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ARTICLE 27.3(b), THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY, AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

Communication from Switzerland

Revision

The present document is a revised version of the Swiss communication previously circulated in document IP/C/W/400. It contains, as an annex, Switzerland's proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, which was circulated as WIPO document PCT/R/WG/4/13 to the Fourth Session of the Working Group on Reform of the Patent Cooperation Treaty held on 19-23 May 2003.

EXECUTIVE SUMMARY

The present communication from Switzerland complements the communication of 15 June 2001[1] on the review of Article 27.3(b) and addresses the issues set out in paragraph 19 of the Doha Ministerial Declaration. As a concrete and practical measure, Switzerland presents proposals regarding the declaration of the source of genetic resources and/or traditional knowledge in patent applications.

I. A FAIR AND BALANCED APPROACH

With regard to the issues addressed in this communication, 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. Switzerland considers the current wording of Article 27.3(b) to provide a well-balanced solution that takes into account the interests and needs of all Members of the WTO. 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.

II. PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

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

[1] See document IP/C/W/284.

(PCT) of the World Intellectual Property Organization (WIPO) 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 based on or uses 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) of WIPO. 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.

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, including 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 WIPO; and the TRIPS Council. The proposals are intended to enhance the cooperation between these international forums and the mutual supportiveness of the applicable international agreements.

III. THE FARMERS' PRIVILEGE

In the view of Switzerland, the current wording of Article 30 of the TRIPS Agreement allows the national legislator to introduce the Farmers' Privilege in the national patent law. In the ongoing revision of the Swiss Federal Law on Patents for Inventions (LPI), it is foreseen to introduce the Farmers' Privilege in the Swiss patent legislation.

IV. THE PROTECTION OF TRADITIONAL KNOWLEDGE

In the view of Switzerland, the IGC of WIPO is the primary international forum to deal with the intellectual property-related issues of the protection of traditional knowledge. The work of the TRIPS Council on these issues should benefit from and draw upon the work being carried out by the IGC of WIPO. This approach will help to avoid the duplication of efforts and outcomes.

At the outset of the discussions on the protection of traditional knowledge, it is necessary to at least establish a working definition of the term "traditional knowledge" and to determine the objectives of this protection. Only the clarification of these two very fundamental issues will allow to focus the discussions and bring the results necessary for an effective protection of traditional knowledge.

With regard to specific measures for the protection of traditional knowledge, Switzerland considers the international gateway it proposed and described in greater detail in its communication of 15 June 2001, to be of crucial importance.

V. THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

Switzerland generally takes the view that the relationship between the trade regime as established by the WTO and multilateral environmental agreements (MEAs) should be governed by the principles of no hierarchy, mutual supportiveness and deference. With regard to the TRIPS Agreement and the CBD, Switzerland thus holds the view that they can and should be implemented without conflict. Accordingly, there is no need to modify the provisions of either one of these agreements.

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OVERVIEW

1. Switzerland expressed its views on the review of Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in its communication of 15 June 2001[2], and in several oral interventions to the TRIPS Council. This present communication further elaborates the views of Switzerland on Article 27.3(b) and addresses the issues set out in paragraph 19 of the Doha Ministerial Declaration, that is, the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), the protection of traditional knowledge, and other relevant new developments. As a practical measure supporting a fair and balanced approach, Switzerland presents proposals regarding the declaration of the source of genetic resources and/or traditional knowledge in patent applications, if an invention is based on or uses such resources or knowledge.

I. A FAIR AND BALANCED APPROACH

2. With regard to the issues addressed in this communication, 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. As stated in its communication of 15 June 2001, Switzerland considers the current wording of Article 27.3(b) to provide a well-balanced solution, which takes into account the interests and needs of all Members, whether they are developing or developed countries. Switzerland is thus in favor of the current wording of Article 27.3(b) and the existing level of protection of biotechnological inventions and the flexibility of Members it provides for.

3. 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. Given the complexity and multiplicity of issues to be dealt with in this regard, their examination should not imply that satisfactory answers will be found to all issues at the same time and in a single forum. Furthermore, given the variety of mechanisms and measures and competent institutions, which could be instrumental to find appropriate solutions, a pragmatic, phased approach could be worthwhile. This is why Switzerland has been actively supporting efforts to find these solutions in various international forums, including the 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 TRIPS Council.

