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THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN THE SWISS PATENT ACT AND RELATED SWISS REGULATIONS ON GENETIC RESOURCES – SUBMISSION BY SWITZERLAND IN RESPONSE TO DOCUMENT WIPO/GRTKF/IC/30/9

Document submitted by the Delegation of Switzerland

INTRODUCTION

1. On September 9, 2016, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Delegation of Switzerland to submit a document entitled “The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9” to the Thirty-First Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), as a working document under Agenda Item 6 “Traditional Knowledge”.

2. Pursuant to the request above, the Annex to this document contains the submission referred to.

3. The Committee is invited to take note of the submission in the Annex to this document and its appendices.

[Annex follows]

THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN THE SWISS PATENT ACT AND RELATED SWISS REGULATIONS ON GENETIC RESOURCES - SUBMISSION BY SWITZERLAND IN RESPONSE TO DOCUMENT WIPO/GRTKF/IC/30/9

I. INTRODUCTION

1. During the thirtieth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC-30), the Delegation of the United States submitted a document entitled: "*Seeking a better understanding of Switzerland's "Federal Act on the Protection of Nature and Cultural Heritage" and "Federal Act on Patents for Inventions" by hypothetically applying them to U.S. Patent Number 5,137,870*" (the US document).[1]

2. The US document was prepared without consulting Switzerland, and without verifying the accuracy of the content with any competent Swiss authorities. In addition, the document contains a number of serious shortcomings and errors. In particular, the US document confuses (1) the disclosure of the source requirement as stipulated in the Swiss Federal Act on Patents for Inventions (PatA); (2) the notification of the due diligence obligation according to the Swiss Federal Act on the Protection of Nature and Cultural Heritage (NCHA), which implements the provisions of the Nagoya Protocol (NP); and (3) the product marketing approval procedures. Furthermore, the US document does not take into account several important provisions of these Acts, and completely ignores the Ordinances that implement them. Finally, the hypothetical example used in the document, namely U.S. Patent Number 5,137,870, is outdated.

3. Due to this, the US document does not accurately interpret the Swiss approach for a disclosure requirement and is thus misleading. The present submission by Switzerland corrects the errors and shortcomings of the US document and intends to facilitate a fact-based discussion in the IGC on a possible disclosure requirement.

4. The content of this submission can be summarised as follows: Section II explains the provisions on the declaration of the source of genetic resources and associated traditional knowledge in patent applications according to the PatA as well as the Swiss Federal Ordinance on Patents for Inventions (PatO). Section III describes the relationship between the declaration of the source in the PatA and other regulations related to genetic resources and associated traditional knowledge, in particular the relevant provisions implementing the NP and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Section IV contains conclusions and considerations on a possible international disclosure requirement currently under discussion in the IGC. Finally, Appendix 1 lists the Swiss laws, ordinances and other relevant documents related to genetic resources and associated traditional knowledge, and Appendix 2 contains specific comments by Switzerland on US document WIPO/GRTKF/IC/30/9, which correct the misleading and false interpretation of the Swiss legal framework.

[1] WIPO/GRTKF/IC/30/9.

II. THE DECLARATION OF THE SOURCE IN THE FEDERAL ACT ON PATENTS FOR INVENTIONS AND ITS IMPLEMENTING ORDINANCE

A. Introduction

5. In summary, the provisions of the PatA stipulate that the patent application must contain information on the source of a genetic resource, to which the inventor or the patent applicant had access, provided the invention is directly based on this resource. Similarly, the patent application must contain information on the source of traditional knowledge of indigenous and local communities associated with genetic resources, to which the inventor or the applicant had access, provided the invention is directly based on this knowledge. The PatA also contains sanctions for not, or for wrongfully, disclosing the source. The PatO lists the most important sources and stipulates that the source must be contained in the description of the invention (see Appendix 1 for the relevant provisions of the PatA and PatO).

6. In 2010, Switzerland submitted a document entitled "*Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Provisions of the Swiss Patent Act*" as an information document for IGC-16,[2] which summarizes and explains the relevant provisions of the PatA on the disclosure of the source.

7. In the present submission, we provide additional information on these provisions.

B. Policy objectives and general principles

8. The declaration of the source requirement was introduced in the PatA in 2008. According to the Dispatch[3], the objective of this measure is to increase transparency about the specific genetic resource(s) and the traditional knowledge related to genetic resources, on which an invention is directly based on. This measure should support compliance with the access and benefit-sharing regulatory requirements of other countries. In addition to increased transparency, the disclosure of source should also (1) strengthen mutual trust between users and providers of such resources or knowledge, (2) enhance the traceability of these resources and knowledge, and (3) facilitate the establishment of technical prior art.

9. At the same time, it is crucial to keep in mind that the disclosure of source requirement will, by itself, not be sufficient to resolve all issues arising in the context of access and benefit-sharing. Many genetic resources are utilised without leading to an invention, for instance in non-commercial research projects, or may result in commercial products that are not protected by patents. Thus, in the view of Switzerland, and in line with the provisions of the Nagoya Protocol, additional measure have to be taken outside of the patent system in other fields of law. The Swiss measures outside of the patent system are described in Section III below.

10. The inclusion of a disclosure requirement in the PatA was elaborated in a democratic process. It followed a balanced approach and took into account various, and sometimes divergent, interests. These interests are those of users and providers of genetic resources, developed and developing countries, indigenous peoples, patent examiners and patent applicants, researchers, private industry, and civil society representatives. Moreover, efforts were made to keep the requirement as practical and simple as possible without losing its effectiveness.

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[2] WIPO/GRTKF/IC/16/INF/14.

[3] The Dispatch of 23 November 2005 concerning the revision of the PatA is available in German, French, and Italian.

11. The disclosure requirement in the PatA is based on the following key principles:

a) it is flexible enough to cope with the wide range of circumstances related to genetic resources and traditional knowledge associated with genetic resources,
b) it has a clear scope in order to easily determine whether the disclosure requirement will be triggered,
c) it includes effective and proportionate sanctions in order to ensure legal certainty for both users and providers of genetic resources and associated traditional knowledge, and
d) it has to be understood in the broader context of measures to implement the international regime on access and benefit-sharing[4] at the national level.

The following paragraphs will address principles a) to c), while Section III addresses principle d).

C. Rationale for the concept of "source": the need to cope with the wide range of circumstances related to genetic resources and traditional knowledge

12. The provisions of the PatA and the Swiss proposals on the disclosure requirement submitted to WIPO are based on the concept of "source." The rationale for this concept is based on the following reasoning:

- *Diversity of sourcing locations:* Genetic resources can be sourced from a variety of different locations, including from *in-situ* conditions in different ecosystems (aquatic, agricultural, forest, etc.) as well as from *ex-situ* collections, which may or may not be located in the countries of origin. Moreover, the same or similar genetic resources can often be sourced in more than just one country, and there is often more than just one country of origin for a specific genetic resource (see illustration below).

- *Diversity of legal situations:* Access regulations in different countries vary considerably, ranging from comprehensive "prior informed consent" (PIC) and "mutually agreed terms" (MAT) requirements, to simple notification procedures, to no regulations at all[5]. Moreover, access regulations often vary depending on the specific type of genetic resources, the ecosystems, and purposes of the intended uses of the genetic resources. For instance, a number of plant genetic resources for food and agriculture (PGRFA) fall within the scope of the Multilateral System (MLS) of the ITPGRFA of the Food and Agriculture Organization (FAO). Other genetic resources again may be sourced in areas beyond national jurisdictions (e.g., marine genetic resources in the high seas) or through international organisations, such as influenza viruses with human pandemic potential under the Pandemic Influenza Preparedness (PIP) Framework of the World Health Organization (WHO), and are thus subject to the respective provisions.

