

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Forty-First Session
Geneva, August 30 to September 3, 2021

AN INTERNATIONAL DISCLOSURE OF SOURCE REQUIREMENT FOR GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS – A CONTRIBUTION TO THE EVIDENCE-BASED APPROACH

Document submitted by the Delegation of Switzerland

INTRODUCTION

1. On March 2, 2020, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Delegation of Switzerland to submit a document entitled “An International Disclosure of Source Requirement for Genetic Resources and Associated Traditional Knowledge in Patent Applications – A Contribution to the Evidence-Based Approach”, for discussion by the Forty-First Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).
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 and consider the submission in the Annex of this document.*

[Annex follows]

An International Disclosure of Source Requirement for Genetic Resources and Associated Traditional Knowledge in Patent Applications – A Contribution to the Evidence-Based Approach

Executive Summary

Patent disclosure requirements (PDRs) related to genetic resources (GRs) and traditional knowledge associated with genetic resources (ATK) have been discussed at the World Intellectual Property Organization (WIPO) for many years. It is therefore **time to assess whether an international PDR is still useful to support the protection of GRs/ATK.**

This submission provides an **overview of the legal, technological and patent landscapes related to GRs/ATK** (see Section 2). Evidence shows that **these landscapes have evolved significantly** in the last years, both at the international and the national level:

- **Legal landscape:** International instruments related to GRs/ATK have been adopted, revised or are currently under negotiation. At the national level, more than 30 PDRs have been introduced. They vary greatly in terms of geographical scope, subject matter, “trigger,” “content,” and consequences for non-compliance. Without a standard for PDRs in an international legal instrument of WIPO, it is likely that the variability of national PDRs will increase further, leading to fragmented regulations and possible negative impacts on innovations based on GRs/ATK.
- **Technological and patent landscapes:** A few specific GRs make up the majority of GRs referred to in patent applications, and many GRs can be obtained from various sources, including from multiple countries of origin. Additionally, technologies and practices to use GRs have evolved. Today, innovations rely increasingly on international collaboration. This leads to GRs often being exchanged multiple times and among different jurisdictions. Therefore, in many cases, at the time of applying for a patent it is unlikely that there is a “straight line” to the country of origin of a GR, which could easily be disclosed, but rather a complex web of providers and users of this GR.

Based on these findings, Section 3 describes key modalities on how **an international PDR in a WIPO instrument could still become a useful tool.** In particular, the modalities should:

- be drafted as a **“transparency measure” about the source of GRs/ATK.** GRs should thereby be understood as defined in the Convention on Biological Diversity (CBD);
- contain a **“trigger”**, which provides sufficient clarity for which GRs/ATK the PDR will apply, and a **“content”** that reflects the actual circumstances under which GRs/ATK can be sourced;
- include a **“maximum standard”** for sanctions and remedies. In particular, **revocation or invalidation of established patent rights should not be an option.** Should the IGC consider revocation or invalidation for exceptional circumstances, the patent owner should in any case first be granted the possibility to rectify the failure and to provide the information specified in the Instrument within a reasonable amount of time.

A carefully drafted international PDR should not only support **better protection of GRs/ATK, but also innovations based on GRs/ATK.** It should also contribute to the **enhancement of patent quality and to the prevention of granting erroneous patents.**

From the Swiss perspective, the **Chair’s Text on GRs and ATK goes in the right direction** to achieve these objectives; however, it should be further improved.

Finally, Section 3 also **introduces two new ideas, namely a “reciprocity clause” and an “international information system,”** which could enhance the “attractiveness” of an international PDR to all WIPO Member States.

