Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge

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World Intellectual Property Organization
34, chemin des Colombettes, P.O. Box 18
CH-1211 Geneva 20, Switzerland

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Foreword

Transparency through the disclosure of patented inventions has been a defining feature of the modern patent system since its inception. As modern innovation continues to build upon and further advances the diversity of genetic resources, recent discussions have identified questions as to whether existing patent disclosure requirements should be additionally expanded through specific disclosure requirements for genetic resources and traditional knowledge to further improve the transparency and efficacy of the patent system.

In 2002, the World Intellectual Property Organization (WIPO) was requested by the Conference of the Parties to the Convention on Biological Diversity (CBD) to prepare a technical study on questions pertaining to patent disclosure requirements related to genetic resources and traditional knowledge. The resulting WIPO Technical Study was made available to the Conference of the Parties of the CBD in 2004, and it was widely appreciated.

More recently, and as policy, legal and practical questions pertaining to patent disclosure requirements related to genetic resources and traditional knowledge are being discussed at WIPO in the context, in particular, of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC), many have called for updated and improved empirical information on these questions. At its Twenty-Ninth Session in 2016, the IGC endorsed the updating and improving of the Technical Study from 2004 and requested the WIPO Secretariat to complete the exercise as soon as possible.

The current publication is an update and improvement of the original WIPO Technical Study from 2004, incorporating the latest practical and empirical information provided by Member States and stakeholders. It provides a purely technical account of the legal and operational questions that have been identified as arising in the context of patent disclosure requirements related to genetic resources and traditional knowledge, and does not promote or propose any particular position, approach or perspective on this matter. The study looks at the key questions identified from the point of view of the patent system and in relation to other relevant legal and policy frameworks.

I am confident that this new publication responds to the request for up-to-date empirical information and that it will make a valuable contribution to reflections by policymakers and others as to whether existing patent disclosure requirements should be additionally expanded through specific disclosure requirements for genetic resources and traditional knowledge.

Francis Gurry

Director General, WIPO

Preface

Modern scientific research and the exploitation of genetic resources and traditional knowledge may offer great benefits to humankind. How can the patent system help scientists, commercial enterprises and civil society at large to realize those benefits while safeguarding the rights and interests of biodiversity-rich countries, and indigenous and local communities?

It has been argued that new patent disclosure requirements related to genetic resources and traditional knowledge are part of the answer, and several countries have already implemented them. But different countries have varying approaches and priorities to this question. Policymakers in each country need to find the right approach for them. If a country decides to introduce new patent disclosure requirements, a key challenge is to establish a coherent legal and policy framework for them, to ensure their balanced and synergetic implementation in the context of national innovation systems. Asking the right questions at the outset should help in this challenging task.

This study from the World Intellectual Property Organization (WIPO) is intended to fill a gap in the existing literature and so inform policy dialogue, implementation and training in this area. It:

- reviews, complements and updates existing WIPO resources and research from leading scholars;
- identifies the key questions that all policymakers need to address in this area;
- discusses approaches in many different developed and developing countries; and
- presents policy options in a user-friendly format, with helpful graphics, case studies and further reading.

This study is not a substitute for legal advice. It aims to contribute to discussion and analysis, and to help clarify some of the legal and policy matters raised. It offers a comprehensive but scrupulously neutral treatment of the subject. With a focus on practical experiences, it does not advocate any particular approach or expound a definitive interpretation of any treaty. It does not express a policy position on the part of WIPO, its Secretariat or its Member States, and is not intended to preempt or interfere with the deliberations of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

This study was produced by WIPO's Traditional Knowledge Division. The lead authors are Claudio Chiarolla, Legal Officer, Traditional Knowledge Division, WIPO and Burcu Kılıç, consultant to WIPO. Support and comments were provided by Wend Wendland, Daphné Zografos Johnsson, Olga Begoña Venero Aguirre, Shakeel Bhatti, Fei Jiao, Alice Manero and Rhona Rwangyezi. Special thanks are due to Graham Dutfield, Manuel Ruiz Muller and Jayashree Watal for peer-reviewing the first draft. The final draft was peer-reviewed by Marco Aleman, Tomoko Miyamoto, Ewald Glantschnig and Eun-Joo Min, and edited by Toby Boyd.