- *Diversity of types of genetic resources*: The CBD defines *genetic resources* as "genetic material of actual or potential value," and *genetic material* as "any material of plant, animal, microbial or other origin containing functional units of heredity." Therefore, there exist various types of genetic resources with very different properties. Some genetic resources may have been cultivated and/or modified for years, and therefore differ in their properties from those that occur in nature (e.g., specific cultures of microorganisms). Some genetic

[4] The preamble of the decision UNEP/CBD/COP/DEC/X/1 adopting the Nagoya Protocol speaks about the "international regime on access and benefit-sharing". The preamble as well as Article 4 of the Nagoya Protocol make it clear that there is not just one international instrument to implement "access and benefit-sharing".

[5] Article 15.5 of the Convention on Biological Diversity (CBD) and Article 6.1 of the NP state that "access to genetic resources shall be subject to prior informed consent…, unless otherwise determined by that Party". Therefore, Parties can determine not to require PIC for accessing their genetic resources. This is the case in various countries. In Switzerland, so far, the majority of genetic resources will only be subject to an information and notification requirement by the time of commercialisation or marketing approval (see Art. 8 NagO).

resources may even consist of genetic material with multiple countries of origin (e.g., modern crop varieties).

- *Diversity of sectorial approaches*: There are various sectors utilising genetic resources, and their approaches to sourcing, exchanging and utilising genetic resources differ considerably[6]. Moreover, there is usually a considerable time span between the sourcing of a genetic resource *in-situ* in a specific country, and applying for a patent for an invention directly based on this resource. During this time span, a genetic resource may be transferred among several users located in the same or in different countries.

- *Diversity of traditional knowledge associated with genetic resources*: Unlike genetic resources, traditional knowledge is intangible. Commonly, the holders of such knowledge are indigenous peoples and local communities. Article 8(j) of the CBD links traditional knowledge to indigenous and local communities embodying traditional lifestyles, and Article 7 of the NP refers to PIC or approval and involvement of indigenous and local communities in accordance with national law. However, the legal situations, the customary practices, and the approaches to protect traditional knowledge differ considerably between indigenous peoples and between different countries.

13. Based on the legal and factual circumstances mentioned above, it is evident that it is not always feasible to disclose information about the "country of origin of genetic resources," the "country providing genetic resources," or the establishment of "PIC" and "MAT." A more flexible and comprehensive approach is thus needed.

14. In the view of Switzerland, the concept of "source" as stated in Article 49*a* of the PatA, as well as in the international proposals submitted by Switzerland[7], is an approach, which allows taking into account these legal and factual circumstances.

15. Depending on the specific situation, there are different types of sources. According to the Swiss approach, these can be separated into primary and secondary sources. Patent applicants must declare the primary source. However, if the primary source is not known to the applicant, the secondary source must be declared.

16. Based on the provisions of the relevant international instruments on access and benefit sharing, one can distinguish the following primary sources:

- According to the CBD and the NP, primary sources include: (1) The "country providing genetic resources," (2) the "country of origin of genetic resources," and (3) the "Party providing genetic resources which is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention."

- For an invention, which is directly based on a PGRFA covered by the MLS of the ITPGRFA, the country of origin is not applicable, and the patent applicant would need to disclose the "MLS" as the primary source. Similarly, the country of origin would not be applicable for marine genetic resources sourced in areas beyond national jurisdiction as well as for genetic resources covered by the PIP-Framework. In these cases, the patent applicant would need to disclose the relevant marine area or the PIP-framework as the primary source.

- Moreover, for traditional knowledge associated with genetic resources and for genetic resources sourced from indigenous peoples and local communities, disclosing individual countries may not be suitable. In line with the United Nation Declaration of Rights of Indigenous Peoples (UNDRIP) and with Articles 5.5, 6.2, 7 and 12 of the NP, it seems more

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6 Secretariat of the Convention on Biological Diversity (2008). Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors. Montreal, Technical Series No. 38, 140 pages.

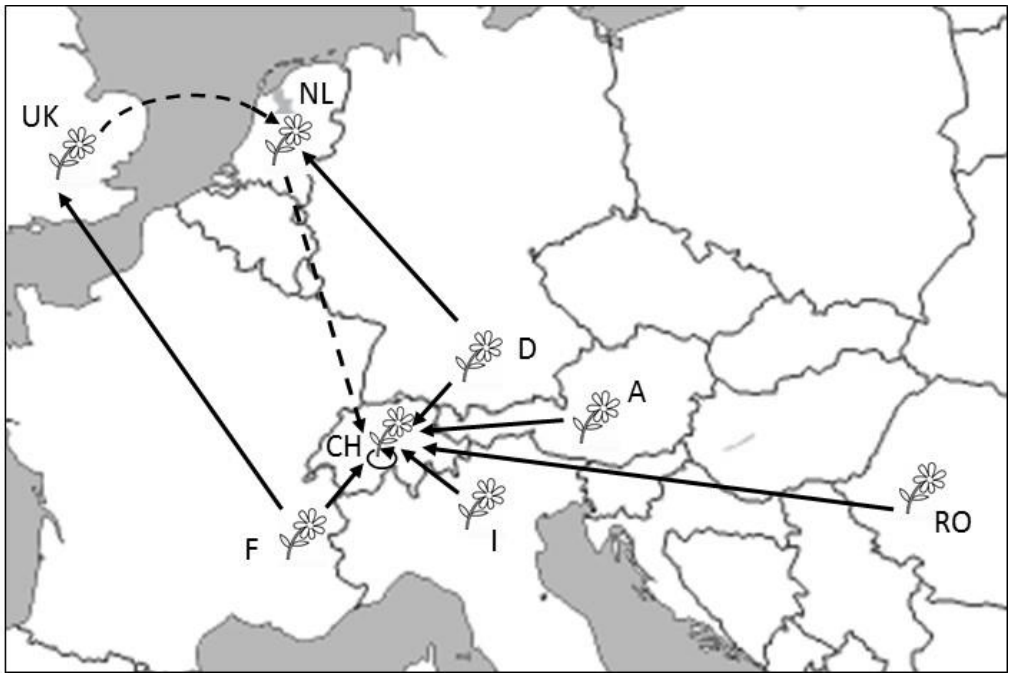
7 WIPO/GRTKF/IC/11/10.

appropriate in these cases to require patent applicants to disclose the indigenous peoples and local communities holding such knowledge or that provided the genetic resources as the primary source.

17. However, primary sources are not always known to patent applicants, and sometimes they can only be determined with unreasonable efforts, if at all. For example, many genetic resources have been sourced a long time ago, even prior to the entering into force of the CBD, and in many cases, there is not a simple linear relationship between the "original" genetic resource, and the genetic resource on which the invention is directly based. Therefore, some genetic resources simply lack the relevant information to determine the primary source. In these cases, the patent applicant must disclose a secondary source. Depending on the circumstances, secondary sources can, for example, be an *ex-situ* collection or, in the case of traditional knowledge, scientific literature.

18. In the rare cases where both the primary and secondary source are unknown to the patent applicant, or if they can only be determined with unreasonable efforts, a declaration to that effect must be made. Article 45*a* of the PatO lists the most important primary sources (letters a. to g) as well as secondary sources (letters e. to f.) (see Appendix 1).

19. These rather technical explanations can be illustrated with the example of the Alpine Edelweiss (*Leontopodium alpinum*). This species contains pharmaceutical and cosmetic properties and can be sourced *in-situ* in alpine countries that are the countries of origin of this plant, such as Austria (A), France (F), Germany (D), Italy (I), Switzerland (CH), and others (see illustration below). However, it can also be sourced *in-situ* in countries of the Carpathians, such as Romania (RO), as well as in some Balkan countries, which therefore are also countries of origin. Moreover, today, the plant is also grown in *ex-situ* conditions. Therefore, it may also be sourced for instance in botanical gardens, which may not be located in a country of origin, such as in the Netherlands (NL) or in the United Kingdom (UK). Moreover, there are other Edelweiss species or cultivated species, for which the Alpine countries may not be the countries of origin.