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1. Introduction

Patent disclosure requirements (PDRs) related to genetic resources (GRs) and traditional knowledge associated with genetic resources (ATK) have been discussed at the World Intellectual Property Organization (WIPO) and in other international fora (e.g., the Convention on Biological Diversity – CBD, the World Trade Organization – WTO) for several years. Proposals by Member States range from “no new PDRs,” to “PDRs as transparency measures” of origin/source of GRs/ATK, to “fully-fledged PDRs” linked to compliance with access and benefit-sharing (ABS) requirements and far-reaching sanctions for non-compliance. All of these options are reflected – at least to some degree – in the heavily bracketed *Consolidated Document Relating to Intellectual Property and Genetic Resources* (Consolidated GR Document: [WIPO/GRTKF/IC/41/4](https://www.wipo.int/patent/gerp/gerp41/41_4.html))

The Chair's *Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources* (Chair's Text: [WIPO/GRTKF/IC/41/5](https://www.wipo.int/patent/gerp/gerp41/41_5.html)) provides a clearer model of an international PDR. It may thus allow the IGC to further advance its work and to make informed decisions about an international legal instrument related to GRs/ATK.

To further advance the work of the IGC, it remains important to follow the evidence-based approach as set out in the [IGC Mandate 2020/2021](https://www.wipo.int/patent/gerp/gerp41/41_6.html). This also means that the IGC should not look at PDRs in isolation from other international agreements related to GRs/ATK. In fact, since the discussions at WIPO on PDRs began, the international and the national regulatory environments related to GRs/ATK have changed. In addition, technologies and practices to use GRs/ATK have also evolved.

This submission first provides an overview of the current legal, technological and patent landscapes related to GRs/ATK (Section 2). It then assesses whether an international PDR in an international legal instrument of WIPO is still useful to support the balanced and effective protection of GRs/ATK. Finally, it describes the key modalities of an international PDR and two

new ideas on how the Instrument related to GRs could be made more attractive to all WIPO Member States (Section 3).¹

2. Changes in the legal, technological and patent landscapes related to GRs and ATK

2.1 The legal landscape

Since the first discussions on PDRs took place at WIPO, the legal landscape related to GRs/ATK has evolved significantly, both at the international and the national level.

At the international level:

- legally binding and non-binding instruments have been adopted;²
- existing instruments or parts thereof are under revision or have been amended;³ and
- a number of international fora are working on issues related to GRs/ATK, including negotiations on a new instrument for certain types of GRs.⁴

At the national level:

- Over 30 PDRs have been introduced in the national legal systems in developing and industrialized countries. These national PDRs vary significantly in terms of scope, content, relationship with ABS regimes, and sanctions.⁵
- Some countries have introduced legal measures for the protection of GRs/ATK of other countries outside of the IP regimes, namely in the environmental regimes (e.g., EU and Switzerland⁶).
- It is likely that the national regimes related to GRs/ATK will change further in the near future. In fact, with the entry into force of the Nagoya Protocol (October 2014), all Parties to this Protocol are obliged to take so-called “ABS user-compliance measures.”⁷ It is

¹ This submission does not address all aspects, which are currently under discussion in the IGC, nor does it provide a comprehensive analysis of all information, which may be available and relevant for the IGC. Moreover, it focuses on GRs, while issues related to ATK are only addressed on the side.

² E.g., the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) of the Food and Agriculture Organization (FAO) in 2001, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) in 2007, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the CBD (Nagoya Protocol) in 2010, and the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) of the World Health Organization (WHO) in 2011.

³ The Plant Treaty has been working on enhancing the Multilateral System of the Plant Treaty through a possible revision of the SMTA and an extension of crops listed in Annex I. The World Health Assembly 72 (2019) amended a footnote of the SMTA2 (Standard Material Transfer Agreement 2) of the PIP Framework in order to apply the SMTA to those manufacturers that indirectly use PIP biological materials on behalf of another entity.

⁴ The Intergovernmental Conference is working on an International Legally Binding Instrument (ILBI) under the United Nations Convention on the Law of the Sea (UNCLOS) on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ). Relevant work is also carried out by the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), the CBD Working Group on Article 8(j) and Related Provisions, and the CBD Science and Policy-Based Process on Digital Sequence Information on Genetic Resources.