List of boxes and figures

List of acronyms

ABS	Access and Benefit Sharing
ARIPO	African Regional Intellectual Property Organization
CBD	Convention on Biological Diversity
COP	Conference of the Parties
EPO	European Patent Office
FAO	Food and Agriculture Organization
GH	genetic heritage
GRs	genetic resources
IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IP	intellectual property
IPR	intellectual property rights
IPLCs	indigenous peoples and local communities
ITPGRFA FAO	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	The International Union for Conservation of Nature
MATs	mutually agreed terms
MTAs	material transfer agreements
PDRs	patent disclosure requirements
PGRFA	plant genetic resources for food and agriculture
PIC	prior informed consent
PVP	plant variety protection
SMTA	Standard Material Transfer Agreement
TCEs	traditional cultural expressions
TK	traditional knowledge
UPOV	Union internationale pour la protection des obtentions végétales (International Union for the Protection of New Varieties of Plants)
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization

1. Introduction

There is keen interest in patent disclosure requirements (PDRs) related to genetic resources and traditional knowledge. It has been argued that they may have a valuable role to play within intellectual property (IP) and innovation systems. In order to obtain patent protection for any invention, it is necessary, among other things, to disclose detailed technical information about it. By extending that disclosure obligation, it is argued that it may be possible to simultaneously enhance the transparency of the patent system and monitor the contribution of traditional knowledge and genetic resources to new patentable inventions, potentially helping to ensure that such knowledge and resources are used with the permission of the countries and/or communities from which they originated, and that some benefits from the resulting inventions are shared with those countries and/or communities.

In other words, it is claimed that disclosure requirements may help to prevent the *misappropriation* of genetic resources and traditional knowledge by ensuring that they are used with the *prior informed consent* of the provider countries and/or their legitimate holders, on *mutually agreed terms*.

Thus, it is argued, new disclosure obligations may promote the fair and equitable sharing of benefits between holders of genetic resources and traditional knowledge – mostly biodiversity-rich countries and indigenous peoples and local communities (IPLCs) – and those with the modern technologies to characterize them[1] and exploit their scientific and commercial potential. They may also increase legal certainty, transparency and efficiency within patent systems and/or IP systems,[2] for example by helping to identify relevant prior art and so reducing the risk that patent protection is wrongly awarded to inventions that do not meet the requirements of novelty and inventive step. And there may be complementarity and mutual supportiveness between such disclosure requirements and international agreements relevant to conservation, sustainable use and benefit sharing of genetic resources and associated traditional knowledge.

However, the creation and implementation of disclosure requirements related to genetic resources and traditional knowledge are not straightforward. There are many options to consider – different ways in which laws might be framed, important differences in terms of the possible scope and content of obligations, the consequences of breaching those obligations, the mechanisms and institutions that might enforce them, and so on. Each of these different options may entail risks and costs which will vary depending on the national context in which a disclosure requirement is implemented.

At the international level, negotiations have been taking place since 2010 under the aegis of the World Intellectual Property Organization (WIPO) with the objective of reaching agreement on the text of an international legal instrument or instruments to ensure the balanced and effective protection of traditional knowledge, traditional cultural expressions and genetic resources. The forum for those text-based negotiations is WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which met for the first time in 2001. As part of the negotiations, WIPO's Member States have been debating the possibility of introducing an internationally harmonized patent disclosure requirement related to genetic resources and traditional knowledge. At the time this study was published, more than 30 countries – including both developed and developing countries – had implemented such requirements through national or regional laws (see the Disclosure Requirements Table annexed to this study), some others had expressed their interest in doing so, while others had expressed their intention not to implement such requirements.

The aims of this study

This study analyses the choices available to policymakers regarding patent disclosure requirements related to genetic resources and traditional knowledge. It is *not* intended to promote patent disclosure requirements related to genetic resources and traditional knowledge as such, and does *not* advocate any particular approach to implementing them. On the contrary, its aim is to emphasize the variety of issues at stake and the many options available, exploring and illustrating them through examples from different national and regional jurisdictions.[3] The treatment of these different options is neutral. But by identifying all the options, it should enable policymakers to reach informed decisions and facilitate understanding, implementation and training on these issues at the national and regional levels.