II. PROPOSALS BY SWITZERLAND REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS UNDER THE PATENT COOPERATION TREATY (PCT) OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)[3]

(1) OVERVIEW

4. The just mentioned international forums have been addressing 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"). Some of the proposals put forward concern patent law. They include:

- the declaration of the source of genetic resources and/or traditional knowledge;

[2] See document IP/C/W/284.
[3] A more detailed description of these proposals is contained in the Annex to this communication.

- evidence of prior informed consent (PIC) from the competent authority in the country of origin of the genetic resource; and

- evidence of fair and equitable benefit sharing;

in patent applications, if an invention is based on or uses such resources or knowledge.[4]

5. Switzerland holds the view that transparency measures are an important element in the fair and balanced approach that should be taken with regard to the issues addressed in this communication. 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 submitted proposals to the fourth session of the Working Group on Reform of the PCT held between 19 and 23 May 2003. These proposals are summarized below.

6. By submitting these proposals, Switzerland intends to continue its active and constructive participation in the discussions on 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 proposals are a clear sign of the willingness of Switzerland to find solutions to issues that are of importance to developing countries. In the view of Switzerland, the proposals submitted present one simple and practical solution that could be introduced in a timely manner and would not require extensive changes to the provisions of the relevant international agreements. Additionally, because the proposed transparency measures do not require modifications of the TRIPS Agreement, they are further evidence of the flexibility that this agreement provides for.

(2) SUMMARY OF THE PROPOSALS BY SWITZERLAND

7. Switzerland proposes to 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 based on or uses such resource or knowledge.[5] 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.[6] In case an international patent application does not contain the required declaration, national

[4] See paragraph 10 of the communication by Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe (document IP/C/W/356). For similar such proposals see footnotes 37-39 of document IP/C/W/368.

[5] The proposed new subparagraph (g) of Rule 51*bis*.1 of the Regulations under the PCT would 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."

[6] The proposed new subparagraph (vi) of Rule 4.17 of the Regulations under the PCT would read as follows:

law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.

(3) APPLICATION BY REFERENCE OF THE PROPOSALS TO THE PATENT LAW TREATY (PLT) OF WIPO

8. With regard to "requirements relating to form or contents of an application," Article 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 Article 6.1 of the PLT, the proposed 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 Article 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.

(4) ASSESSMENT OF THE PROPOSALS BY SWITZERLAND

9. The proposals made by Switzerland will enable the Contracting Parties of relevant international agreements, including the TRIPS Agreement, the PCT, the PLT, the CBD and the FAO-IT, to fulfill their respective obligations. This applies in particular to the Articles 27.1 and 62.1 of the TRIPS Agreement as well as Articles 8(j), 15.4, 15.5, 15.7 and 16.5 of the CBD. These proposals provide the means to ensure that the international agreements on intellectual property and the CBD can be implemented in a mutually supportive way. Furthermore, the Swiss proposals will enable the Contracting Parties of the CBD to implement the provisions of the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" (Bonn Guidelines), in particular their paragraph 16(d), as well as paragraph 46 of Decision VI/10 and paragraph 1 of Section C of Decision VI/24 adopted by COP6. And finally, the possibility to require the declaration of the source will also support the determination of prior art with regard to traditional knowledge, as it will simplify searching the databases on traditional knowledge that are increasingly being established at the local, regional and national level.

10. The implementation of the proposals submitted by Switzerland in the national legislation may require legal and technical cooperation and assistance to developing and least-developed countries. The same applies to other measures introduced at the national level with regard to genetic resources and traditional knowledge, such as for example the creation and management of databases on traditional knowledge. The implementation of national legislation and measures concerning genetic resources and traditional knowledge may, in many cases, only be achieved if national institutions are reinforced and public-private partnerships are developed. Switzerland therefore invites the appropriate international forums to provide, upon request by governments, such cooperation and assistance.

