment by the EPO:* "This was mentioned by some delegates during the last meeting of the PCT Reform Working group, however we have reservations as to the feasibility of such a system and in any event would oppose any move to restrict the possibility of designated Offices carrying out their own supplementary search reports after entry to the national/regional phase."

*Comment by Russian Federation:* "Top-up" searches could be beneficial, but we have some concerns about time limits. It seems to us that such searches should be performed in conjunction with the preparation of an IPER."

*Comment by Singapore:* "The proposal on top-up searches as we understand from previous PCT documents, is focused on giving applicants an opportunity to file such requests with another Authority (An Authority different from the Authority that conducted the International Search) if time permits and the applicant furnishes whatever fees necessary. The results of such searches could be relied upon during the national or regional Phase, and possible fee reductions could be in place, where appropriate. Such top-up searches could be beneficial but a more detailed time/cost/benefit analysis of having this feature in the international phase of the PCT should be made."

*Comment by Sweden:* "During the times there have been proposals for additional searches, for parallel searches, for stocked searches and now for top-up search. The international search is done normally within 16 months from priority date and in that case 4 months from the international filing date. At that time the documentation databases should be updated with relevant material. The cost to make a new database-search must be weighed against the possibility to find relevant material added after the ordinary search. We think that service can be given by other than the ISA. Thus we oppose to introduce the proposed top-up-search."

*Comment by the United States of America:* "The concept of performing a "top-up" or updated search may have some benefit so long as it is envisioned that such a search is only to be performed in conjunction with the preparation of an IPER (i.e. not at a time prior to 30 months in cases where no Demand has been filed or where the issuance of the IPER occurred substantially prior to the 30 month period."

*Comment by FICPI:* "The PCT searching system at present suffers from the disadvantage that it is not able to find prior art, especially prior patent applications, which were filed shortly before the international filing date. For this reason FICPI strongly support the proposal to provide for additional "top-up" searching later in the international phase."

(F) IN RELATION TO THE REFERENCES TO "INVENTIVE CONCEPT(S)" IN THE SUGGESTED QUALITY CRITERIA IN THE APPENDIX, THE SEARCH COULD CONSIDER THE LIMITATIONS OF EVERY CLAIM, RATHER THAN A GENERAL INVENTIVE CONCEPT

*Comment by Austria:* "It is not clear to us what this proposal means. However, we have the vague impression this has nothing to do with the question of quality."

*Comment by Canada:* "CIPO does not believe that this suggestion would add any value to the process as the claims may change during both the international and national phase."
*Comment by the EPO:* "Not feasible."

*Comment by Spain:* "We are not able to support this point."

*Comment by Sweden:* "Not support. The quality of search and examination in PCT is defined through PCT Articles, Rules, Administrative Instructions and Guidelines for search and examination. In the agreement between the ISA/IPEA and WIPO it is stated that in carrying out search and examination the ISA and IPEA shall apply and observe all the common rules for search and examination."

*Comment by the United States of America:* "The United States supports this proposal. We believe that it would increase the usefulness of the Preliminary Reports on Patentability to all national and regional Offices."

(G) THE DEFINITION AND MONITORING OF QUALITY MAY BE A MATTER TO BE DEALT WITH IN THE AGREEMENT BETWEEN THE INTERNATIONAL BUREAU AND VARIOUS AUTHORITIES

*Comment by Australia:* "Assuming that the quality system is set up appropriately, we believe that this should be part of the agreement between an Authority and WIPO and that it should be a requirement to be met by all new Authorities."

*Comment by Austria:* "Also in this point we are not clear what is meant. Does this mean that the International Bureau shall control the work of the Authority? However in this case it would mean that only the formal aspects of the report would be reviewed because the IB lacks the technical staff and knowledge to review the contents of the reports."

*Comment by Canada:* "CIPO feels that the quality assurance framework and the associated standards should be reflected in the Search and Preliminary Examination Guidelines and not in the agreement between the International Bureau and the respective International Authorities."

*Comment by the EPO:* "Once again our view is that quality must remain an issue for each international Authority and would not be appropriate for inclusion in the agreement between the authority concerned and the International Bureau."

