

COMMENTS BY SWITZERLAND ON

“EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS” (FIRST DRAFT)

“MEMBER STATE PROPOSALS AND SUGGESTIONS REGARDING THE INVITATION TO WIPO FROM THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY ON ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS” (PROVISIONAL COMPLATION)

I. GENERAL COMMENTS

1. Switzerland welcomes the first draft examination of issues relating to the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. Switzerland considers it to be of great importance that WIPO provides a timely and comprehensive response to the CBD’s invitation to examine, and where appropriate address, these issues. Switzerland regrets the small number of submissions by WIPO Member States with regard to the CBD’s invitation and hopes that additional replies will be submitted in due time.

2. Switzerland has played an active and constructive role in the international discussions on disclosure requirements in patent applications: Switzerland submitted specific and detailed proposals on the disclosure of the source of genetic resources and traditional knowledge in patent applications to the Working Group on Reform of the Patent Cooperation Treaty (PCT) of WIPO in May 2003.¹ Switzerland presented two more submissions containing additional comments and further observations on its proposals in May and October 2004, respectively.² Moreover, Switzerland also presented submissions on its proposals to other international fora, namely the TRIPS Council³ and the CBD⁴.

3. In the view of Switzerland, the first draft of this examination provides a thorough analysis of the issues at hand. This first draft, however, does not fully reflect all aspects of the Swiss proposals on the declaration of the source and the various documents submitted by Switzerland to the relevant international fora. Accordingly, Switzerland proposes several amendments to the first draft examination (see below “Comments on draft examination”).

II. COMMENTS ON DRAFT EXAMINATION

- ad “Part II”: Switzerland considers Part II “Overview of Existing Proposals and Mechanisms” to be of great value to the examination. Accordingly, Part II should be retained in the document.

¹ See WIPO-document PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev.

² See WIPO-documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

³ See WTO-documents IP/C/W/400/Rev.1, IP/C/W/423 and IP/C/W/433.

⁴ See CBD-document UNEP/CBD/WG-ABS/3/INF/7.

- ad para. 35: We propose to add in the list of submissions to the TRIPS Council the submission by Switzerland entitled “*Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge*” of 18 June 2003 (see doc. IP/C/W/400/Rev.1). This submission not only presents the proposals of Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, but also contains the position of Switzerland on the proposed requirements to provide evidence of prior informed consent and of benefit sharing in patent applications.
- ad para. 42: We propose to add a footnote containing the references to the three submissions presented by Switzerland on its proposals (that is, WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev; PCT/R/WG/6/11; and PCT/R/WG/7 Paper No. 7).
- ad “Proposal by Switzerland to amend the PCT Regulations” (paras. 42-44): We propose to add text summarizing the proposals by Switzerland of May 2003 regarding the establishment of an information system on patent applications containing declarations of the source:

“Additionally, Switzerland invited WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies competent to receive information on the declaration of the source in patent applications. According to this proposal, the office receiving a patent application containing a declaration of the source of a genetic resource or the associated traditional knowledge would inform the competent 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. This list of competent government agencies 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.”
- ad para. 54: To better reflect the state of play of the discussions in the TRIPS Council, we propose to amend para. 54 as follows: “It then cites a checklist that was submitted by a group of WTO Members in 2004 to the WTO Council for TRIPS ~~as a recent overview containing of issues that these Members propose to be that are currently under~~ considered by the TRIPS Council ~~and that may therefore~~ be considered relevant to the present examination.”
- ad “TRIPS Council Checklist of Issues” (para. 81): Again, to better reflect the state of play of the discussions in the TRIPS Council, we propose to amend the current title of the subsection “TRIPS Council Checklist of Issues” to “Checklist of issues submitted to the TRIPS Council by a group of WTO Members.”
- ad para. 87 and footnote 28: Besides the proposals submitted by Brazil mentioned in footnote 28, other delegations have also submitted proposals with regard to these issues as well. Switzerland submitted detailed proposals with regard to the disclosure of the source of genetic resources and traditional knowledge in patent applications (see the documents mentioned in footnotes 1 and 2 above). Switzerland also expressed its position on the proposed requirement to provide evidence of prior informed consent and of benefit sharing in

patent applications (see WTO-document IP/C/W/400/Rev.1). Accordingly, we propose to include the just mentioned documents by Switzerland in footnote 28.

- ad “Some possible functions of disclosure requirements” (para. 89): We propose to add the following text:

“Switzerland views the declaration of the source of genetic resources and traditional knowledge in patent applications to be a measure that increases transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, in particular with regard to the obligations of the users of genetic resources and traditional knowledge, and terms these measures ‘transparency measures’.”