(5) ESTABLISHMENT OF A LIST OF GOVERNMENT AGENCIES COMPETENT TO RECEIVE INFORMATION ON DECLARATION

11. The proposed transparency measure could be further strengthened by establishing a list of government agencies competent to obtain information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge. For easy reference, this list could be made accessible on the internet. Patent offices receiving patent applications containing such declaration could inform the competent government agency that the respective State is declared as the source. This information could be provided in a standardized letter sent to the competent

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"(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)."

government agency. Switzerland invites WIPO, in close collaboration with the CBD, to further consider the possible establishment of such a list of competent government agencies.

III. POSITION OF SWITZERLAND WITH REGARD TO OTHER TRANSPARENCY MEASURES PROPOSED UNDER PATENT LAW: EVIDENCE OF PRIOR INFORMED CONSENT (PIC) AND OF FAIR AND EQUITABLE BENEFIT SHARING IN PATENT APPLICATIONS

12. In the discussions on transparency measures, it has been proposed to require patent applicants – in addition to disclosing the source of genetic resources and traditional knowledge – to provide evidence of: (1) PIC of the country providing the genetic resources; and (2) fair and equitable benefit sharing.[7] With regard to these proposals, Switzerland holds the following views:

(1) EVIDENCE OF PRIOR INFORMED CONSENT (PIC)

13. Article 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". Contracting Parties may thus decide that PIC is not required under their national law. Additionally, the CBD leaves it up to the Contracting Parties to specify the elements and modalities of their national system of PIC. The Bonn Guidelines contain more detailed provisions on PIC in paragraphs 24 to 40; according to paragraph 25, these provisions are intended to assist Contracting Parties in the establishment of a national system of PIC. Some Contracting Parties of the CBD already implemented national legislation on PIC, while others have not done so. Existing and future national systems on PIC can be expected to differ substantially; some of the national systems of PIC may provide that PIC is not necessary at all or only in certain cases, whereas other national systems may spell out in detail the elements and modalities of PIC.

14. Transparency measures have been called for that enable the Contracting Parties of the CBD to verify whether their national system of PIC has been adhered to. In this context, Brazil proposes to "require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights: [...] (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes".[7] According to this proposal, providing the required evidence would be a condition for acquiring patent rights. Patent granting authorities would thus have to verify whether the provided evidence is correct and whether the national system of PIC has been followed. For several practical reasons, patent granting authorities are not in a position to carry out this verification:

- These authorities are neither designed to carry out this task nor do they have the necessary legal and technical competence to determine the correctness of the provided evidence.

- Patent granting authorities would need to search for and have access to the various national legislations on PIC and would have to familiarize themselves with each of the national systems of PIC each time a patent application is submitted containing such evidence. This would burden patent granting authorities with substantial administrative work.

- It seems questionable whether any such determination could be done with the necessary legal certainty.

[7] See paragraph 10 of the communication by Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe (document IP/C/W/356).

- The requirement to provide evidence of PIC in patent applications is also problematic with regard to the plant genetic resources for food and agriculture (PGRFA) covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO-IT). This treaty does not foresee that PIC must be obtained from the Contracting Party providing the PGRFA. Thus, if this requirement were to be introduced, it would apply to the genetic resources covered by the CBD, but not the PGRFA covered by the FAO-IT. Patent granting authorities would thus not only have to verify whether the provided evidence is correct, but also whether the genetic resources in question were obtained according to the provisions of the CBD or the FAO-IT.

15. Consequently, the task of verifying whether the national systems of PIC have been adhered to can best be done by the Contracting Party providing the genetic resources in accordance with Article 15.5 of the CBD. In order to simplify this task, Switzerland proposed at the fourth session of the Working Group on Reform of PCT to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. Furthermore, it proposed discussion on the establishment of a list of government agencies that could be informed by the office receiving a patent application containing such a declaration. The declaration and the respective information will allow the Contracting Parties providing the genetic resources to verify whether the patent applicant has fulfilled the requirements and procedures of their national system of PIC. It is therefore neither necessary nor feasible to require, in addition to the declaration of the source of genetic resources, evidence of PIC in patent applications. This is acknowledged in Paragraph 1 of Section C of Decision VI/24 adopted by COP6 of the CBD, according to which the declaration 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". The solution proposed by Switzerland is also in accordance with Article 62.1 of the TRIPS Agreement, according to which "Members may require, as a condition of the acquisition or maintenance of intellectual property rights [...] compliance with reasonable procedures and formalities".