Explanation: Sourcing from *in-situ* conditions is indicated by solid lines, while sourcing from *ex-situ* conditions is indicated by the dashed lines.

20. According to the example illustrated above, the following sources can apply:

- if the plant was sourced either in Austria, France, Germany, Italy, Romania or Switzerland, the respective country would need to be disclosed as the primary source;

- if the plant was sourced from the *ex-situ* collection in the Netherlands, the primary source would be Germany, if the plant was initially sourced in Germany. In contrast, the primary source would be France, if the plant was initially sourced in France, and obtained by the *ex-situ* collection in the Netherlands through another *ex-situ* collection in the UK. If the information on these primary sources is not known to the patent applicant, or if it can only be obtained with unreasonable efforts, the *ex-situ* collection in the Netherlands would have to be disclosed as the secondary source.

21. If, however, the patent applicant would need to disclose the "the country of origin," as is proposed by some delegations in the IGC negotiations, the patent applicant could disclose any of the countries of origin, namely Austria, France, Germany, Italy, Romania or Switzerland, irrespective of whether the plant was actually sourced in the country of origin that he disclosed. The concept of "country of origin" would thus provide a possibility to avoid disclosing the country that actually provided the genetic resource. This would run counter to the objective of enhancing transparency in access and benefit-sharing.

D. Rationale for the trigger of the disclosure requirement: "directly based on"

22. In general, in the description of a biotech patent, one finds references to a variety of genetic resources. The research and development phase before completing an invention often involves several genetic resources, including experimental animals or plants as well as laboratory tools, such as plasmids, viruses, bacteria, and yeasts. These tools are often consumables, and may be acquired from commercial suppliers. However, it is obvious that the purpose of the disclosure requirement is not to declare the source of laboratory consumables that might have been used as tools during the research and development phase that lead to the invention, but rather the source of the genetic resource on which the invention is actually directly based on.

23. To clarify this, the PatA states that the invention needs to be "directly based" on the genetic resource, and that the inventor or patent applicant needs to have had access to this genetic resource. As indicted in paragraph 17 of document WIPO/GRTKF/IC/16/INF/14, "access" in the context of the disclosure of source means that the inventor must have been in the possession of the specific genetic resource, or at least that the contact to the genetic resource was sufficient to identify the specific properties relevant for the invention. "Directly based on" thus means that the invention must make immediate use of and depend on the identified specific properties of the genetic resource.

24. It is important to note that the properties of a genetic resource might also include biochemical compounds isolated from the genetic resource, or in other words, derivatives that are isolated from genetic resources. "Directly based on" therefore does not exclude biochemical compounds that are isolated from a specific genetic resource. However, it clarifies that there has to be a clear link to the genetic resource from which the biochemical compound was isolated.

25. In the context of "traditional knowledge", "directly based on" means that the inventor must know that the invention is based on traditional knowledge, that is, that the inventor must have consciously derived the invention from this knowledge.

E. Rationale for "proportionate and effective sanctions"

26. One of the main purposes of the patent system is to foster innovation and economic growth. Legal certainty is a key factor in this regard, in particular since there is a considerable time span between the planning of a research project, the actual research and development phase, applying for a patent, the obtaining of marketing approval, and the marketing of a product to allow for a return on investment. It is therefore important to include effective and

proportionate sanctions in a disclosure requirement, which at the same time do not hinder innovation.

27. The disclosure requirement according to the approach put forward by Switzerland distinguishes between pre-grant and post-grant sanctions:

- Pre-grant sanctions concern the processing of patents. If the patent application does not contain a declaration of the source, the Swiss Federal Institute of Intellectual Property (IPI) will allow the applicant a period of time to correct the application. If this period of time expires without correction, the IPI rejects the application (Art. 59 para. 2 and Art. 59a para. 3 subpara. b PatA).

- Post-grant sanctions consist of a fine of up to 100,000 Swiss Francs for the intentional wrongful declaration of a source (Art. 81*a* PatA). Moreover, the judge may order the publication of his ruling.

28. Not available as a sanction in the context of non-compliance with the disclosure requirement is the revocation of granted patents. This is because revocation would destroy the very basis for benefit-sharing – namely, the patent – because no monetary benefits could be generated anymore through the patent system, since the invention protected by the revoked patent would fall into the public domain. In addition, revocation would contradict legal certainty.

III. RELATIONSHIP OF THE DISCLOSURE REQUIREMENT WITH OTHER REGULATIONS RELATED TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

A. Introduction

29. There are several international instruments, which are relevant in the context of genetic resources and traditional knowledge. Of particular importance are the CBD and its NP, as well as the ITPGRFA of FAO.

30. Switzerland implemented the NP and the ITPGRFA at the national level in a mutually supportive manner. This was achieved by introducing new measures in the NCHA and in the Federal Act on Agriculture (AgricA). The provisions of these Acts have been further specified in implementing ordinances, specifically the Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (NagO), and the Ordinance on Plant Genetic Resources for Food and Agriculture (PGRFAO). Both ordinances entered into force in early 2016 (see Appendix 2).

31. Therefore, a disclosure requirement within the patent system has to be understood in the broader context of measures to implement the international regime on access and benefit-sharing. Moreover, since document WIPO/GRTKF/IC/30/9 submitted by the US also addresses the implementation of the NP at the Swiss national level, it seems appropriate to provide a comprehensive summary of these provisions in the present document. The following sections thus describe the relationship between the declaration of source according to the PatA, and the national regulations resulting from the implementation of the NP and the ITPGRFA.

B. Relationship with the regulations implementing the Nagoya Protocol (NP)

32. Although the NP does not address IP issues as such (with the exception of Art. 6.3 (g) (ii) as well as the non-exhaustive list of potential benefits in the Annex), the declaration of the

source according to the PatA is in line with the NP. Furthermore, the IPI can be regarded as a checkpoint according to Article 17 of the NP[8].

33. The legal measures to implement the NP in Switzerland, in particular the so called "user compliance measures" according to Articles 15 and 16 of the NP, which are applicable to all Parties of the NP, are contained in Chapter 3 of the NCHA (see Appendix 1). These can be summarized as follows:

- Any person who utilises genetic resources or benefits directly from their utilisation (users) must apply due diligence to ensure that the resources have been accessed in accordance with the domestic access and benefit-sharing regulatory requirements of the Party to the NP that provides these resources.

- Prior to applying for market authorisation or the commercialisation of products developed on the basis of utilised genetic resources, compliance with the due diligence requirement must be notified to the Federal Office for the Environment (FOEN).

- These measures also apply to the traditional knowledge associated with genetic resources of indigenous and local communities unless such traditional knowledge is already freely available to the public.

34. These measures only apply to cases related to access to genetic resources that occur after the said provisions came into force, i.e., 12 October 2014. These measures thus have no retroactive effect. Additionally, the genetic resources in question must originate from countries that are Parties to the NP, and that have domestic access and benefit-sharing regulatory requirements in place. Moreover, these measures do not apply to human genetic resources, to commodities or goods in trade that are not utilised as genetic resources in terms of the NP (see Art. 23*n* para. 2, and Art. 25*d* NCHA).