⁵ WIPO (2017), [Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge](#). A closer look at these national PDRs shows that many go beyond a simple disclosure of source/origin requirement and include, for instance, evidence of compliance with ABS regulations. At the same time, many have a limited geographical scope, i.e., they only apply to GRs that originate from a country's own territory (e.g., Brazil, Egypt and Costa Rica), or from territories under a common ABS regime (e.g., the Andean Community).

⁶ An overview of the Swiss legal framework related to GRs and ATK is contained in Appendix 1 of [WIPO/GRTKF/IC/31](#).

⁷ According to the analysis of the National Interim Reports for the Nagoya Protocol, only around 50% of the Parties to the Nagoya Protocol had developed “ABS user-compliance measures” by 2018.

likely that some countries will implement the Nagoya Protocol by amending their national patent legislation, as has already been done in some countries.⁸

Implications for the work of the IGC:

- The IGC should take into account that the legal landscape related to GRs/ATK has changed significantly since the discussions on PDRs began at WIPO.
- Those aspects related to GRs/ATK, which have been addressed in existing international agreements (such as the Nagoya Protocol), should not be duplicated in an international legal instrument of WIPO. In fact, it is important that the work of the IGC remains focused on IP aspects related to GRs/ATK.
- Without a standard for PDRs in an international legal instrument of WIPO, the number and diversity of national PDRs, including those that are linked to ABS-compliance, is likely to increase further in the future. This could lead to further fragmented regulations, and to a chilling effect on innovations based on GRs/ATK.
- ABS regulatory requirements differ considerably in those countries that implemented such requirements at the national level.⁹ Linking patent applications to ABS compliance could introduce legal uncertainties in the patent system and lead to significant patent delays and economic impacts.¹⁰

2.2 The technological landscape

Technologies and practices for utilizing GRs have also evolved. In particular, genetic sequencing technologies have advanced rapidly, leading to a drastic decrease in the cost of sequencing, and a dramatic increase in genetic sequence data.¹¹ The technological advances may be one reason why suggestions have been made for extending PDRs to intangible aspects of GRs, such as “digital sequence information” – (DSI), and to “derivatives.” From the Swiss perspective, the following points should be considered in this context:

a) Intangible aspects of GRs

In 2018, the CBD established a science and policy-based process on DSI, and similar work related to GRs for food and agriculture is undertaken by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the Food and Agriculture Organization (FAO). The studies by the CBD illustrate the complexity and uncertainties related to DSI, among others, due to a lack of clear terminology and a common understanding of the concepts discussed.¹² Some findings of these studies are in our view also relevant in the context of a PDR, namely:

- There exists a large number of different databases where genetic sequence data are stored.¹³

⁸ See, for instance, the [draft ABS Guidelines of the National Biodiversity Authority in India](#), or the Spanish [Law 24/2015 of 24 July on Patents](#) (Article 23) and its [Regulations](#) (Article 2). The latter sets forth the obligation to include the information of the use of genetic resources in accordance with the provisions of the rules implementing the Protocol. Particularly, the registration number of the declaration of due diligence pursuant to Royal Decree 124/2017 shall be recorded at the Spanish Patent Office.

⁹ See [ABS Clearing House](#).

¹⁰ See for instance: https://www.ifpma.org/wp-content/uploads/2018/06/Economic-impact-DRs-for-GRs-final-report_June2018.pdf, or [WIPO/GRTKF/IC/40/11](#).

¹¹ According to GenBank and WGS Statistics, since 1982, the number of bases in GenBank has doubled approximately every 18 months: <https://www.ncbi.nlm.nih.gov/genbank/statistics/>

¹² The CBD work has been carried out with the aim to better understand the possible implications of DSI on the three objectives of the CBD (namely the conservation of biological diversity, the sustainable use of its components, and the sharing of benefit-sharing from the utilization of GRs). Further information, see <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

¹³ The CBD DSI study on traceability and databases indicates that there are more than 1700 entries of public databases in the Nucleic Acids Research (NAR) annual summary of biological databases (Figure 1).