(2) EVIDENCE OF FAIR AND EQUITABLE BENEFIT SHARING

16. According to Article 15.7 of the CBD, the sharing of the benefits arising out of the utilization of genetic resources shall be on mutually agreed terms. Generally, the mutually agreed terms will be laid down in a contract between the provider and the user of the genetic resources in question. The relationship between the provider and the user is thus of a purely contractual nature, and the enforcement of that contract the task of the respective contracting parties.

17. In order to simplify the task of these contracting parties when verifying whether the other contracting party is complying with its benefit sharing obligations, and when enforcing these obligations, suitable transparency measures may be of use. In this context, Brazil proposes to "require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights: [...] (iii) evidence of fair and equitable benefit sharing under the relevant national regimes".[8]

18. The proposal does not specify whether the patent applicant must provide evidence of the fact that benefits have actually been shared in a fair and equitable way, or whether evidence must be provided that in the mutually agreed terms provision has been made for benefits to be shared in the future in accordance with the relevant national regimes. In the first case, it has to be considered that benefits can only be shared if and when they arise, that is, once a product is being commercialized.[9]

[8] See paragraph 10 of the communication by Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe (document IP/C/W/356).

[9] This is expressly stated in Article 13.2(d)(ii) of the FAO-IT.

In contrast, at the time when a patent application is submitted to the patent granting authority, the commercial success of the invention is generally unknown and no monetary benefits will have arisen yet. Furthermore, not all patents that are applied for will be granted, and a large part of the granted patents will never be commercialized. In most instances, the patent applicant will thus not be able to provide evidence that benefits have actually been shared in a fair and equitable way at the point in time when submitting a patent application. In the second case, the proposed requirement could be met by submitting a copy of the contract concluded between the provider and user of genetic resources.

19. In either case, the following practical and legal problems arise: According to the Brazilian proposal, providing this evidence would be a condition for acquiring patent rights. The patent granting authority would thus have to verify whether the provided evidence is correct and whether the sharing of the benefits is "fair and equitable" and in accordance with "the relevant national regime". Patent granting authorities, however, will generally be ill equipped to determine the correctness of the provided evidence. Benefit sharing is on mutually agreed terms between the provider and the user of the genetic resource or traditional knowledge, that is, for example, between a State agency and a university or a private company, and may vary, among others, with regard to the form of benefits shared, the timing, or other conditions. In many cases, these conditions remain confidential and are thus not accessible by the patent granting authority. Furthermore, what has to be considered "fair and equitable" can only be determined on a case by case basis[10], and, because of the contractual autonomy, is primarily the competence and task of the contracting parties to the contract containing the mutually agreed terms on benefit sharing. Any such determination by the patent granting authorities would unduly impair this contractual autonomy.

20. To avoid these practical and legal problems, Switzerland proposed at the fourth session of the Working Group on Reform of PCT to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. Furthermore, it proposed discussion on the establishment of a list of government agencies that could be informed by the office receiving a patent application containing such a declaration. In the view of Switzerland, the declaration of the source and the respective information will allow contracting parties to a contract on access and benefit sharing to verify whether the other contracting party is complying with its obligations arising under that contract, and will thus assist in and simplify the enforcement of these obligations. Should patent applicants additionally be required to provide evidence of fair and equitable benefit sharing in patent applications, they would have to submit double and triple information that would bring little advantage to the contracting parties of the contract regulating access and benefit sharing with regard to genetic resources. Furthermore, such an additional requirement would likely be contrary to Article 62.1 of the TRIPS Agreement, which only allows for "reasonable procedures and formalities".

IV. THE FARMERS' PRIVILEGE

21. As stated above, Switzerland holds the view that with regard to the issues addressed in this communication, a fair and balanced approach must be taken. One possible measure to achieve this approach is the so-called "Farmers' Privilege". In the ongoing revision of the Swiss Federal Law on Patents for Inventions (LPI), it is foreseen to introduce the Farmers' Privilege in the Swiss patent legislation.