The study focuses on the key questions that policymakers will need to consider at each stage of the policy development process, if they are interested in introducing such requirements, from the basic concepts – what are patent disclosure requirements related to genetic resources and traditional knowledge, how do they differ from conventional patent disclosure requirements and why might a government wish to introduce them – to the different interests that may need to be balanced in introducing new patent disclosure requirements and the many different ways in which they might be designed.

The study also seeks to explore how patent disclosure requirements have been used by some governments as tools for compliance with any national (domestic) legislative, administrative or policy measures on access and benefit sharing (ABS) that they have established, including measures under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.[4] According to the accounts of these governments, different patent disclosure requirements related to genetic resources and traditional knowledge may offer different potential risks and opportunities in this regard. A broader aim of the study is to further understanding of the interactions between patent disclosure requirements, the fair and equitable benefit-sharing objective of the UN Convention on Biological Diversity (CBD) and its complementary instruments, such as the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

How to use this study

This study is designed to be as accessible and easy to read as possible while providing a full, balanced and accurate treatment of the subject. It simplifies, updates, and complements existing WIPO resources covering patent disclosure requirements related to genetic resources and traditional knowledge, and seeks to integrate them into a single user-friendly publication.[5]

As far as possible, the text avoids overly complex scientific, legal and technical language. However, the discussion necessarily involves the use of some terms of art. For convenience, and to reflect the style normally used in discussions on this subject, acronyms are often employed, most notably for patent disclosure requirements (PDRs), genetic resources (GRs) and traditional knowledge (TK).

The study is split into short sections, so readers can quickly zoom in on issues of particular interest. However, the issues are explained in a logical order, and so readers new to the subject should start at the beginning. The body text presents a succinct discussion of each issue illustrated with examples of relevant provisions from national or regional laws. There are also optional boxes and figures for readers seeking to deepen their understanding – these are color coded as follows:

Spotlight: examples or case studies

Suggested "deep-dive" readings from the WIPO Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge (2004)

Legislation (e.g., country laws or relevant international instruments, including draft instruments and non-legally binding instruments)

Figures

Full references are provided at the end of this study.

2. Background and concept

What are patent disclosure requirements related to GRs and TK?

A patent is a legal right granted in relation to an invention. It confers on the patent holder the right to exclude others not having the patent holder's consent from doing or making anything that falls within the subject matter of the invention, as defined and bounded by the patent claims. Disclosure of the invention sufficient for others to repeat it is part of a *quid pro quo,* the patentee providing this in exchange for the benefits of patent protection,[1] hence the theory that patents represent a bargain between the inventor and society. Thus, the patent holder can stop others not having the patent holder's consent from using, making, selling or importing the invention for a limited period of time (generally, the standard patent term is 20 years as from the filing of the application). In return, they must pay patent application and renewal fees and must disclose the invention in sufficient detail for others to repeat it. Through this "bargain" – disclosure of the invention in exchange for protection for a limited period – the patent system encourages the disclosure of technical information that would otherwise remain secret. From society's point of view, a proper scope of disclosure is critical to promote scientific and technological progress and spur further innovation, so conventional patent disclosure is one of the most important elements of the patent system and one of its primary justifications.

Historically, there have been policy tensions between patent law and biodiversity-related legislation which have often been the subject of controversies.

Box 1: Spotlight
Brazzein berries in Gabon

The patented product "Brazzein" is derived from the Oubli berry, a West African fruit of the climbing plant Oubli (*Pentadiplandra brazzeana Baillon*). The protein derived from the berry is 500 to 2,000 times sweeter than sugar and is used as a substitute or natural, low-calorie sweetener.[2] Brazzein is recognized as an alternative to available low-calorie sweeteners as it is suitable for diabetics.[3] It is thermostable, which makes it suitable for heat processes utilized in food manufacturing.[4]

The West African people of Gabon originally discovered and nurtured the plant, which was used to help nursing infants "forget" their mother's milk.[5] A researcher from the University of Wisconsin (UW) observed people and animals eating the berries in West Africa and brought them to the attention of the University. UW was granted three US patents (5,326,580; 5,346,998; 5,527,555) and one European patent (684995) for isolating and reproducing the protein in a laboratory. One claim for the berry in patent US 5,527,555 is to "provide Brazzein in large quantities, at low cost, by artificial means". The researchers have since concentrated on the reproduction of the protein in a laboratory, obviating the need to collect and cultivate the plant in Gabon.[6] UW maintains that Brazzein is "an invention of a UW-Madison researcher"[7] and offers no recognition or benefit-sharing to the people of Gabon. It is claimed that the synthetic substitution has caused a significant fall in the price of Brazzein, and many Gabonese women who used to harvest the fruit have lost their source of income.[8]