- Whether it is possible to trace the genetic sequence data to the specific tangible GR, from which they were generated, and further to the specific source/origin of that GR, depends on a variety of factors.¹⁴

In addition, in a PDR context, it is also important to note that:

- Naturally occurring genetic sequences are not patentable as such in many jurisdictions.¹⁵ Moreover, genetic sequences contained in patent descriptions are not necessarily “patented” per se. They may merely be disclosed because they are required to enable a person skilled in the art to carry out the invention.
- Additionally, applying a PDR to genetic sequence data or to any other type of DSI does not generally provide more transparency with regard to the tangible GR, which in our view should be the focus of the PDR: (1) not all entries of genetic sequences in databases are linked to a specific source/origin of the tangible GR; (2) genetic sequences are often not unique to a specific GR; identical or very similar genetic sequences may be found in different GRs;¹⁶ and (3) a specific genetic sequence may have been sequenced many times, which results in multiple entries of the same or a similar genetic sequence in a specific database.¹⁷ For these reasons, a patent applicant may not necessarily know from which GR the genetic sequence was first generated.
- Finally, applying a PDR to genetic sequence data or to any other type of DSI would also lead to substantial legal and practical challenges. This is because for an invention, the inventor is often not just using one single genetic sequence. In fact, the informational value of a genetic sequence often arises from its comparison with other genetic sequences, rather than in the use of one single genetic sequence. Therefore, extending a PDR to genetic sequence data or any other type of DSI would certainly be very burdensome on patent applicants and patent offices and could likely be unworkable in practice. An applicant would need to disclose the source of multiple, sometimes hundreds, of genetic sequences involved in the invention.

b) Derivatives

“Derivatives” are another issue, which has been proposed to be included in the Consolidated Document on GRs, likely due to the negotiations of the Nagoya Protocol. Article 2 of the Nagoya Protocol defines the term “derivative” as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.” It is important to note that none of the operational provisions of the Nagoya Protocol refer to “derivatives” as such; thus derivatives are not covered by the Nagoya Protocol in isolation of the GR.

Similar practical problems may arise when extending a PDR to derivatives as is the case with the intangible aspects of GRs. Again, the same derivative (understood as naturally occurring biochemical compound) may occur in various types of GRs, and the same derivative may be obtained from various sources, without the need to access the specific GR itself. Requiring the disclosure of the origin/source for derivatives therefore does not generally enhance the

¹⁴ The CBD DSI study on concept and scope indicates, among others, that the proximity of the specific type of information to the GR has significant implications for the traceability to a particular GR and also in identifying the source of information, including whether it has been generated through the utilization of a genetic resource or independently among others from the proximity of information to the underlying genetic resource.

¹⁵ See for instance Art. 1*b* para. 1 of the Swiss Patent Act.

¹⁶ Not only humans share more than 98% of the DNA and almost all of their genes with their close relative, the chimpanzee, but also animals and plants have many genes in common.

¹⁷ See for instance: Qingyu Chen, Justin Zobel, Karin Verspoor. Duplicates, redundancies and inconsistencies in the primary nucleotide databases: a descriptive study. Database, Volume 2017, <https://doi.org/10.1093/database/baw163>.

transparency about the source/origin of the GR itself, but would result in legal and practical challenges for patent applicants and patent offices.

Implications for the work of the IGC:

- Extending PDRs to genetic sequence data or any other type of DSI, or to derivatives, will result in substantial legal and practical challenges, without generally enhancing the transparency of the source/origin of the tangible GRs as such. An international PDR should therefore remain focused on GRs as defined in the CBD and in the Nagoya Protocol.
- Additionally, issues such as “DSI” are currently being addressed by the international fora dealing with ABS. Transferring these unresolved issues into the work of the IGC would add an additional layer of complexity, and thus further delay finding a solution for a workable international PDR.