22. According to Article 30 of the TRIPS Agreement, "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". In the view of

[10] This is acknowledged by the Bonn Guidelines, which state in paragraph 45 that "[m]utually agreed terms could cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared. These will vary depending on what is regarded as fair and equitable in light of the circumstances".

Switzerland, the Farmers' Privilege as foreseen in the draft for a revised LPI is covered by this provision. There is thus no need to change the wording of the TRIPS Agreement to allow the national legislator to introduce the Farmers' Privilege in national patent laws.

V. THE PROTECTION OF TRADITIONAL KNOWLEDGE

23. In the view of Switzerland, the realization of effective and timely mechanisms and measures to protect traditional knowledge are a further important element in the fair and balanced approach that was advanced above. In this respect, Switzerland welcomes the mandate given to the TRIPS Council in paragraph 19 of the Doha Ministerial Declaration to examine the issue of traditional knowledge in pursuing its work programme.

(1) INTERNATIONAL FORUMS COMPETENT TO DISCUSS THE INTELLECTUAL PROPERTY-RELATED ISSUES OF THE PROTECTION OF TRADITIONAL KNOWLEDGE

24. Various international forums are discussing the protection of traditional knowledge. They include the IGC of WIPO, the TRIPS Council, the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the CBD, UNCTAD and several other UN forums. With regard to intellectual property-related issues, Switzerland holds the view that these issues should be dealt with by the international forums competent for intellectual property, that is, the IGC of WIPO and the TRIPS Council.

25. The IGC of WIPO was established by the General Assembly of WIPO in the fall of 2000 and held so far four sessions. The fifth session is scheduled for July of 2003. Since its establishment, the IGC has been able to substantially advance the discussions on the protection of traditional knowledge. It decided to undertake a number of tasks that will help to further clarify the issues arising and advance the effective and efficient protection of traditional knowledge. As the IGC is rather a technical than a political body, it seems best suited to deal with the many technical issues related to intellectual property that arise in the discussions on the protection of traditional knowledge.

26. In the view of Switzerland, the IGC is thus in the foreground as the international forum to deal with the intellectual property-related issues of the protection of traditional knowledge. The work of the TRIPS Council on these issues should benefit from, and therefore draw upon, the work being carried out by the IGC of WIPO. This approach will help to avoid the duplication of efforts and outcomes.

27. This notwithstanding, Switzerland will actively contribute to the discussions on the intellectual property-related issues of the protection of traditional knowledge in the TRIPS Council: This concerns issues which in the view of other Members are not or not adequately dealt with by the IGC and that these Members wish to address in the TRIPS Council. Furthermore, this concerns issues that are directly linked to the TRIPS Agreement.

(2) TWO FUNDAMENTAL ISSUES: WORKING DEFINITION OF "TRADITIONAL KNOWLEDGE" AND OBJECTIVES OF ITS PROTECTION

28. At the outset of the discussions on the protection of traditional knowledge, two very fundamental issues should be clarified. First, the establishment of at least a working definition of the term "traditional knowledge", and, second, the determination of the objectives of the protection of traditional knowledge. Only the clarification of these issues will allow to adequately focus the discussions and bring the results necessary for an effective protection of traditional knowledge.

29. For these reasons, Switzerland proposed in different international forums, in particular the IGC of WIPO and the CBD, to further pursue the two issues. Based on a Swiss proposal, the Conference of the Parties of the CBD requests in paragraph 34(a) of Decision VI/10 the Ad Hoc

Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, when addressing the sui generis protection of traditional knowledge, to clarify relevant terminology. Furthermore, Switzerland proposed that the IGC of WIPO establish at least a working definition of the term "traditional knowledge". It thus welcomes the decision of the IGC to further pursue work on operational terms and definitions with regard to traditional knowledge at its future sessions. At the request of Switzerland, the WIPO Secretariat will furthermore prepare a document that will lay out the possible objectives of the protection of traditional knowledge.

