

**Switzerland**  
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**Reply by Switzerland to Note C. 7092 related to the invitation of the Convention on Biological Diversity (CBD) to the World Intellectual Property Organization (WIPO) to examine, and where appropriate address, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications**

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**Executive summary**

The seventh Conference of the Parties (COP-7) of the Convention on Biological Diversity (CBD) invited the World Intellectual Property Organization (WIPO) “to examine, and where appropriate address, [...] issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications[.]” In Note C. 7092, WIPO invites its Member States to present their proposals and suggestions with regard to these issues. This present document contains the reply by Switzerland to Note C. 7092.

In the context of disclosure requirements, Switzerland recalls the proposals it submitted to WIPO with regard to the declaration of the source in patent applications.<sup>1</sup> More specifically, Switzerland proposes to amend the Regulations Under the Patent Cooperation Treaty (PCT-Regulations) to explicitly enable the Contracting Parties of the PCT to require patent applicants to declare the source of genetic resources and traditional knowledge, if an invention is directly based on such resources or knowledge.

With regard to the issues to be examined and addressed by WIPO, the views of Switzerland can be summarized as follows:

(a) *Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties:* Switzerland considers the requirement to disclose the source of genetic resources and traditional knowledge in patent applications to be in the nature of a formal requirement. Due to this formal nature, the PCT and the Patent Law Treaty (PLT) are the two treaties clearly in the foreground with regard to the introduction of a disclosure requirement in patent law. In order to explicitly enable the Contracting Parties of these treaties to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications, Switzerland proposes to amend the PCT-Regulations.<sup>2</sup>

(b) *Options for model provisions on proposed disclosure requirements:* The proposals by Switzerland to amend the PCT-Regulations are sufficiently specific and clear to be directly implemented at the national level. Accordingly, Switzerland sees no need for model provisions on proposed disclosure requirements.

(c) *Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements:* According to the proposals by Switzerland, the trigger of the disclosure of the source should be designed according to the differing characteristics of genetic resources and traditional knowledge: 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.

(d) *Options for incentive measures for applicants:* 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.

(e) *Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance:* Since the elaboration and negotiation of the international regime as mandated by COP-7 has not yet begun, the intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance cannot be

<sup>1</sup> See WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11, and WIPO-documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

<sup>2</sup> For an overview of the Rules of the PCT-Regulations proposed to be amended, see Appendix of WIPO-document PCT/R/WG/7 Paper No. 7.

anticipated at this point in time. In the view of Switzerland, the international regime and its elements, including any certificate of origin/source/legal provenance, should be mutually supportive with the existing international legal order and the relevant international instruments. Furthermore, any intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance are to be dealt with by the competent international fora, in particular WIPO.

## 1. Background

Switzerland holds the view that with regard to genetic resources, traditional knowledge and intellectual property rights 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 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) and the Working Group on Reform of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO); and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council).

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 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”). Transparency 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.

The CBD does not contain specific provisions on transparency measures that the Contracting Parties should introduce in their national legislation.<sup>3</sup> Such measures are addressed in greater detail in para. 16(d) of the “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization” (Bonn Guidelines) and in several decisions of the CBD’s Conference of the Parties.<sup>4</sup> Furthermore, disclosure of the source is one of the elements to be considered by the CBD’s Ad Hoc Open-ended Working

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<sup>3</sup> 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.”

<sup>4</sup> See para. 46 of Decision VI/10 and para. 1 of Section C of Decision VI/24. Furthermore, para. 8 of Section E of Decision VII/19 “[i]nvites the World Intellectual Property Organization to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the Convention on Biological Diversity, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:

- (a) Options for model provisions on proposed disclosure requirements;
- (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
- (c) Options for incentive measures for applicants;
- (d) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;
- (e) Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the Convention on Biological Diversity on its work, in particular on actions or steps proposed to address the above issues, in order for the Convention on Biological Diversity to provide additional information to the World Intellectual Property Organization for its consideration in the spirit of mutual supportiveness[.]”

Group on Access and Benefit-sharing for inclusion in the international regime on access to genetic resources and benefit-sharing.<sup>5</sup>

Switzerland holds the view that transparency measures are an important element in the fair and balanced approach advanced above. It views transparency measures not only as increasing transparency in the context of access and benefit sharing, but also as building trust among the various stakeholders involved. Switzerland considered in detail the various options available for such measures and their possible modalities and implications. Based on these considerations, it elaborated proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications. In summary, Switzerland proposes to amend the Regulations Under the PCT (PCT-Regulations) to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. 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.