2.3 The patent landscape

A number of recent studies examined patent landscapes in general or addressed specific types of GRs and sectors utilizing GRs. Based on these recent studies, which are further summarized below, it seems safe to conclude that the patent landscape related to GRs/ATK has changed significantly since the first discussions about an international PDR took place in the IGC.

Important findings are:

- a) a few specific GRs make up the majority of GRs in patent applications;
- b) the same or similar GRs can often be obtained from various sources; and
- c) innovations rely increasingly on international collaborations, in particular for high quality patents.

a) Major types of grs in patent applications

One study estimates that human innovative activity involving biodiversity in the patent system focuses on only approx. 4% of all taxonomically described species (0.8–1% of predicted global species).¹⁸ The most prominent species that appeared in the claims were *Zea mays* (maize), *Escherichia coli*, *Saccharomyces cerevisiae*, *Oryza sativa* (rice), *Bacillus thuringiensis* and *Bacillus subtilis*. These organisms are frequently used to explore the fundamental genetics of organisms and they often serve as research tools in biotechnology (e.g., *E. coli*). Moreover, they are widely diffused all over the globe.

The 2014 [Patent Landscape Report on Animal Genetic Resources](#), prepared for WIPO in cooperation with FAO, found, inter alia, that despite a surge of patent activity in the late 1990s, the trend in patent filings involving animal GRs for food and agriculture has steadily decreased. In addition, most patent activity focuses on dominant breeds, and does not involve genetic material from rarer breeds from specific countries or the use of traditional knowledge. In fact, key technologies relating to animal breeding have a long history, and breakthroughs typically involve new methods or technologies rather than depending on genetic material *per se*.

Similarly, the 2016 [Patent Landscape Report on Microalgae-Related Technologies](#) found that only two major strains, namely *Spirulina* and *Chlorella*, cover 36% of the patents in the field of microalgae. These microalgae are well known for their nutritional properties, particularly in Asia. Based on an initial patent filing location analysis, the study reveals that the highest patent activity with microalgae takes place in Asia (75%), followed by the US (13.5%) and Europe (13.1%).¹⁹

¹⁸ Oldham P, Hall S, Forero O (2013) Biological Diversity in the Patent System. PLoS ONE 8(11): e78737. doi:10.1371/journal.pone.0078737.

¹⁹ Percentages calculated based on figure 4 of the Report.

b) Various sources of GRs and ATK

Plant and animal species are often not unique to just one country of origin. An earlier [submission by Switzerland](#) to the IGC illustrated this fact for the Alpine Edelweiss (*Leontopodium alpinum*).²⁰ This plant, which contains pharmaceutical and cosmetic properties, can be sourced *in-situ* in Austria, France, Germany, Italy, Switzerland, but also in the Carpathians and in some Balkan countries. All these countries are “countries of origin” of the Alpine Edelweiss. However, the plant can also be sourced from *ex-situ* locations, such as botanic gardens, within or outside of the countries of origin. This is also the case for many other species.

In Switzerland, out of the 45'000 known species, only 40 (less than 0.1%) are endemic, i.e., for which Switzerland can be considered as the only country of origin.²¹ Even for countries with a high percentage of endemic species (e.g., Madagascar with approx. 90%), this does not necessarily mean that a specific GR can only be obtained from Madagascar. Many GRs can be accessed in *ex-situ* locations outside of the countries of origin.²²

Based on this, this submission concludes that in most cases, there exists a diversity of locations and legal situations under which a specific GR can be found and sourced. The same may be true for ATK, as different IPLCs may hold similar traditional knowledge over GRs, or knowledge may be documented in various locations outside of the communities.

c) Enhanced international collaboration

WIPO's 2019 [World Intellectual Property Report](#) analyzed millions of patent and scientific publication records across several decades to conclude that innovative activity has grown increasingly collaborative and transnational, while taking place in a few large clusters located in a small number of countries. One of the key findings of the report is that before 2000, Japan, the US and Western European economies accounted for 90% of patenting and more than 70% of scientific publishing activity worldwide. From 2015 to 2017, however, these percentages have fallen to 70% and 50% respectively, amid increased activity in China, India, Israel, Singapore, and the Republic of Korea, among others.