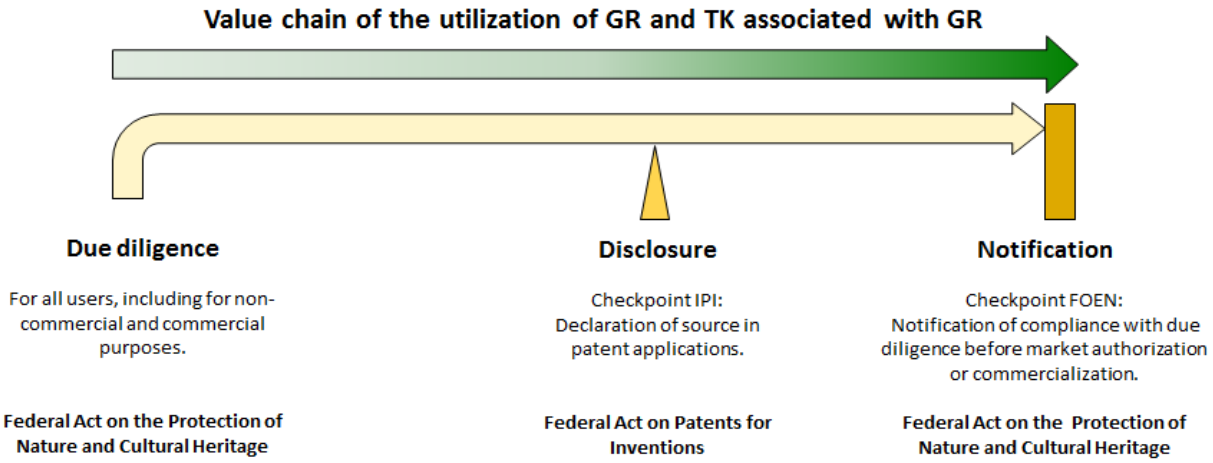
35. The NagO further specifies the measures contained in the NCHA. In particular, the NagO (1) contains detailed provisions about the specific information that needs to be recorded, kept, and transferred in the context of the due diligence requirement; (2) specifies the procedural aspects of the notification requirement; (3) contains provisions with regard to access to genetic resources in Switzerland; and (4) defines the specific duties of the different Swiss authorities involved.

36. It is important to note that from a procedural perspective there is no direct link between the declaration of the source in the PatA, and the provisions in the NCHA and the NagO. In particular, the notification of the due diligence requirement to the FOEN is not triggered by the application for a patent, but by the request for a market authorisation or the commercialisation of a product developed on the basis of a utilised genetic resource and/or associated traditional knowledge. The NagO defines "commercialisation" as meaning "to sell products developed on the basis of utilised genetic resources or associated traditional knowledge, as well as other legal transactions in connection with utilised genetic resources or traditional knowledge that result in monetary benefits, in particular licences, pledge agreements or similar legal transactions" (see Art. 2 letter e NagO).

37. The declaration of the source according to the PatA, and the due diligence requirement according to the NCHA, are mutually supportive. The information which has to be recorded, kept and transferred to subsequent users according to the due diligence requirement allows for the

[8] Art. 17.1 (a) (i) NP states that "*To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include: (a) The designation of one or more checkpoints [that] would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate.*"

relevant information relating to the source of genetic resources and/or related traditional knowledge to be more readily available to patent applicants without additional efforts or costs involved. Similarly, the enhanced transparency due to the declaration of the source requirement in the PatA will facilitate the implementation of the due diligence requirement in the NCHA.



Explanation: Illustration of the relationship between the declaration of source in the PatA and the due diligence and notification requirements in the NCHA. The IPI is a checkpoint to enhance transparency within the patent system, while the FOEN is the centralized checkpoint to implement the NP. The due diligence requirement allows that relevant information to be disclosed at the checkpoints will be readily available along the innovation and value chain of a genetic resource and/or of traditional knowledge associated with genetic resources.

C. Relationship with the regulations implementing the ITPGRFA

38. Article 10.2 of the ITPGRFA states that in the exercise of their sovereign rights, the Contracting Parties agree to establish a Multilateral System (MLS), which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture (PGFRA), and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis. Article 12.4 provides that facilitated access under the MLS shall be provided pursuant to a Standard Material Transfer Agreement (SMTA). Therefore, the concept of "country of origin of genetic resources" is not applicable for material derived from the MLS.

39. In Switzerland, access to PGRFA in the national gene bank as well as the fair and equitable sharing of benefits arising from their utilisation are regulated by the PGRFAO. All PGRFA that can be included in the national gene bank are subject to the conditions of the MLS of the ITPGRFA, no matter whether these resources are listed in Appendix 1 of the Treaty or not (see Art. 4 and 5 of the PGRFAO).

40. For inventions that are directly based on PGRFA and covered by the MLS, a patent applicant will thus not be able to disclose a "country of origin." The primary source would therefore be the MLS. However, it is important to note, that in accordance with Article 4 para. 4 of the NP, the due diligence requirement does not apply to genetic resources that are covered by the MLS of the ITPGRFA (see also Art. 23*n* para. 2 NCHA).

IV. CONCLUSIONS AND A POSSIBLE WAY FORWARD WITH REGARD TO AN INTERNATIONALLY AGREED DISCLOSURE REQUIREMENT

41. Switzerland's declaration of source requirement in the PatA has been designed as a measure to enhance transparency about genetic resources and/or associated traditional knowledge, with the intention to support compliance with the access and benefit-sharing

regulatory requirements of other countries. This requirement is mutually supportive with the specific measures adopted to implement the NP as well as the ITPGRFA. However, it is not in itself sufficient to implement these agreements. Both, the NP and the ITPGRFA, have been implemented through other measures outside of the patent system.

42. Because the majority of patent applicants in Switzerland submit their applications through the European Patent Office (EPO), Switzerland has limited practical experience with the implementation of the declaration of source requirement according to the PatA. Similarly, so far Switzerland has only limited experience with the implementation of the ordinances to implement the NP as well as the Treaty, since both ordinances only entered into force early in 2016. However, these provisions have all been elaborated based on sound principles, and they went through impact assessments as well as public and democratic consultations prior to their adoptions.

43. In the future, due diligence systems, such as the ones recently introduced in Switzerland as well as in the EU[9] in order to implement the NP, are likely to further facilitate and foster the implementation of the disclosure requirement in the patent system and vice-versa in a mutually supportive manner.

44. Based on the provisions of the CBD and the NP, several countries have already introduced disclosure requirements in their national patent systems, or are likely to do so in the near future. In the view of Switzerland, it remains important to keep these requirements as simple as possible in order to ensure their practicability. There are thus various advantages in adopting such a requirement also at the international level:

1. It would *foster the international harmonisation of disclosure requirements within the patent system,* and thus *increase legal certainty and support innovation* on products based on genetic resources and/or associated traditional knowledge at the global level.

2. It would *build mutual trust and support access and benefit-sharing among providers and users* of genetic resources and/or associated traditional knowledge. In doing so, it would contribute towards the achievement of the objectives of the CBD, the NP, the ITPGRFA and more generally the sustainable developmental goals (SDG)[10].

3. An international disclosure requirement established under WIPO would *increase WIPO's role and credibility* in governing issues related to intellectual property, genetic resources and/or associated traditional knowledge, which would be to the benefit of the patent system in the long term.

45. In the view of Switzerland, an international disclosure requirement under WIPO should strike a delicate balance between the interests of all stakeholders concerned. One way to achieve this balance would be to elaborate an international disclosure requirement not only with minimum standards (i.e., an international obligation to declare the source of genetic resources and/or traditional knowledge associated with these resources in patent applications), but also with maximum standards (i.e., in particular, no revocation of patents for non-compliance with the disclosure requirement). This would increase legal certainty for both users and providers of genetic resources and associated traditional knowledge.

46. Moreover, such an international disclosure requirement should be as simple as possible, in order to ensure its practicability and effectiveness. This also means that the international instrument negotiated by the IGC should clearly focus on issues related to the patent system.

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[9] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

[10] http://www.un.org/sustainabledevelopment/sustainable-development-goals/.

Issues related to access and benefit-sharing can and should be implemented through other measures, as explained in Section III of this submission.

47. Finally, an international disclosure requirement under WIPO should not change access and benefit-sharing provisions contained in other international agreements, such as the ones in the NP, as WIPO is not the competent forum to address such issues. For instance, the inclusion of "derivatives" would run counter to the international consensus found with the adoption of the NP, which refers to derivatives in Article 2, but not in its operational provisions. Moreover, the concept of "country of origin" is neither supported by the ITPGRFA, nor contained as such in the NP. The latter refers to "Party providing genetic resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention," and in its Article 17, specifically refers to the "source of the genetic resource."