Switzerland presented its proposals to the fourth session of WIPO's Working Group on Reform of the PCT in May 2003.<sup>6</sup> In order to further advance the discussions on its proposals, Switzerland presented two more submissions to the Working Group on Reform of the PCT containing additional comments and further observations, respectively, in May 2004 and October 2004.<sup>7</sup> The additional comments address the use of terms, the concept of the „source“ of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, and the possible legal sanctions for failure to disclose or wrongful disclosure of the source. The further observations address the formal vs. the substantive nature of the disclosure requirement, the optional vs. the mandatory introduction of the disclosure requirement at the national level, and the concept of the “source.”

## **2. Proposals and suggestions by Switzerland concerning the invitation of the CBD to WIPO on issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications<sup>8</sup>**

- (a) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties<sup>9</sup>

### *(1) Relevant treaties administered by WIPO*

The policy objective of the disclosure requirement is to increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising

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<sup>5</sup> See para. (d)(xiv) of the Annex to Section D of Decision VII/19.

<sup>6</sup> See WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11.

<sup>7</sup> See WIPO-documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.

<sup>8</sup> In order to facilitate cross-references with the Swiss Proposals, the order of the questions has been modified accordingly.

<sup>9</sup> See para. 8(d) of Section E of Decision VII/19.

out of their utilization. To achieve this policy objective, the disclosure requirement has to be examined for the purposes of determining if a complete patent application has been filed. However, this policy objective neither requires nor justifies that the disclosure requirement is linked to the search, examination or grant of patents, or to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement.

Due to the formal nature of the disclosure requirement, Switzerland considers the PCT and the Patent Law Treaty (PLT) to be in the foreground with regard to the disclosure of the source of genetic resources and traditional knowledge in patent applications. Both treaties are administered by WIPO and deal with the formal aspects of international (PCT) and national and regional (PLT) patent applications.

According to Art. 27.1 of the PCT, “[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 51*bis*.1 of the Regulations under the PCT are of particular importance:

- Rule 4.1 enumerates the mandatory and optional contents of the request of an international patent application. According to Rule 4.1(c)(iii), such request may contain “declarations as provided in Rule 4.17.” Rule 4.17 deals with certain declarations that are required by national laws in accordance with Rule 51*bis*.1(a). Rule 4.17 permits applicants to include in the request certain declarations corresponding to the matters set out in Rule 51*bis*.1(a)(i) to (v), relating to which designated Offices may require evidence or documents. According to Rule 4.18(a), “[t]he request shall contain no matter other than that specified in rules 4.1 to 4.17 [...]”; furthermore, Rule 4.18(b) requires the receiving Office to delete ex officio any such additional matter.
- Present Rule 51*bis*.1 lists in subparas. (a) to (f) a number of matters relating to which the applicant may be required to furnish documents or evidence under the national law applicable by the designated Office. This rule provides clarity for both applicants and designated Offices that such items may be required to be furnished by the applicant under the national law applicable by the designated Office.

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

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

“[e]xcept where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:

- (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;

- (ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started[.]’

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

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).

## (2) *Proposals by Switzerland to amend the PCT-Regulations*

Based on the relevant developments at the international level and the provisions of the applicable 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 submitted the following proposals to the Working Group on Reform of the PCT:

### (i) *Amendment of Rule 51bis.1 of the PCT-Regulations*

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

“(g) *Subject to Rule 51bis.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish:*

- (i) *a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource;*
- (ii) *a declaration as to the source of traditional knowledge related to genetic resources, if the inventor knows that the invention is directly based on such knowledge;*

(iii) *a declaration that the source referred to in (i) or (ii) is unknown to the inventor or applicant, if this is the case.*”

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 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.

(ii) Proposal to amend Rule 4.17 of the PCT-Regulations

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

*“(vi) a declaration as to the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in Rule 51bis.1(g).”*

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.

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

(iii) Other amendments to the PCT-Regulations

In addition to the proposed new subpara. (g) in Rule 51bis.1 and subpara. (vi) in Rule 4.17, Switzerland proposes several other amendments to the Rules of the PCT-Regulations.<sup>10</sup> These amendments concern the international publication (Rule 48: International Publication; Rule 51bis.2: Circumstances in Which Documents or Evidence May Not Be Required and Rule 51bis.3: Opportunity to Comply with National Requirements).