[End of Annex II and of document]

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WIPO

PCT/R/WG/4/13
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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)

## Fourth Session
## Geneva, May 19 to 23, 2003

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

*Document prepared by the International Bureau*

1. The proposals appearing on the following pages were made by Switzerland in a submission to the International Bureau received on May 1, 2003.

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

[Annex follows]

ANNEX

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


## SUMMARY

The present document contains the proposals by Switzerland regarding the declaration of the source of genetic resources and knowledge, innovations and practices of indigenous and local communities (traditional knowledge), in patent applications, if an invention is directly based on such resources or traditional knowledge. These proposals are to be seen in the wider context of the efforts of various international fora in the area of access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization. These international fora include in particular the Convention on Biological Diversity (CBD); the Food and Agriculture Organization (FAO); the "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" (IGC) of the World Intellectual Property Organization (WIPO); and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO). The proposals are intended to enhance the cooperation between these international fora and the mutual supportiveness of the applicable international agreements.

With regard to the underlying issues, Switzerland holds the view that a fair and balanced approach must be taken: on one hand, Switzerland supports the effective protection of biotechnological innovations through intellectual property rights, in particular patents. On the other hand, a fair and balanced approach necessitates effective, efficient, practical and timely solutions 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. Various approaches are currently being discussed at the international level, including the realization of measures that increase transparency in the context of access and benefit sharing, in particular, with regard to the obligations of the users of genetic resources and/or traditional knowledge (transparency measures). Switzerland considered in detail the options available and the possible modalities and implications of such transparency measures. Based on these considerations, Switzerland submits the following proposals:

Switzerland proposes to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. More specifically, Switzerland proposes to amend the Regulations under the Patent Cooperation Treaty (PCT) 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. 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.

By reference, the proposed amendment to the PCT would also apply to the Patent Law Treaty (PLT). Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications. Based on the PLT, national law may foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention.

In the view of Switzerland, the proposed amendments to the PCT-Regulations 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.

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

TABLE OF CONTENTS

## I. OVERVIEW

1. The present document contains proposals by Switzerland regarding the declaration of the source of genetic resources and knowledge, innovations and practices of indigenous and local communities (traditional knowledge), in patent applications, if an invention is directly based on such resources or traditional knowledge.

2. Part II outlines the general approach that according to Switzerland should be taken with regard to the underlying issues (see paras. 3-4). Part III summarizes the recent developments at the international level that are of importance with regard to transparency measures under patent law (see paras. 5-11), and Part IV provides an overview of the current international legal framework affecting the form, structure and contents of such measures (see paras. 12-19). Part V presents the proposals of Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications (see paras. 20-29): Switzerland proposes to amend Rules 51*bis*.1 and 4.17 of the Regulations under the Patent Cooperation Treaty (PCT) to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in international patent applications, if an invention is directly based on such resources or knowledge. By reference, these amendments would also apply to national patent applications that are in accordance with the provisions of the Patent Law Treaty (PLT). Finally, in Part VI, Switzerland invites the World Intellectual Property Organization (WIPO), in close collaboration with the Convention on Biological Diversity (CBD), to consider the establishment of 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 (see paras. 30-32).

## II. A FAIR AND BALANCED APPROACH

3. With regard to the issues addressed in this document, Switzerland holds the view that a fair and balanced approach must be taken: On one hand, Switzerland supports the effective protection of biotechnological innovations through intellectual property rights, in particular patents. On the other hand, a fair and balanced approach necessitates effective, efficient, practical and timely solutions 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. This is why Switzerland has been actively supporting efforts to find these solutions in various international fora, including the CBD;[1] the Food and Agriculture Organization (FAO); the "Intergovernmental Committee on Intellectual Property and Genetic

[1] In the CBD, Switzerland presented the "Draft Guidelines on Access and Benefit-Sharing Regarding the Utilization of Genetic Resources," which formed an important basis in the discussions that led to the adoption of the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" by the sixth Conference of the Parties (COP6) of the CBD in April 2002. At COP6, Switzerland furthermore presented a study on the certification for bioprospecting activities (see Lyle Glowka, Towards a Certification System for Bioprospecting Activities (document UNEP/CBD/COP/6/CH/RPT); this document can be found at <http://www.biodiv.org/doc/meetings/cop/cop-06/other/cop-06-ch-rpt-en.pdf>).

