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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 page 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 forums 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 forums 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 forums 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 law 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. d

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TABLE OF CONTENTS

I. OVERVIEW	4
II. A FAIR AND BALANCED APPROACH	4
III. RECENT DEVELOPMENTS AT THE INTERNATIONAL LEVEL	5
IV. THE CURRENT INTERNATIONAL LEGAL FRAMEWORK	7
(1) The Patent Cooperation Treaty (PCT)	7
(2) The Patent Law Treaty (PLT)	8
(3) The TRIPS Agreement	9
(4) The Convention on Biological Diversity (CBD)	9
(5) The International Treaty on Plant Genetic Resources for Food and Agriculture of FAO (FAO -IT)	10
V. PROPOSALS BY SWITZERLAND REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND THE RELATED TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS	10
(1) Proposal to Amend Rule 51 <i>bis</i> .1 of the Regulations Under the PCT	10
(2) Proposal to Amend Rule 4.17 of the Regulations Under the PCT	13
(3) Effect of the Proposals by Switzerland on the PLT	13
VI. ESTABLISHMENT OF A LIST OF GOVERNMENT AGENCIES COMPETENT TO RECEIVE INFORMATION ON THE DECLARATION	13
VII. CONCLUSIONS	14

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 innovation 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; 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 discussion 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.”

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 jurisdictions 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:

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 application s 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 of 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]ational law shall require compliance with requirements relating to the form or content 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 51 bis.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 51 bis.1(a). Rule 4.17 permits applicants to include in the request certain declarations corresponding to the matters set out in Rule 51 bis.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 15.7⁸ and 16.5⁹ 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 Guidelines¹⁰ as well as para. 46 of Decision VI/10 and para. 1 of Section C of Decision VI/24¹¹ all refer to the disclosure of the source of genetic resources and traditional knowledge in patent applications.

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 (M-TA). 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 the various 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 measures should be mutually supportive with existing obligations of relevant international agreements. Based on these considerations, Switzerland submits the following proposal to the fourth session of the Working Group on Reform of the PCT:

(1) *Proposal to Amend Rule 51 bis. 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 sources 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 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 this 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.

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.”

¹⁴ This term is used in 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.

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 51 *bis*.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 known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents[.]”

(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 51 *bis.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) *Effect of the Proposals by Switzerland on the PLT*

29. With regard to “requirements relating to former contents of an application,” Art. 6.1 of the PLT refers to the provisions of the PCT, in particular Rules 4.1 and 51 *bis* 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 51 *bis.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 applicants submit 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 officer receiving a patent application containing a declaration of the source of 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 forth 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

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 resource 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]