48. For Switzerland, it remains crucial that an international WIPO instrument related to genetic resources ensures mutual supportiveness with other international agreements, including those addressing access and benefit-sharing requirements. In accordance with the mandate of the IGC, such an instrument should ensure the balanced and effective protection of genetic resources and associated traditional knowledge.

[Appendices follow]

Appendix 1

Overview of the Swiss Legal framework related to genetic resources and associated traditional knowledge

The Swiss legal framework related to genetic resources and associated traditional knowledge is regulated in a number of Acts and Ordinances. Additional documents, such as the dispatches submitted by the Swiss Federal Council to the Swiss Federal Parliament and explanatory notes, are also relevant to correctly understand and apply the Swiss legal framework. This Appendix 1 contains the links to the most relevant laws and other documents, and lists the most important articles.

Please note that this Appendix 1 is not intended to be comprehensive. There exist interlinkages with other relevant legal provisions, which are not specifically mentioned in Appendix 1. Moreover, English is not an official language of the Swiss Confederation. Thus, the English translations, where available, are provided for information purposes only and have no legal force.

Declaration of the source requirement in patent applications:

- SR 232.14 - Federal Act of 25 June 1954 on Patents for Inventions (Patents Act, PatA): https://www.admin.ch/opc/en/classified-compilation/19540108/index.html
  See, in particular, Articles 49*a*, 58*a*, 59 para. 2, 59*a* para. 3 letter b, 81*a*, and 138 letter b.

- SR 232.141 - Ordinance of 19 October 1977 on Patents for Inventions (PatO), available in German, French, or Italian.
  See, in particular, Chapter 6 “Information on the source of genetic resources and traditional knowledge” (Article 45*a*), and Article 67 para. 2.

- Dispatch of 23 November 2005 concerning the revision of the PatA, available in German, French, or Italian.
  See, in particular, Section 2.1.6 “Requirements for the patent application”.

Regulations and other relevant documents to implement the Nagoya Protocol:

- SR 0.451.43 – Convention of 5 June 1992 on Biological Diversity: https://www.cbd.int/doc/legal/cbd-en.pdf

- SR 0.451.432 - Nagoya Protocol of 29 October 2010 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From their Utilization to the Convention on Biological Diversity: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

- SR 451 - Federal Act of 1 July 1966 on the Protection of Nature and Cultural Heritage (NCHA): https://www.admin.ch/opc/en/classified-compilation/19660144/index.html
  See, in particular, Articles 1 letter d^{bis}, 23*n*, 23*o*, 23*p*, 23*q*, 24*a* para. 2, 24*h* para. 3, and 25*d*.

- SR 451.61 - Ordinance of 11 December 2015 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization (Nagoya Ordinance, NagO): https://www.admin.ch/opc/en/classified-compilation/20150120/index.html

- Dispatch of 10 April 2013 concerning the adoption and implementation of the Nagoya Protocol, available in German, French, or Italian.
  See, in particular, Section 3, or the non-official English translation of selected parts of the message.

- Explanatory notes of 11 December 2015 to the Nagoya Ordinance, available in German, French, or Italian.

Regulations to implement the International Treaty on Plant Genetic Resources for Food and Agriculture:

- SR 0.910.6 - International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture: ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf

- SR 910.1 - Federal Act of 29 April 1998 on Agriculture (Agriculture Act, AgricA):
  https://www.admin.ch/opc/en/classified-compilation/19983407/index.html
  See, in particular, Articles 147*a* and 147*b.*

- SR 910.181 – Ordinance of 28 October 2015 on Plant Genetic Resources for Food and Agriculture (PGRFAO), available in German, French and Italian.

Provisions related to the implementation of the Nagoya Protocol in the Ordinance on Therapeutic Products:

- SR 812.212.21 - Ordinance of 17 October 2001 on Therapeutic Products (TPO), available in German, French, and Italian.
  See, in particular, Article 3 para. 1^{bis} and 7 para. 1^{bis}

[Appendix 2 follows]

Appendix 2

Document WIPO/GRTKF/IC/30/9, submitted by the United States of America, with comments by Switzerland

This Appendix 2 contains document WIPO/GRTKF/IC/30/9, which was submitted by the Delegation of the United States of America to the Thirtieth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The comments by Switzerland to those sections of the document that contain erroneous, incomplete, or misleading interpretations of the Swiss legislation related to genetic resources are added in italic under each relevant section. Not commented and not included in this Appendix 2 is the Appendix of the US document with the hypothetical example "U.S. Patent Number 5,137,870".

SEEKING A BETTER UNDERSTANDING OF SWITZERLAND'S FEDERAL ACT ON THE PROTECTION OF NATURE AND CULTURAL HERITAGE AND FEDERAL ACT ON PATENTS FOR INVENTIONS BY HYPOTHETICALLY APPLYING THEM TO U.S. PATENT NUMBER 5,137,870

I. INTRODUCTION

Disclosure requirements have been characterized as simple transparency requirements, which will not be burdensome to patent applicants. Our review of disclosure requirements, however, suggest that these requirements will be difficult for applicants to satisfy, and that applicants will be required to disclose many sources of any genetic resource (GR) used at some point in making the invention, as well as those which could have been used. As a result of the enormous information potentially required, we question the feasibility of a disclosure mandate providing transparency and have concerns that it could be burdensome. Also, we question whether this requirement would discourage applicants from filing patent applications on certain inventions, thus further decreasing transparency.

Comment by Switzerland: In the view of Switzerland, a disclosure requirement within the patent system should not be burdensome and difficult for applicants to satisfy. This is why such a requirement should be designed as a simple, practical and effective measure to enhance transparency with regard to genetic resources and traditional knowledge.

To better understand disclosure requirements, we have chosen the law of Switzerland as a first example. If this exercise improves our understanding of the disclosure requirement in Switzerland, then we plan to undertake the same exercise using the laws of other World Intellectual Property Organization (WIPO) Members.

Comment by Switzerland: The US document not only addresses the declaration of source in the PatA, but also the Swiss regulations to implement the Nagoya Protocol. Unfortunately, the US document confuses in several paragraphs these measures (see in particular comments by Switzerland on Section III below).

To comply with its access and benefit sharing (ABS)-user measures, Switzerland requires, among other things: (1) due diligence of compliance with domestic ABS provisions, (2) notification of said due diligence, and (3) disclosure of the source of GRs in patent applications. The sanctions for failing to comply with these provisions are significant fines, court-ordered publications of the judgments, and the possibility of a rejected patent. To better understand the application of the above laws, and to stimulate a factual discussion, the above laws are applied in this document to a selected patent.

Comment by Switzerland: This paragraph gives the impression that the due diligence must always be notified. However, the notification is only required before market authorisation or commercialisation of products developed on the basis of utilised genetic resources and/or utilised associated traditional knowledge. Moreover, the disclosure of source requirement only applies when a patent is filed. These are thus two separate measures applicable at separate instances.

II. **LEGAL FRAMEWORK**

Switzerland's ABS provisions on due diligence and notification can be found in the Federal Act on the Protection of Nature and Cultural Heritage ("NCHA"), Articles 23n and 23o, respectively. NCHA Article 24a describes the penalties for their non-compliance. Additionally, Article 49 of the Federal Act on Patents for Inventions ("Patents Act") mandates disclosure in patent applications. Violators of this provision are subject to the pre-grant penalties of Article 59a and post-grant sanctions of Article 81a.