Resources, Traditional Knowledge and Folklore" (IGC) of WIPO;[2] and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council).[3]

4. One crucial issue that these international fora have been addressing is the need for and the realization of measures that increase transparency in the context of access to genetic resources and/or 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 (hereinafter "transparency measures"). Such measures will enhance the mutual supportiveness of the applicable international agreements and can only be successfully realized if all relevant international fora coordinate their efforts closely and strive for coherent results. Switzerland holds the view that transparency measures are an important element in the fair and balanced approach that was advanced above. This is why Switzerland considered in detail the various options available for such measures and their possible modalities and implications. Based on these considerations, Switzerland elaborated proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications presented in Part V, below.

## III. RECENT DEVELOPMENTS AT THE INTERNATIONAL LEVEL

5. When addressing the issue of transparency measures under patent law, the developments in several international fora need to be considered. Of primary importance are the following:

6. The PLT, adopted 1 June 2000 by a diplomatic conference convened by WIPO, aims at harmonizing certain formalities in national patent laws with regard to the acquisition and maintenance of patents. Among others, it contains provisions on the formal requirements that patent applicants must fulfill and limits the freedom of its Contracting Parties to introduce additional such requirements in their national patent laws.

7. The 31st FAO Conference adopted 3 November 2001 the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO-IT). This treaty contains, among others, provisions on access to plant genetic resources for food and agriculture (PGRFA) and the sharing of the benefits arising out of their utilization.

8. The Doha Ministerial Declaration, adopted 14 November 2001, states in para. 19 that the TRIPS Council is instructed, "in pursuing its work program including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1."

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[2] In the past meetings of the IGC, Switzerland proposed several practical and concrete steps and solutions with regard to the issues on the agenda of the committee. Furthermore, Switzerland supported a proposal that WIPO shall provide additional financial means allowing for the increased participation of indigenous and local communities in the future meetings of the IGC.

[3] Among others, Switzerland proposed an international gateway for traditional knowledge (see paras. 16-19 of document IP/C/W/284).

9. The sixth meeting of the Conference of the Parties (COP6) of the CBD was held in April 2002. Among others, COP6 adopted the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" (Bonn Guidelines). According to its para. 1, this voluntary instrument "may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10(c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing." With regard to transparency measures, the Bonn Guidelines state in para. 16(d) that

> "Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, inter alia, the following measures:
>
> [...]
>
> (ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights[.]"[4]

10. The IGC of WIPO decided at its third meeting held in June 2002 to carry out the technical study referred to in para. 4 of Section C of Decision VI/24 adopted by COP6. In this paragraph, WIPO is invited

> "to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia:

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[4] The following decisions adopted by COP6 also refer to the disclosure of the source of genetic resources and traditional knowledge in patent applications: In para. 1 of Section C of Decision VI/24 ("Access and benefit-sharing as related to genetic resources"), the Conference of the Parties

> "[i]nvites Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted[.]"

Furthermore, in para. 46 of Decision VI/10 ("Article 8(j) and related provisions"), the Conference of the Parties

> "[i]nvites Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant to the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development[.]"

(a) Genetic resources utilized in the development of the claimed inventions;

(b) The country of origin of genetic resources utilized in the claimed inventions;

(c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;

(d) The source of associated traditional knowledge, innovations and practices; and

(e) Evidence of prior informed consent[.]"

11. The World Summit on Sustainable Development (WSSD), held in August/September 2002, calls in para. 42(o) of the Plan of Implementation on States to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources." The General Assembly of the United Nations invites in para. 8 of Resolution A/Res/57/269 adopted at the 57th session the COP of the CBD "to take appropriate steps in this regard." It is foreseen that the seventh meeting of the Conference of the Parties (COP7) of the CBD, to be held in April 2004, will address the issue of an international regime.