(3) THE DETERMINATION OF PRIOR ART: INTERNATIONAL GATEWAY FOR TRADITIONAL KNOWLEDGE

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

31. One way to substantially improve this situation is the collection of traditional knowledge in databases. Patent authorities could search these databases when dealing with patent applications raising questions regarding traditional knowledge as an element of prior art. Various governments, indigenous and local communities and non-governmental organizations (NGOs) have become active in the establishment of such databases at the local, regional and national levels. Examples are the "China Traditional Chinese Medicine Patents Database" of China, the "Health Heritage Database" and the "Traditional Knowledge Digital Library" of India, the "Biozulua Database" of Venezuela, and the "StoryBase Database" of the Tulalip Tribes of Washington State, USA.

32. The number of such databases can be expected to further increase in the future. These databases are likely to have differing structures and to store traditional knowledge in different forms and formats. Great variability of the structure and contents of these databases, however, will seriously hinder the efficient access of patent authorities to these databases and the effective search for prior art. To avoid these problems, at least a minimum harmonization of the structure and contents of these databases should be achieved. This would also allow to make the local, regional or national databases available through an international gateway for traditional knowledge to be administered by WIPO, as was proposed by Switzerland in its communication to the TRIPS Council of 15 June 2001.[11]

VI. THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

33. Switzerland holds the view that the TRIPS Agreement and the CBD are mutually supportive.[12] The two agreements can and should thus be implemented without conflict. Accordingly, there is no need to modify the provisions of either one of these agreements.

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[11] See document IP/C/W/284, paragraphs 16-19. At its third meeting held in June 2002, the IGC of WIPO discussed document WIPO/GRTKF/IC/3/6, entitled "Inventory of Existing Databases of Disclosed Traditional Knowledge". Among others, this document deals with the structure of such databases. Switzerland notes with great satisfaction that the IGC decided to further pursue the issue of databases for traditional knowledge, including the possible harmonization of the structures and contents of such databases and the idea of an international gateway for traditional knowledge.

[12] See also documents WT/CTE/W/139, WT/CTE/W/168 and TN/TE/W/4, which present the views of Switzerland on the relationship between the rules of the World Trade Organization and multilateral environmental agreements (MEAs) in general.

34. It is sometimes asserted that the TRIPS Agreement and the CBD are at present not mutually supportive and that therefore modifications to these agreements are necessary.[13] It is claimed that these modifications would have to be made in the TRIPS Agreement. Such an approach would mean, however, that the CBD is superior to the TRIPS Agreement. Switzerland finds no grounds for any such hierarchy between the two agreements neither in the CBD nor in the TRIPS Agreement, and considers them to be mutually supportive instead.

35. To dispel any uncertainties that may nevertheless exist with regard to the relationship between the WTO-rules and multilateral environmental agreements (MEAs), Switzerland proposes to clarify this relationship through an interpretative decision to be adopted by the WTO Members. Switzerland recalls the several proposals it submitted to the WTO's Committee on Trade and Environment (CTE) and its Special Session on this relationship which, if accepted, would provide guidance to the dispute settlement bodies in cases of conflict of the rules of the WTO and MEAs.

36. The existing mutual supportiveness of the CBD and the TRIPS Agreement can be enhanced by introducing, when implementing one or both of these agreements, appropriate measures and mechanisms promoting the objectives of the other agreement. This is, for example, the case with the introduction of the requirement to declare the source of genetic resources and/or knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, in patent applications, if the invention in question is based on or has used such resources or knowledge, innovations and practices, as is proposed by Switzerland in Part II of this communication. While such a declaration will promote the objectives of the CBD, it is not prohibited by the TRIPS Agreement.

[13] See document IP/C/W/356.

ANNEX

The text of a submission by Switzerland to the International Bureau of WIPO, circulated as WIPO document PCT/R/WG/4/13 to the Fourth Session of the Working Group on Reform of the Patent Cooperation Treaty held on 19-23 May 2003

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.

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I. OVERVIEW

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38. 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 51bis.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 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

[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>).

[2] In the 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).

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."

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:
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> [...]

(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:

(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 57 th 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.

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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[.]"

(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 51bis.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 51bis.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 51bis.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.

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

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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.

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 51bis.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
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> (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

[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 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

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.

- 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 51bis.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

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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."

[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").

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 fulfils the conditions of the new Rule 51bis.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.

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

26. Complementary to the new subpara. (g) of Rule 51bis.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 51bis.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.

[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[.]"

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 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.

[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."