Similar trends can be observed by looking into specific sectors, which more likely rely on GRs for their inventions, such as the plant biotechnology sector,²³ marine scientific research,²⁴ or the pharmaceutical sector.²⁵ This also means, that GRs are often exchanged many times among various collaborating partners, both within and between different jurisdictions. Therefore, in many cases there is not a “straight line” from the country of origin of the GR to the GR, on which

²⁰ See Section II.C. of [WIPO/GRTKF/IC/31](#).

²¹ [Webpage of the Federal Office for the Environment](#), accessed on 22.11.2019.

²² It has been estimated that natural history collections are housing around 2 to 4 billion specimens worldwide. Moreover, collections frequently hold a large volume of unsorted material, and today the majority of newly described species are discovered within existing collections. See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6282082/#RSTB20170386C29>.

²³ See chapter 4 of the 2019 [World Intellectual Property Report](#).

²⁴ The 2019 [Patent Landscape Report: Marine Genetic Resources](#) reveals, inter alia, that marine genetic research in the ASEAN region is increasingly international in nature. It identified collaborations between researchers from over 130 countries, and an emerging network of funding agencies from within and across the region. Marine genetic research in this region is dependent on an important network of international funding agencies from Japan, China, the US and Europe, who support collaborative research with researchers within and outside the region.

²⁵ See <https://www.future-science.com/doi/10.4155/ppa-2019-0017>. This study by IPI found that on a global scale the number of active pharmaceutical patent families has tripled since 2000. The quantitative growth results mostly from a surge of patents from China. Half of the pharmaceutical patents from China are classified in A61K36 (“medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants”), which indicates the importance of GRs. It also shows that the highest concentration of high-quality patents was found when selecting patents listing inventors from at least two out of the five most important countries of origin for pharmaceutical patents: China, European countries, Japan, South Korea and the US.

an invention is directly based on. This makes it more difficult to trace back the specific GR, on which an invention is directly based on, to the country of origin.

Implications for the work of the IGC:

- A few specific GRs make up the majority of GRs mentioned in patent applications.
- Many GRs found in patent applications can be obtained from various sources, including from multiple countries of origin.
- Patenting activities in various countries in different regions increased significantly over the last few years. Innovations rely increasingly on international collaboration, in particular for high quality patents.
- Before coming up with an invention, GRs are often exchanged many times across different jurisdictions. Therefore, it is not always possible to easily trace back a GR to the country of origin that provided the GR.

3. Key modalities of an international PDR

Based on the findings described in Section 2, Switzerland remains convinced that an international PDR should be drafted as a “transparency measure,” and it should support innovations based on GRs/ATK. Higher transparency about the source/origin of GRs/ATK could facilitate the implementation of ABS-requirements in countries providing GRs/ATK. At the same time, it would also facilitate the work of patent examiners to find appropriate databases or other information to avoid the granting of erroneous patents. Moreover, since GRs obtained from different *in-situ* and *ex-situ* locations may contain different biochemical or genetic properties, disclosing the source/origin of GRs/ATK may additionally assist a person skilled in the art to carry out the invention. Therefore, enhanced transparency could ultimately also result in higher patent quality.

The following subsections highlight some modalities of an international PDR, which in our view are important in order to provide sufficient legal certainty and ensure practicability and effectiveness of an international PDR. This section, also describes two new ideas, which could make an international PDR more attractive to all WIPO Member States.