## IV. THE CURRENT INTERNATIONAL LEGAL FRAMEWORK

12. When addressing the issue of transparency measures under patent law, the provisions of several international agreements need to be considered. These are in particular the PCT, the PLT once it enters into force, the TRIPS Agreement, the CBD and the FAO-IT once it enters into force.

### *(1) The Patent Cooperation Treaty (PCT)*

13. The PCT provides a widely used centralized system for receiving and searching international patent applications. According to Art. 27.1, "[n]o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this treaty and the regulations." In this regard, Rules 4.1 and 51bis.1 of the Regulations under the PCT are of particular importance:

- Rule 4.1 enumerates the mandatory and optional contents of the request of an international patent application. According to Rule 4.1(c)(iii), such request may contain "declarations as provided in Rule 4.17." Rule 4.17 deals with certain declarations that are required by national laws in accordance with Rule 51bis.1(a). Rule 4.17 permits applicants to include in the request certain declarations corresponding to the matters set out in Rule 51bis.1(a)(i) to (v), relating to which designated Offices may require evidence or documents. According to Rule 4.18(a), "[t]he request shall contain no matter other than that specified in rules 4.1 to 4.17 [...]"; furthermore, Rule 4.18(b) requires the receiving Office to delete ex officio any such additional matter.

- Present Rule 51*bis*.1 lists in subparas. (a) to (f) a number of matters relating to which the applicant may be required to furnish documents or evidence under the national law applicable by the designated Office. This rule provides clarity for both applicants and designated Offices that such items may be required to be furnished by the applicant under the national law applicable by the designated Office.

14. The current Rule 4 of the Regulations under the PCT does not require the declaration of the source of genetic resources and/or traditional knowledge in international patent applications. Furthermore, Rule 4 prevents patent applicants submitting an international patent application from voluntarily including any such information as part of the PCT procedure, except in the specification, that is, the description, of the invention. Furthermore, Rule 51*bis*.1, as currently worded, does not expressly mention the possibility of designated Offices to require the applicant to furnish information on the source of genetic resources and/or traditional knowledge under the national law applicable by the designated Office.

*(2) The Patent Law Treaty (PLT)*

15. Art. 6.1 of the PLT, which deals with the form and contents of national patent applications, states that

> "[e]xcept where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:
>
> (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;
>
> (ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started[.]"

In this context, Rules 4.1 and 51*bis*.1 of the Regulations under the PCT are of particular importance.

16. Art. 10 of the PLT states that "[n]on-compliance with one or more of the formal requirements referred to in Articles 6(1) [...] with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention." The validity of granted patents is thus not affected should the patent applicant not comply with the formal requirements enumerated in Art. 6.1. The only exception to this general rule is where such non-compliance results from fraudulent intention. Art. 10 of the PLT, however, only applies once a patent is granted, whereas it does not apply to the national patent granting procedure as such. Art. 10 does therefore not prevent Contracting Parties of the PLT from introducing sanctions for non-compliance with formal requirements prior to the granting of a patent (see Art. 6.8 of the PLT).

*(3) The TRIPS Agreement*

17. Art. 27.1 of the TRIPS Agreement does not allow for any other substantive conditions for patentability than (1) novelty, (2) inventive step or non-obviousness, and (3) capability of industrial application or usefulness. Members are therefore prohibited from introducing different or additional substantive conditions for patentability. Furthermore, according to Art. 29, patent applicants must "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art [...]." And finally, Art. 62.1 only allows for "reasonable procedures and formalities,"[5] prohibiting Members from burdening patent applicants with procedures and formalities that are not reasonable within the meaning of Art. 62.1.

*(4) The Convention on Biological Diversity (CBD)*

18. With regard to access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, Arts. 8(j),[6] 10(c), 15.4, 15.5,[7] 15.7[8] and 16.5[9] of the CBD are of particular relevance. The CBD itself does not prescribe specific transparency measures that the Contracting Parties should introduce in their national legislation. These measures are addressed in greater detail in the Bonn Guidelines and in two decisions adopted by COP6: Para. 16(d) of the Bonn Guidelines[10] as well as para. 46 of Decision VI/10 and para. 1 of Section C of Decision VI/24[11] all refer to the disclosure of the source of genetic resources and traditional knowledge in patent applications.