- ad “Other guidance on options for disclosure requirements” (paras. 90-98): We propose to add the following text:

“The Swiss proposals use the terms “genetic resources” and “traditional knowledge related to genetic resources” to ensure consistency with the CBD, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Bonn Guidelines) and the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) of the Food and Agriculture Organization (FAO). As a measure under patent law, the focus is on traditional knowledge that can give rise to a technical invention.

Switzerland proposes to require patent applicants to declare the “source” of genetic resources and traditional knowledge. The term “source” should be understood in its broadest sense possible. This is because according to the international instrument referred to above, a multitude of entities may be involved in access and benefit sharing. In the foreground to be declared as the source is the entity competent (1) to grant access to genetic resources and/or traditional knowledge or (2) to participate in the sharing of the benefits arising out of their utilization. Depending on the genetic resource or traditional knowledge in question, one can distinguish primary sources, including in particular Contracting Parties providing genetic resources, the Multilateral System of FAO’s International Treaty, indigenous and local communities, and secondary sources, including in particular ex situ collections and scientific literature. Accordingly, there is a “cascade” of possible primary and secondary sources: Patent applicants must declare the primary source to fulfil the requirement, if they have information about this primary source at hand. A secondary source may only be declared if patent applicants have no information at hand about the primary source.

With regard to genetic resources, the proposed new Rule 51bis.1(g)(i) of the PCT Regulations makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51bis.1(g)(ii) of the PCT Regulations makes clear that the inventor must know that the invention is directly based on such

knowledge, that is, the inventor must consciously derive the invention from this knowledge.”

- ad „B. Triggers for disclosure requirements“ (paras. 104-114): Para. 104 distinguishes the “trigger” for disclosure requirements in a substantive and in a procedural sense. Switzerland expressed its views on both of these senses in detail. Accordingly, we propose to add the following text:

“With regard to the trigger of the disclosure requirement in the substantive sense, the proposals by Switzerland distinguish between genetic resources and traditional knowledge: With regard to genetic resources, the proposed new Rule 51bis.1(g)(i) makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51bis.1(g)(ii) makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

With regard to the trigger of the disclosure requirement in the procedural sense, the proposals by 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.”

- ad “C. Incentive Measures for Applicants” (paras. 115-128): In its submissions on its proposals, Switzerland addressed incentive measures in detail. Accordingly, we propose to add the following text:

“In the view of Switzerland, the sanctions currently allowed for under the PCT and the PLT should apply to failure to disclose or wrongful disclosure of the source of genetic resources and traditional knowledge in patent applications.

Accordingly, if the national law applicable by the designated Office requires the declaration of the source of genetic resources and traditional knowledge, Rule 51bis.3(a) of the PCT Regulations requires the designated Office to invite the applicant, at the beginning of the national phase, to comply with the disclosure requirement within a time limit which shall not be less than two months from the date of the invitation. If the patent applicant does not comply with this invitation within the set time limit, the designated Office may refuse the application or consider it withdrawn on the grounds of this non-compliance. If, however, the applicant submitted with the international application or later during the international phase the proposed declaration containing standardized wording relating to the declaration of the source (see proposal by Switzerland for new subpara. (vi) of Rule 4.17), the designated Office must accept this declaration and may not require any further document or evidence relating to the source declared, unless it may reasonably doubt the veracity of the declaration concerned.

Furthermore, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, such failure to comply with the disclosure requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.”

- ad para. 164 and 166: As the fifth element of the CBD COP invitation states, the proposed certificate could also cover the “source.” Accordingly, we propose to amend para. 164 as follows: “*This proposed system of certification [...] potentially has bearing on specific requirements concerning the declaration of the source, evidence of prior informed consent and of equitable benefit sharing.*” With regard to para. 166, we propose the following amendment: “As noted above, certification may be relevant to any specific requirement concerning *the declaration of the source*, evidence of prior informed consent and of equitable benefit sharing, or more broadly to comply with any requirement to demonstrate that relevant materials have been acquired lawfully.”
- ad “comments on certification issues” (paras. 168-171): In this context, Switzerland proposes to establish a list of government agencies competent to receive information on the declarations of the source. Accordingly, we propose the following amendments to the text:

“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. 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.

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.”

III. COMMENTS ON PROVISIONAL COMPILATION OF MEMBER STATE PROPOSALS AND SUGGESTIONS

4. Pages 30 to 40 of the provisional compilation contain the reply by Switzerland to Note C. 7092. The table of contents provided for on pages 30 to 31, however, refers to text not contained in the Swiss reply; this concerns the text referred to on page 8 and pages 44 to 51 in the table of contents. The table of contents should thus be revised accordingly.