3.1 Trigger, content and sanctions

In a number of earlier submissions, Switzerland describes possible modalities for an international PDR.²⁶ Some of the key aspects of these modalities are summarized here again:

- **As regards the “trigger,”** the submissions highlight the importance of clarifying the relationship between the invention and the GRs/ATK that trigger the PDR. This is important because in the description of many biotech patents, one finds references to a variety of GRs. Some of these GRs are experimental animals or plants as well as laboratory consumables, such as plasmids, viruses, bacteria, and yeasts. In the view of Switzerland, GRs which were somewhere involved in the upstream research and development activities before coming up with the invention (e.g., initial basic scientific research) as well as laboratory tools should not trigger the disclosure.

Therefore, we proposed to use the term “directly based on” as a simple and concise way to clarify the relationship that a GRs/ATK must have with the invention in order to trigger the

²⁶ See earlier submissions by Switzerland to WIPO, such as [WIPO/GRTKF/IC/31](#) or [WIPO/GRTKF/IC/11/10](#)

PDR. The Chair's Text uses the trigger "[materially/directly] based on," in combination with a definition. This could also be a possible way forward. Should the IGC decide to follow this approach, the definition would need to be drafted carefully in order to provide sufficient clarity for which GRs/ATK a disclosure would be triggered. The IGC should also carefully consider whether the same definition makes sense for GRs as well as for ATK.

- **As regards the "content,"** it is important to keep in mind that GRs/ATK can be sourced under a wide range of different circumstances, including from different geographical locations and different legal situations (see Section 2 above). Therefore, in many cases it is not possible to indicate the country of origin of the GRs.

In this regard, the Chair's Text has its merits, as it only requires the disclosure of the country of origin, if known to the applicant, and if applicable. However, since there may be various countries of origin for many GRs, it should be further specified that the applicant should only disclose the country of origin from which the GR was actually obtained. Moreover, it is important to clarify that the "country of origin" is also a "source," and to explicitly include IPLCs in the definition of the "source."²⁷

- **As regards the sanctions and remedies,** it is important to set a clear maximum standard (or a "ceiling"), in order to provide sufficient legal certainty for patent applicants and patent holders, and to support innovations based on GRs/ATK. In this regard, the articles on sanctions and remedies in the Chair's Text as well as the articles in the Consolidated GR Document are not sufficiently elaborated.

In particular, the article on sanctions and remedies should clarify possible pre-grant and post-grant sanctions, and differentiate whether non-compliance occurred intentionally or by mistake. In our view, each Party should provide for post grant sanctions or remedies where an applicant, either willfully or with fraudulent intent, failed to disclose the minimum information specified in the international Instrument on a PDR. However, post grant sanctions should not allow for revocation or invalidation of the established patent rights, as this would have negative effects on innovative activities based on GRs/ATK. It would also destroy the basis for the patent holder to share any benefits. In any case, before revoking a patent or invalidating established patent rights, the patent owner should have a possibility to rectify his failure and to provide the required information specified in the Instrument (e.g., the information specified in Article 3 of the Chair's Text) within a reasonable time period. Only if the patent owner still refuses to provide this minimum information, revocation or invalidations of the established patent rights may be an option.

3.2 A reciprocity provision as an incentive to ratify the Instrument

For any international legal instrument related to GRs/ATK to be effective, it is important to have a broad membership. In order to achieve this, the international Instrument on GR could include an incentive to ratify or join the Instrument. Such an incentive could consist of a so-called "reciprocity clause," which would allow Parties to the Instrument to require the information specified in the Instrument only for GRs/ATK obtained from other Parties. In contrast, it would be optional to require such information for GRs/ATK from non-Parties to the Instrument.²⁸

²⁷ See for instance also Art. 17.1(a)(i) of the Nagoya Protocol, which specifically refers to the "source" of the GR, and not to the "country of origin."