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5 Art.62.1 of the TRIPS Agreement states that "Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this agreement."

6 Art. 8(j) of the CBD requires Contracting Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices[.]"

7 Art. 15.5 of the CBD states that "[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."

8 Art. 15.7 of the CBD states that "[e]ach Contracting Party shall take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

9 Art. 16.5 of the CBD states in the context of access to and transfer of technology that "[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

10 See para. 9 above.

11 See footnote 4 above.

*(5) The International Treaty on Plant Genetic Resources for Food and Agriculture of FAO (FAO-IT)*

19. With regard to access to PGRFA and the sharing of the benefits arising out of their utilization, Arts. 12.2, 12.3(b), 12.4, 12.5 and 13.2 of the FAO-IT are of particular relevance. The FAO-IT introduces a specific transparency measure, that is, an internationally agreed standard material transfer agreement (MTA). This measure, however, is not related to the international intellectual property rights system.

## V. PROPOSALS BY SWITZERLAND REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND THE RELATED TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

20. Based on the aforementioned developments at the international level and the applicable provisions of relevant international agreements, Switzerland considered in detail the various options available for transparency measures and their possible modalities and implications. These considerations were guided by the following principles: First, any such measure should allow to attain the desired transparency in an effective and efficient manner. Second, any transparency measure should ensure legal certainty, be practicable and avoid unnecessary administrative burdens and costs for patent applicants and patent authorities. Third, any measure should leave States with as much freedom as possible, enabling them to introduce solutions at the national level that take into account national needs and interests. And fourth, the proposed transparency measure should be mutually supportive with existing obligations of relevant international agreements. Based on these considerations, Switzerland submits the following proposals to the fourth session of the Working Group on Reform of the PCT:

*(1) Proposal to Amend Rule 51bis.1 of the Regulations Under the PCT*

21. Switzerland proposes to introduce a new subpara. (g) in Rule 51*bis*.1 of the Regulations under the PCT, which could read as follows:

> "(g) The national law applicable by the designated Office may, in accordance with Article 27, require the applicant
>
> (i) to declare the source of a specific genetic resource to which the inventor has had access, if an invention is directly based on such a resource; if such source is unknown, this shall be declared accordingly;
>
> (ii) to declare the source of knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity, if the inventor knows that an invention is directly based on such knowledge, innovations and practices; if such source is unknown, this shall be declared accordingly."

22. With regard to the terminology used in this proposal, the following can be said:

- First, the proposal uses the rather general term "source." This term is intended to be understood in its broadest sense possible: It not only includes other terms used

in this context such as "origin," "geographical origin,"[12] "country of origin of genetic resources"[13] or "Contracting Party providing genetic resources,"[14] but also any other source such as publications in scientific journals or books,[15] databases on traditional knowledge, or *ex situ* collections of genetic resources. This broad meaning of the term "source" will help to avoid the difficulties and uncertainties that could arise with other terms used in this context. Furthermore, it allows to indicate whether the genetic resource in question was obtained from the Multilateral System established under the FAO-IT or on mutually agreed terms according to the CBD. This is of importance since the rules of the FAO-IT on access to PGRFA and the sharing of the benefits arising out of their utilization differ from the respective rules of the CBD. Additionally, the term "source" allows to specifically declare the region, community or individual that provided the knowledge, innovations and practices. And finally, if genetic resources or traditional knowledge have more than one source, this can be declared accordingly. This may, for example, apply to traditional knowledge of a local community that is described in a scientific journal. In this case, the declaration of the secondary source "scientific journal" would not be adequate; instead, the local community would have to be declared as the primary source as well.

- Second, the proposal uses the term "genetic resource" instead of terms such as "biological material"[16] to ensure consistency with the CBD and the FAO-IT. Art. 2 of the CBD defines the term "genetic resources" as meaning "genetic material of actual or potential value," and the term "genetic material" as meaning "any material of plant, animal, microbial or other origin containing functional units of heredity." These definitions are in harmony with the definitions of the terms "PGRFA"[17] and "genetic material"[18] in Art. 2 of the FAO-IT.