Comment by Switzerland: The Swiss legal framework related to genetic resources and traditional knowledge consists of further relevant Articles, Laws and Ordinances, which are not reflected or only in an incomplete manner in the US document. In particular, Articles 23p, 23q, 24h para. 3, and 25d of the NCHA, the Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization (NagO), and the Ordinance on Patents for Inventions (PatO) are not at all reflected in the US document. Furthermore, there is no reference to the regulations implementing the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), namely Articles 147a and 147b of the Federal Act on Agriculture and the Ordinance on Plant Genetic Resources for Food and Agriculture (PGRFAO). Finally, in order to correctly understand and apply the Swiss legal framework, it is important to also take into account the Dispatches submitted by the Swiss Federal Council to the Swiss Federal Parliament, and the explanatory notes on the regulations. The Articles selected by the US-Delegation therefore do not allow to fully and correctly understand the Swiss legal framework. A comprehensive description of the Swiss legal framework is found in the main part of the present document; additionally, the relevant legal provisions are listed in Appendix 1 above.

1. Federal Act on the Protection of Nature and Cultural Heritage Requirements

A. **Due Diligence Requirement**

Article 23n of the NCHA includes:

1. Any person who in accordance with the Nagoya Protocol utilises genetic resources or benefits directly from their utilisation (users) must apply due diligence appropriate to the circumstances to ensure that:

a. the resources have been accessed lawfully; and

b. mutually agreed terms for the fair and equitable sharing of the benefits have been established.

2. Genetic resources are not subject to the due diligence requirement if they:

a. originate from a country that is not a Party to the Nagoya Protocol; and

b. originate from a country that has no domestic access and benefit-sharing regulatory requirements;

…

5. If the requirements of paragraph 1 letters a and b are not met, users must ensure that they are met subsequently, or must refrain from utilising the genetic resources concerned or from benefiting directly from their utilisation.

B. Notification/Market Authorization Requirement

Comment by Switzerland: This title is misleading, as it mixes up notification and market authorisation requirements.

Art. 23o of the NCHA includes:

1. Notification of compliance with the due diligence requirement must be given to the FOEN before market authorisation has been obtained or, if such authorisation is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

…

C. **Criminal Penalties**

Art 24a of the NCHA reads:

…

2. Any person who wilfully fails to provide information or provides false information under Article 23*o* shall be liable to a fine not exceeding 100,000 Swiss francs; in cases of negligence, the penalty shall be a fine not exceeding 40,000 Swiss francs. The court may order the publication of the judgment.

…

2. Federal Act on Patents for Inventions Requirements

A. Source of Genetic Resources

Art. 49a of the Patents Act reads:

1 The patent application must contain information on the source:

a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource;

b. of traditional knowledge of indigenous or local communities of genetic resources to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.

2 If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing.

B. Pre-Grant Penalties

Art. 59 of the Patents Act reads:

…

2 If the patent application does not meet the other requirements of this Act or the Ordinance, the Institute shall set a time limit for the patent applicant by which the deficiencies must be remedied.

…

Art. 59a of the Patents Act reads:

…

3 The Institute shall reject the patent application if: …

b. the deficiencies mentioned in Article 59 paragraph 2 have not been remedied.

C. Post-grant Penalties

Art. 81a of the Patents Act reads:

1 Any person who wilfully provides false information under Article 49*a* is liable to a fine of up to 100,000 francs.

2 The court may order the publication of the judgment.

…

III. PATENT INTRODUCTION

The patent that will be used in this analysis is U.S. Patent 5,137,870 ("'870 Patent"), entitled "Didemnins and Nordidemnins." The '870 Patent was filed in the U.S. on February 20, 1990 and claims domestic priority to parent application 186,932, which was filed on September 12, 1990. The inventor was Kenneth L. Rinehart ("Rinehart") and the assignee the University of Illinois at Urbana.

Comment by Switzerland: The U.S. Patent 5,137,870 was filed 20 February 1990; this is thus an outdated example to be used for the analysis of the Swiss legislation on genetic resources, which entered into force many years later. The GRs used in the research leading to this patent were accessed even before the CBD entered into force. In the decades since, approaches on how research involving genetic resources is carried out have changed in most cases, as have the regulations on GRs in Switzerland and, most likely, also in Mexico, Panama, Honduras, Colombia and Belize. A more recent patent application would have been more appropriate for a proper and meaningful analysis of the relevant legal regimes.

The Brief Summary of the Invention reads:

Novel antibiotics didemnin A, didemnin B, didemnin C, nordidemnin A, nordidemnin B, and nordidemnin C are extracted from a marine tunicate of the family Didemnidae, and tentatively identified as a Tridemnum sp. These antibiotics are active against DNA viruses, for example, herpes simplex virus types 1 and 2, and vaccinia virus; RNA viruses, for example, coxsackie virus and equine rhinovirus; and B388 leukemia in mice. Thus these antibiotics can be used to treat infections in humans, animals and plants caused by these viruses and other DNA and RNA viruses. Didemnin A and didemnin B also inhibit L1210 mouse leukemia cells in vitro. Acid addition salts and acyl derivatives of the didemnins can be made and used for the same biological purposes are the parent compounds.

…

The Detailed Description of the Invention reads:

Specific locations from which these organisms have been obtained are as follows:
(1) Southwest side of Long Cay, Lighthouse Reef, Belize, 17.degree. 11.8' N by 87.degree. 36.5' W at a depth of 50 to 100 feet; (2) Rada el Cove, Isla San Andres**, Colombia**, 12.degree. 31'46" N by 81.degree. 44'5" W at 25 to 33 feet; (3) Palancar Reef, Isla de Cozumel, **Mexico**, 20.degree. 18.2' N by 87.degree. 2.5' W at 60 to 100 feet; (4) on the west side of the southern tip of Turneffe Island**, Belize,** 17.degree. 11.3' N by 87.degree. 55.6' W at 50 to 75 feet; (5) Punta Oeste, Coxen's Hole Harbor, Isla Roatan, **Honduras**, 16.degree. 15' N by 86.degree. 38' W at 10 to 70 feet; (6) on the leeward side of the western-most Holandes Cay, Isla San Blas, **Panama**, 9.degree. 35.6' N by 78.degree. 47' W at 60 feet.
…

Comment by Switzerland:

1. *The description of the US patent already contains the source of the genetic resources, including the precise coordinates of the access locations. This even goes beyond the information that a patent applicant would need to disclose according to the PatA in Switzerland, which in the case at hand would only require the disclosure of the name of the relevant countries, i.e. Columbia, Mexico, Belize, Honduras, and Panama.*

2. *The description of the invention in the patent application also shows that although the US does not have an explicit requirement to disclose the source of the genetic resources in their patent system, the precise sources are indicated in the description of the invention. It is therefore difficult to follow the argument that a simple disclosure requirement could be burdensome or difficult to apply for a patent applicant, if the relevant information in the example used for the analysis of the Swiss legal system already contains the relevant information.*

Claim 1 of the '870 Patent reads:

A process for treating an animal or human hosting leukemia comprising: administering an effective amount of a didemnin selected from the group consisting of didemnin A, didemnin B, and didemnin C or a pharmaceutically acceptable salt thereof, to said host.

IV. ANALYSIS

If the subject matter of the '870 Patent is filed in Switzerland in 2016, what would the patent applicant be required to do in order to comply with Swiss law?

A. Due Diligence in Mexico, Panama, Honduras, Colombia, and Belize

Comment by Switzerland: We do not comment on the analysis of the laws of other countries in the US document.

As noted in the Specification of the '870 Patent, the inventor obtained samples of marine tunicate from the waters of Mexico, Panama, Colombia, Belize, and Honduras. According to the NCHA, a person who utilizes GRs or benefits directly from their utilization must apply due diligence appropriate under the circumstances. Thus, a first question is whether the inventor of the '870 patent utilized GRs or benefited directly from their utilization. The Nagoya Protocol ("NP") defines "'Utilization of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of GRs, including through the application of biotechnology as defined in Article 2 of the Convention." Assuming that for purposes of Swiss law, "utilization" has the same meaning, the inventor did "utilize" the genetic resources because research and development was conducted on the samples.