(b) Options for model provisions on proposed disclosure requirements<sup>11</sup>

Switzerland proposes several amendments to the PCT-Regulations in order to explicitly enable the Contracting Parties of this treaty to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications. These amendments concern the new subpara. (g) in Rule 51bis.1 and subpara. (vi) in Rule 4.17.

The wording of the proposed new provisions to be introduced in the PCT-Regulations, in particular the proposed new subpara. (g) in Rule 51bis.1 and subpara. (vi) in Rule 4.17, is sufficiently specific and clear to be directly implemented at the national level. Accordingly, Switzerland sees no need for model provisions on proposed disclosure requirements.

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<sup>10</sup> For an overview of the Rules of the PCT-Regulations proposed to be amended, see Appendix of WIPO-document PCT/R/WG/7 Paper No. 7.

<sup>11</sup> See para. 8(a) of Section E of Decision VII/19.

- (c) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements<sup>12</sup>

With regard to the trigger of the disclosure requirement, the proposals by Switzerland distinguish between genetic resources and traditional knowledge:

With regard to genetic resources, the proposed new Rule 51*bis*.1(g)(i) of the Regulations Under the PCT states that the invention must be “directly based” on “a specific genetic resource to which the inventor has had access,” in order for the disclosure requirement to apply. This wording 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 that are relevant for the invention. Thus, for example, the source of a plant would have to be declared in the patent application if the respective invention relates to a chemical compound which the inventor extracted from this plant.

With regard to traditional knowledge, the proposed new Rule 51*bis*.1(g)(ii) of the Regulations Under the PCT requires that “the inventor knows” that the invention is “directly based” on this knowledge. Like any other form of knowledge, traditional knowledge is of intangible nature. Thus, physical access is not possible and therefore not required. Instead, the inventor must know that the invention is directly based on such knowledge, that is, he must consciously derive the invention from this knowledge. This is to avoid cases where, for example, the inventor is using a chemical compound derived from a plant to develop a new pharmaceutical, without knowing that an indigenous community has knowledge concerning the pharmaceutical use of this plant.

- (d) Options for incentive measures for applicants<sup>13</sup>

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 51*bis*.3(a) of the PCT-Regulations requires the designated Office to invite the applicant, at the beginning of the national phase, to comply with 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

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<sup>12</sup> See para. 8(b) of Section E of Decision VII/19.

<sup>13</sup> See para. 8(c) of Section E of Decision VII/19.

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.

- (e) Intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance<sup>14</sup>

COP-7 of the CBD mandates in Decision VII/19 “the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, ensuring the participation of indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention[.]”<sup>15</sup> One of the elements to be considered by this Working Group for inclusion in the international regime is an “[i]nternationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge[.]”<sup>16</sup> The third meeting of this Working Group, to be held 14-18 February 2005, is foreseen to begin the elaboration and negotiation of the international regime.

Since the elaboration and negotiation of the international regime has not yet begun, the intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance cannot be anticipated at this point in time.

In the view of Switzerland, the international regime and its elements, including any certificate of origin/source/legal provenance, should be mutually supportive with the existing international legal order and relevant international instruments. Furthermore, intellectual property-related issues raised by the proposed international certificate of origin/source/legal provenance are to be dealt with by the competent international fora, namely WIPO, the WTO and the Union for the Protection of New Varieties of Plants (UPOV). WIPO is particularly well-suited to deal with these issues, in particular its “Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.” As stated in para. 5 of Section D of Decision VII/19, these and other international fora are to cooperate with the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in elaborating the international regime.

### **3. Documents by Switzerland on its proposals**

With regard to its proposals, Switzerland submitted the following documents to WIPO:

1. *Proposals by Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications.* See WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11.

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<sup>14</sup> See para. 8(e) of Section E of Decision VII/19.

<sup>15</sup> See para. 1 of Section D of Decision VII/19.

<sup>16</sup> See para. (d)(xiii) of the Annex to Section D of Decision VII/19.

2. *Additional Comments by Switzerland on Its Proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications.* See WIPO-document PCT/R/WG/6/11.
3. *Further Observations by Switzerland on Its Proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications.* See WIPO-document PCT/R/WG/7 Paper No. 7.