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12 This term is used in Recital 27 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (EU Biotech Directive).

13 This term is used in Art. 15.3 of the CBD. It is defined in Art. 2 of the CBD as "the country which possesses those genetic resources in in-situ conditions.*î*

14 This term is used Arts. 15.5 and 15.7 of the CBD. Art. 2 of the CBD defines the term "country providing genetic resources" as meaning "the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country."

15 This may, for example, be the case where knowledge, innovations and practices of indigenous and local communities, were found in a scientific journal.

16 This term is used in Recital 27 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (EU Biotech Directive).

17 Art. 2 of the FAO-IT defines the term "PGRFA" as meaning "any genetic material of plant origin of actual or potential value for food and agriculture."

18 Art. 2 of the FAO-IT defines the term "genetic material" as meaning "any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity."

- And third, the proposal uses the term "knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity" instead of the term "traditional knowledge." This is to ensure consistency with Art. 8(j) of the CBD and to avoid difficulties that could arise with the term "traditional knowledge," for which at present no internationally agreed definition exists.[19] As the proposed declaration of the source of knowledge, innovations and practices of indigenous and local communities concerns patent law, it is self-evident that the focus will be on the technical forms of such knowledge, innovations and practices.

23. Rule 51*bis*.1(g) would only apply if the national law of a Contracting Party of the PCT requires patent applicants submitting an international patent application to declare the source of genetic resources and/or knowledge, innovations and practices, in their patent applications. It is thus the national legislator who decides whether such a declaration is required or not. In case an application does not contain the required declaration, the national law may foresee that the application is not processed any further until the patent applicant has furnished the required declaration; the national law may also foresee that non-declaration will not affect the processing of patents.[20]

24. The proposed wording "if an invention is directly based on" makes clear that the requirement is complied with if an invention makes immediate use of the genetic resource and/or the knowledge, innovations and practices.

25. Patent applicants will only be able to declare the source of genetic resources and knowledge, innovations and practices, if in fact they do have information about this source. Patent applicants, however, that have no such information, should not be freed from any obligations. For this reason, it is proposed that patent applicants can be required to declare that the source is unknown to them. Consequently, if an invention fulfills the conditions of the new Rule 51*bis*.1(g), the proposed wording would explicitly enable national legislation to require patent applicants to either declare the source of the genetic resource or knowledge, innovations and practices, or to declare that this source is unknown to them.

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[19] The following definition of the term "traditional knowledge", for example, would seem much too broad for the purposes of the proposed new subpara. (g) in Rule 51bis.1: This term is defined as "encompassing traditional and tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other traditional and tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields." (See para. 13 of document WIPO/GRTKF/IC/Q.2 "Questionnaire of Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing").

[20] This is, for example, the case with the EU Biotech Directive. Recital 27 of this directive reads as follows: "Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if know; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patens[.]"

*(2) Proposal to Amend Rule 4.17 of the Regulations Under the PCT*

26. Complementary to the new subpara. (g) of Rule 51*bis*.1, Switzerland proposes to introduce a new subpara. (vi) in Rule 4.17 of the Regulations under the PCT, which could read as follows:

> "(vi) a declaration as to the source of a specific genetic resource and/or knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity, as referred to in Rule 51bis.1(g)."

27. This proposal 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. This would further simplify procedures related to the declaration of the source of genetic resources and/or knowledge, innovations and practices, with regard to international patent applications.

28. The standard wording in the Administrative Instructions for such a declaration would have to be amended accordingly.

*(3) Effects of the Proposals by Switzerland on the PLT*

29. With regard to "requirements relating to form or contents of an application," Art. 6.1 of the PLT refers to the provisions of the PCT, in particular Rules 4.1 and 51bis of the Regulations under the PCT. Based on the reference to the PCT contained in Art. 6.1 of the PLT, the proposed new Rule 51bis.1(g) of the PCT would also apply to the PLT. The Contracting Parties of the PLT would thus be able to introduce in their national patent laws a declaration requirement that applies to national patent applications. Based on Art. 10 of the PLT, the national patent law may foresee that the validity of a granted patent is affected by a lacking or incorrect declaration of the source, if this is due to "fraudulent intention." This could, for example, be the case if the patent applicant submits an intentional wrongful declaration that the source is unknown.