To meet the due diligence requirements in Switzerland under Art 23n of the NCHA, it appears that Rinehart would need to comply with the access provisions for those countries that are both party to the NP and have domestic ABS laws. Of the above nations, only Mexico and Panama fall under this category.

Comment by Switzerland:

1. *Article 23n para. 3 NCHA, which is not reflected in the US document, reads "The utilisation of genetic resources in terms of paragraph 1 means to conduct research and development on the genetic or biochemical composition of genetic resources, including through the application of biotechnology". Additionally, Article 2 of the NagO defines the term "utilization of genetic" as in the Nagoya Protocol.*

2. *Even in the absence of a due diligence requirement in a country, researchers from that country would have to comply with the national access regulations of the countries where they access genetic resources. This paragraph gives the wrongful impression, that if a country does not have a due diligence system in place, a researcher from that country can just ignore the access regulations of other countries.*

3. *The due diligence requirement is a measure which has been specifically introduced in the Swiss legislation to implement the Nagoya Protocol. It therefore only applies to GRs that have been accessed in countries that are also Parties to the Nagoya Protocol. A clear limitation of the scope of the due diligence requirement according to the Swiss legislation to Parties to the Nagoya Protocol is important, as only those countries have the same rights and obligations, which allow the measure to be implemented.*

Mexico:

Mexican access laws are complex and depend on whether access is being sought on land or in water. To obtain access in federal aquatic areas for research purposes, applicants have to obtain a permit from the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food ("SAGARPA"). Permit applicants must provide the following:[11]

- Names of the supervisors and technical leaders of the project;
- Objectives of the study;
- Application of the results;
- Common and scientific names of the organisms to be researched;
- Location at local, municipal and state levels;
- Geographical coordinates; and
- Justification of the chosen site.

The law also mandates permit holders provide status reports to SAGARPA and be compliant with other Mexican regulations including the Fisheries Act and Fisheries Act Administrative Rules.

Here, Rinehart obtained tunicates from the Palancar Reef in Cozumel, Mexico, an area that is administered by the Arrecifes de Cozumel National Park. He would therefore need to obtain a permit from SAGARPA and complete the numerous application requirements listed above. Rinehart would also have to follow other state and federal rules and regulations.

Panama:

Panama is also a member of the NP, and its domestic ABS rules can be found in Executive Decree No. 25 of April 2009 ("ED 25"). Under ED 25, Panama requires applicants seeking access to the country's genetic heritage, including its marine and coastal

[11] http://www.fao.org/fishery/legalframework/nalo_mexico/en.

environments,[12] to receive permission from the Unit for Access to Genetic Resources (UNARGEN). Applicants must obtain the following:

- Accessory Contract granting Free Prior Informed Consent (FPIC) from owner of the resource;
- Access Contract from UNARGEN; and
- Benefits Contract from UNARGEN.

Applicants must also maintain compliance with various provisions of ED 25 throughout the life of the Access Contract.

As disclosed in the '870 Patent, Rinehart obtained tunicates from the Holandes Cay, Isla San Blas, in Panama. Therefore, he would have to receive FPIC from the owner of the research site. Then he must acquire Access and Benefits Contracts from UNARGEN. Finally, he must comply with additional Panamanian regulations while accessing the site on Holandes Cay.

Honduras, Colombia, Belize:

Rinehart also extracted tunicates from Honduras, Colombia, and Belize. Of these, only Honduras is a party to the NP, but it does not have domestic ABS laws. Switzerland, therefore, would not require Rinehart to provide due diligence of his activities in these countries. Suppose, however, he obtained tunicates from 10 other countries that are party to the NP and have ABS laws. Clearly, for each additional country, he would have added requirements, which could discourage research.

Comment by Switzerland: It is important to note that based on the Nagoya Protocol, many countries are currently in the process of revising their national ABS regulatory requirements, or newly introducing such requirements. Moreover, Parties to the Nagoya Protocol have an obligation to submit their legislative, administrative and policy measures as well as the information on the national focal points and competent national authorities to the ABS Clearing House (see Article 14 of the Nagoya Protocol). This information will also facilitate the evaluation whether the due diligence requirement applies to a specific situation.

B. Notification

After performing due diligence for potentially many countries, applicants in Switzerland are required to submit notification of said due diligence prior to obtaining market authorization or commercialization under Article 23o of the NCHA. This provision mandates that applicants notify the Federal Office for the Environment (FOEN) that it conducted due diligence. In this case, Rinehart would have to notify FOEN that he conducted due diligence for Mexico and Panama.

Comment by Switzerland: The patent applicant of U.S. Patent 5,137,870, Mr. Rinehart, apparently did not commercialize any products. Therefore, contrary to what is suggested in the text, there would be no obligation to notify compliance with the due diligence requirement to FOEN. A notification is only required before applying for marked authorisation or for the commercialisation of a product developed on the basis of utilised GRs (Article 23o NCHA). It is crucial to note that market authorisation and commercialisation does not include the act of applying for a patent.

[12] Panama, Executive Decree No. 25 of April 2009, Article 6(g).

C. Market Authorization for Medicinal and Therapeutic Products

After providing notification to FOEN, certain applicants seeking to do business in Switzerland may need to obtain market authorization. For new medicines and therapeutic products, applicants must receive authorization from Swissmedic, which will ascertain the products' safety before they are allowed to be sold in Switzerland. Here, because Rinehart's research was done in connection with his job at the University of Illinois, it is unlikely the University would market any products containing the didemnin found in the tunicates. However, any commercial applicant would have to obtain authorization from FOEN before marketing pharmaceuticals derived from GRs.

Comment by Switzerland: Contrary to what is stated in the text above, the notification requirement to FOEN is not an authorisation procedure. A commercial applicant would not need to seek authorization from FOEN to place a product on the market. In the context of the notification requirement, it is the responsibility of the applicant to notify the correct information to FOEN. FOEN as well as Swissmedic will only perform formal checks whether the information has been provided (Art. 10 letter h and 11 NagO, as well as Art. 3 para. 1bis and 7 para. 1bis of Therapeutic Products Ordinance (TPO). However, FOEN will verify compliance with the requirements according to the NCHA, if tangible signs of non-compliance exist or when carrying out spot checks (Art. 10 letter i NagO).

D. For Patent Applicants, Source of GRs Must Be Disclosed

In addition to the above requirements, Switzerland mandates its patent applicants include the source of GRs in their patent applications.

Comment by Switzerland: Contrary to what the text suggests, the notification requirement does not apply to patent applicants.

Section 49a of the Patents Act requires that "The patent application must contain information on the source: of the genetic resource to which the inventor or the patent application had access, provided the invention is **directly based** on this resource; of traditional knowledge of indigenous or local communities of genetic resources to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge" (emphasis added). Section 49b goes on to provide that if the source of the GR is unknown then the inventor or applicant must state so in writing.

Our understanding is that with regard to the '870 Patent, Rinehart would need to disclose each location where he obtained the tunicates. Based on the statute, he would first have to determine whether his invention was "directly based" on the tunicates. The definition of "directly based," however, is not clear from the text and a patent applicant cannot assume that he or she understands its meaning but would need to consult with a local patent attorney or research the Swiss patent law. If such research concluded that this phrase has the meaning afforded by the Swiss Delegation at the Twenty-Ninth IGC Session "that [an invention] would not exist without the GR or the TK,"[13] it would appear to necessitate the disclosure of the source for all of the GRs that were used. Almost every GR described in a specification could be implicated, not just the ones in the claims. For example, applicants often use many GRs in the experimental process before completing the actual invention, even though these GRs are not themselves part of the invention. In the case of the '870 Patent, Rinehart performed experiments on plants, animals, humans, DNA viruses and RNA viruses to determine the viability of his invention. Without these, the invention "would not exist" because Rinehart would

[13] Draft Report, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Twenty-Ninth Session, Geneva, February 15 to 19, 2016, Paragraphs 231-232.

not know whether it was effective in the first place. But the "would not exist" test raises the question as to what other GRs should be recognized. For example, but for the discovery of the thermophilic bacterium *Thermus aquaticus* in the United States Yellowstone National Park, biotechnology techniques used in Rinehart's invention, the invention would not exist. Should the source of this GR be disclosed as well?