²⁸ From the Swiss perspective, this provision would be relevant for those GRs, for which a patent applicant knows the country of origin. If the country of origin is not known or not applicable, the provision would have no effect. Moreover, from the Swiss perspective, the international PDR should also apply to marine GRs of areas beyond national jurisdiction and to GRs, which are under a common multilateral regime, such the Multilateral System of the Plant Treaty.

A “reciprocity clause” would provide a strong incentive for countries to ratify the Instrument. In order to ensure that the origin/source of its “own” GRs/ATKs will be disclosed in patent applications in another jurisdiction, a country must become Party to the Instrument. The clause would also contribute to avoid so-called “free riders,” i.e., countries that do not join the Instrument, but still enjoy enhanced transparency about their “own” GRs/ATK in other jurisdictions. Finally, the clause would also increase the legal certainty for patent owners, as the country from which the GR has been obtained would also be a Party to the Instrument and therefore be bound by its provisions.

A possible text proposal of a reciprocity clause is provided in the Appendix for illustration purposes.

3.3 An international information system to simplify the implementation of PDRs

As described in Section 2, a number of national PDRs exist that vary significantly in terms of scope, content, relationship with ABS regimes, and sanctions. While an international legal instrument of WIPO may contribute to the harmonization of national PDRs, national differences are likely to remain in the future. Therefore, patent applicants as well as patent examiners could benefit from an international information system administered by WIPO. This system could provide two main functions:

1. An international gateway (or portal site), which would allow patent examiners of Parties to this Instrument to easily find relevant national databases on GRs and ATK. This function facilitates the task of patent examiners to find the relevant information in databases in order to avoid the granting of erroneous patents. This has been explained further in prior submissions by Switzerland and other delegations.²⁹
2. An obligation to share the information provided in accordance with the PDR with other Parties to the Instrument. Each Party to the Instrument should recognize this information and exempt the applicant from having to provide the same information again, when filing for the same patent in that Party’s jurisdiction. This function would reduce the administrative burden for both patent applicants and patent examiners of Parties to the Instrument:
 - **For patent applicants**, it would reduce the administrative burden, as it would be sufficient to provide the required information specified in the Instrument only to the patent office where the first filing is made. Applicants would not need to submit the same information again to subsequent patent offices in jurisdictions where they seek protection, as the information provided to the first patent office would be shared among Parties to the Instrument.
 - **For patent examiners**, the system would reduce the administrative burden, as they would not need to verify again whether the information provided to the first patent office satisfies the information specified in the Instrument.

A possible text proposal of an international information system is provided for illustration purposes in the Appendix.

[Appendix follows]

²⁹ See for instance [WIPO/GRTKF/IC/40/16](#). See also the 2001 submission by Switzerland on an international gateway on databases in the context of TK to the TRIPS Council [IP/C/W/400/Rev.1](#)

Appendix - Possible text proposals to establish a reciprocity clause and an international information system

The following text proposals are intended to further illustrate the two new ideas presented in this submission. They refer to articles contained in the Chair's Text and should be read in conjunction with the Chair's Text.

ARTICLE 5
NON-RETROACTIVITY AND RECIPROCITY

...

5.2 Contracting Parties may apply the disclosure requirement specified in Article 3 only to genetic resources and traditional knowledge associated with genetic resources of Parties to this Instrument.

ARTICLE 7bis
INTERNATIONAL INFORMATION SYSTEM

7bis.1 An international information system administered by the Secretariat is hereby established. It shall provide the following functions:

- (a) Allow patent examiners from Contracting Parties to this Instrument to access the national information systems established under Article 7 through a centralized gateway/portal site.**
- (b) Allow the sharing of information specified in Article 3 with all other Contracting Parties to this Instrument.**

7bis.2 Offices of First Filing shall submit the information specified in Article 3 to the international information system no later than the publication of the patent application.

7bis.3 Each Contracting Party shall recognize the information made available by other Parties through the international information system as sufficient to satisfy the disclosure requirement specified in Article 3.

[End of Appendix and of document]