## VI. ESTABLISHMENT OF A LIST OF GOVERNMENT AGENCIES COMPETENT TO RECEIVE INFORMATION ON THE DECLARATION

30. Several factors weaken the effectiveness of the proposed requirement to declare the source of a genetic resource and/or knowledge, innovations and practices, in patent applications: If the source of a genetic resource or knowledge, innovations and practices, is merely declared in patent applications, States and other stakeholders interested in verifying whether they are named in patent applications would have to scrutinize the large number of patent applications filed annually worldwide. Additionally, some patent offices do not publish patent applications at all or only after the expiration of a certain period of time; furthermore, it may take several years from the filing of a patent application to the granting of a patent and its publication. Thus, if patent applications are not published, the declaration of the source would not become publicly accessible until the patent is granted and published.

31. This could be changed if the office receiving a patent application containing a declaration of the source of a genetic resource or knowledge, innovations and practices, would inform a government agency of the State declared as the source about the respective declaration. Particularly well suited for this task would seem to be the national focal point for access and benefit sharing as described in para. 13 of the Bonn Guidelines. Switzerland therefore invites WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies competent to receive this information. This list could be made accessible through WIPO and the Clearing House Mechanism (CHM) of the CBD. States interested in receiving such information could indicate to WIPO the competent government agency, which would then be included in the proposed list.

32. The information about the declaration could be provided in a standardized letter which is sent to the competent government agency in the State indicated in the patent application. This letter would inform this government agency that the respective State has been declared as the source of the genetic resource or knowledge, innovations and practices, and contain the name and address of the patent applicant.

## VII. CONCLUSIONS

33. The proposals submitted by Switzerland would explicitly enable the Contracting Parties of relevant international agreements, including the PCT, the PLT, the TRIPS Agreement, the CBD and the FAO-IT, to fulfill their respective obligations. This applies in particular to Art. 27.1 of the PCT, which prohibits additional requirements relating to the form or contents of international patent applications; Art. 6.1 of the PLT, which prohibits additional requirements relating to the form or contents of national patent applications; Arts. 27.1 and 62.1 of the TRIPS Agreement, which prohibit additional criteria of patentability and unreasonable procedures and formalities, respectively; and Arts. 8(j), 15.4, 15.5, 15.7 and 16.5 of the CBD.

34. The proposals submitted by Switzerland furthermore provide the means to ensure that the relevant international agreements on intellectual property, the CBD and the FAO-IT can be implemented in a mutually supportive way. Additionally, the proposals will enable the Contracting Parties of the CBD to implement the provisions of the Bonn Guidelines, in particular their para. 16(d), as well as para. 46 of Decision VI/10 and para. 1 of Section C of Decision VI/24 adopted by COP6.

35. Transparency measures have been called for that enable the Contracting Parties of the CBD to verify whether their national systems of prior informed consent (PIC) have been adhered to and whether benefits arising are shared fairly and equitably. In the view of Switzerland, this task can best be carried out by the Contracting Party providing the genetic resources in accordance with Art. 15.5 of the CBD. In order to facilitate this task, Switzerland proposes to explicitly enable national patent legislation to require the declaration of the source of genetic resources in patent applications.[21] Additionally, Switzerland invites

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[21] This is acknowledged in para. 1 of Section C of Decision VI/24 adopted by COP6 of the CBD, according to which the disclosure of the source of genetic resources in applications for intellectual property rights is “a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted.”

WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies that would be competent to receive information about patent applications containing declarations of the source. The disclosure and the respective information would allow the Contracting Party providing the genetic resources to verify whether the patent applicant has fulfilled the requirements and procedures of its national system of PIC and whether provision has been made for fair and equitable benefit sharing.

[End of Annex and of document]