Table 1 provides an overview of the requirements under the Swiss Patents Act, including the GRs in Rinehart's Specification that would need to be considered whether they fall under Switzerland's definition of "directly based."

TABLE 1. OVERVIEW OF REQUIREMENTS UNDER PATENTS ACT FOR '870 PATENT APPLICANT

Genetic Resource/Traditional Knowledge	**Location in Specification**	**'870 Applicant Meet Disclosure?**
Within the scope of the claim, but not obtained	Claims	No?
Tunicates, Belize Location #1	Col. 1, lines 53-55	Yes
Tunicates, Colombia	Col. 1, lines 55-56	Yes
Tunicates, Mexico	Col. 1, lines 56-58	Yes
Tunicates, Belize Location #2	Col. 1, lines 58-60	Yes
Tunicates, Honduras	Col. 1, lines 60-62	Yes
Tunicates, Panama	Col. 1, lines 62-64	Yes
Experimental Animals	Col. 1, line 30	**Needed**
Experimental Humans	Col. 1, line 30	**Needed**
Experimental Plants	Col. 1, line 30	**Needed**
DNA Viruses	Col. 1, line 31	**Needed**
RNA Viruses	Col. 1, line 31	**Needed**
Traditional knowledge	Not disclosed	**Needed**

Comment by Switzerland: This section contains several erroneous interpretations of the Swiss declaration of source in the PatA:

1. *The "concept of source" as understood in the Swiss PatA does not require the patent applicant to disclose the precise location (coordinates) of a GR. The primary source in the case at hand would be the names of the countries providing the GR. As these names are known to the patent applicant, he could easily fulfill the disclosure requirement.*

2. *The interpretation of the "trigger" of the disclosure requirement is incorrect. The term "directly based" was included in Art. 49*a *PatA in order to exclude the need to disclose GRs which are used in the experimental processes when developing an invention, if these genetic resources are not themselves an essential part of the invention. Therefore, there would be no need to disclose experimental organisms and viruses used in the experiments by Mr. Rinehart.*

E. Penalties for NCHA and Patents Act Violations

Switzerland imposes strict penalties on those violating the due diligence, notification and disclosure requirements. Failing to provide proper notification of due diligence could result in criminal fines of up to CHF100,000.[14] In addition, courts may order the publication of the judgment. Thus, in Rinehart's case, for any country for which he does not properly provide notification of due diligence could mean a fine of CHF100,000. On top of that, the court may order publication of the judgment for any violation of the notification requirement by Rinehart.

On the patent side, the penalty for providing false disclosure information in a patent application is a fine up to CHF100,000.[15] Here too, courts may order publication of the judgment.[16] If information on the source of the GR is missing from the patent application, it must be provided by a deadline or applicants risk denial of the patent. While Rinehart disclosed the source of the tunicates, this was done in 1990, many years before Switzerland had ABS and disclosure requirements on the books. Moreover, under today's law he could be penalized for not disclosing the source of the animals, plants, DNA viruses or RNA viruses on which he performed experiments.

The below table indicates the kind of penalties Rinehart would encounter today. As shown, he could be face up to CHF200,000 in fines, multiple court-ordered published judgments, and at least one denied patent.[17] Clearly, this would have enormous implications on an applicant's decision to file for a patent in Switzerland today.

[14] Federal Act on the Protection of Nature and Cultural Heritage, Art. 24a.
[15] Federal Act on Patents for Inventions, Art. 81(a(1)).
[16] Federal Act on Patents for Inventions, Art. 81(a(2)).
[17] If Rinehart files several related patent applications, for example, multiple patents would be denied in Switzerland.

TABLE 2. OVERVIEW OF PENALTIES UNDER SWISS LAW FOR '870 PATENT APPLICANT

Swiss Provision	**'870 Applicant Meet?**	**Max. Fines**	**Judgment Published**	**Patent Denied**
Due Diligence (Art. 23n NCHA)				
Belize Location #1	Not Needed	NA	NA	NA
Colombia	Not Needed	NA	NA	NA
Mexico	**Needed**	NA	NA	NA
Belize Location #2	Not Needed	NA	NA	NA
Honduras	Not Needed	NA	NA	NA
Panama	**Needed**	NA	NA	NA
Subtotal	**2 statutory requirements**	**NA**	**NA**	**NA**
Notification (Art. 23o NCHA)				
Belize Location #1	Not Needed	No	No	NA
Colombia	Not Needed	No	No	NA
Mexico	**Needed**	Yes	Yes	NA
Belize Location #2	Not Needed	No	No	NA
Honduras	Not Needed	No	No	NA
Panama	**Needed**	Yes	Yes	NA
Subtotal	**2 statutory requirements**	**CHF100,000 max (Criminal)**	**1 Judgment Published**	**NA**
Market Authorization (Federal Law on Medicinal Products and Medical Devices)	Not needed but would need if commercial exploitation of GR	Varies	NA	NA
Disclosure (Patents Act 49a)				
Belize Location #1	Yes	No	No	No
Colombia	Yes	No	No	No
Mexico	Yes	No	No	No
Belize Location #2	Yes	No	No	No
Honduras	Yes	No	No	No
Panama	Yes	No	No	No
Experimental Animals	**Needed**	Yes	Yes	Yes
Experimental Plants	**Needed**	Yes	Yes	Yes
Experimental Humans	**Needed**	Yes	Yes	Yes
DNA Viruses	**Needed**	Yes	Yes	Yes

RNA Viruses	**Needed**	Yes	Yes	Yes
Subtotal	**5 Statutory Requirements**	**CHF100,000 max**	**1 Judgment Published**	**1 + Patent Rejected (depending on number of related patent applications filed)**
Overall Total	**9 Statutory Requirements**	**CHF200,000**	**2 Judgments Published**	**1+ Patent Rejected**

Some may argue that the solution for avoiding heavy fines in Switzerland is for applicants to not willfully submit false origin or notification information. However, there is still a large CHF 40,000 fine for negligence with respect to notification, and the act remains a crime regardless of intent.

Moreover, the potential publication of judgments (criminal in the case of false or negligent notification) and a potential refused patent are major deterrents to small research applicants like Rinehart, who would be discouraged from filing a patent application in Switzerland.

Overall, it is clear that the Swiss disclosure requirement is not a simple “check box” requirement and considerable time would be required to determine whether and how to meet the requirement.

Comment by Switzerland: This section also contains incorrect information:

1. *In the context of the due diligence requirement, the list of possible sanctions is incomplete. In particular, the text is not mentioning the possibility to take administrative sanctions if tangible signs of non-compliance exist (see Art. 10 NagO as well as the explanations in the Dispatch to the adoption and implementation of the Nagoya Protocol). Moreover, users have also the possibility to fulfill the due diligence requirement subsequently if it has not been met (see in particular Art. 23n para. 5 NCHA, Art. 10 NagO).*

2. *Contrary to what is indicated in table 2 above, the notification requirement according to the NCHA is not applicable (not needed) in the context of patent applications. This also means that criminal sanctions (fines) as described in Article 24a NCHA are not applicable to patent applicants when filing a patent.*

3. *As the trigger and the concept of source have been misunderstood, the table also contains incorrect sanctions with regard to the declaration of source in the PatA. In particular, there would be no sanctions for not disclosing the source of the experimental organisms.*

[End of Appendices and of document]