The global market for artificial and high-intensity sweeteners is estimated to be worth around USD 3 billion.[9] Natur Research Ingredients, a US company, acquired a license to produce Brazzein from food-grade bacteria using the UW patented process. The company had indicated that it wished to commercialize Brazzein under the brand name Cweet as a cost-effective alternative to stevia or monk fruit.[10] At present, it is not known whether this product has been commercialized successfully.

Where the invention disclosed in a patent application is shown to have some degree of dependence on the acquisition, analysis and use of genetic resources (GRs) or traditional knowledge (TK), or appears to include one or both of them wholly or partially in its scope, some have expressed concerns regarding how far such dependence or incorporation amounts to the misappropriation or misuse of such GRs and TK through the patent system and/or a violation of biodiversity-related legislation.

Against this backdrop, growing concerns by some about unauthorized access to and use of GRs and TK and their subsequent misappropriation have led to the introduction of additional measures to strengthen or broaden the conventional disclosure obligations in the patent system. In particular, several countries now require patent applicants to disclose, among other things:

- the origin and/or source of GRs and/or TK;
- evidence of prior informed consent for their use connected to research of which the claimed invention was an outcome, from the provider country (and, in some cases, from indigenous peoples and local communities, in accordance with domestic law);[11]
- evidence of having established a contractual arrangement (mutually agreed terms) for the fair and equitable sharing of the benefit derived from such use – if so required by the national legislation of the provider country.

These additional disclosure obligations are generally referred to as *patent disclosure requirements related to GRs and TK* – or, in short, PDRs.

As will be explained in more detail later, these new kinds of PDRs may be aimed at, among other things, promoting a mutually supportive relationship between the need to promote innovation and scientific progress through the patent system, on the one hand, and the objectives of the United Nations Convention on Biological Diversity on the other.

Box 2: Key principles on ABS of the Convention on Biological Diversity

> The Convention on Biological Diversity (CBD) is the first comprehensive international agreement dedicated to biological diversity. Its objectives are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of [GRs], including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding" (CBD Article 1). It also reaffirms "the sovereign rights of States over their natural resources", including GRs. In particular, the CBD provides that "the authority to determine access to [GRs] rests with the national governments and is subject to national legislation" and that "[a]ccess, where granted, shall be on mutually agreed terms[…] and subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party." (CBD Article 15)

WIPO Technical Study, p.10.

How do new PDRs related to GRs and TK differ from conventional disclosure requirements under established patent law principles and procedures?

A conventional duty of disclosure exists with respect to information that is "material" to the patentability of each claim. However, conventional disclosure requirements do not normally require disclosure of the origin and/or source of GRs and TK, because such information is often not strictly relevant to enable the invention or support the claims.

However, information about the origin and/or source of GRs and TK may be voluntarily disclosed in a patent application if the applicant believes that it would be required to meet the requirements for patentability such as novelty,[12] inventive step[13] and industrial application.[14] In these cases, such information could be considered to be "material" to the patentability of the claimed invention.[15] For instance, access to samples of a genetic resource may be necessary to enable a "person skilled in the art" to practice the claimed invention without undue experimentation.

Box 3: The WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

> Inventions involving the use of new microorganisms (that are not yet available to the public) could present problems of disclosure in that often their repeatability cannot be ensured by means of a written description alone – i.e., without accessing the microorganism as such. In such cases the relevant microbiological material can be deposited in an International Depositary Authority under the WIPO Budapest Treaty. Thus, the physical sample can be made available for the purpose of patent procedures and supplement the written description. The Budapest Treaty does not contain any obligation to precisely disclose the sampling site or the collection location of the microorganisms for the purpose of assessing the conventional patentability requirements. Those requirements would have to be incorporated into national or regional patent regulations governing the patent application requirements. If not, the physical deposit of the material would obviate any potential need to precisely disclose in the patent application the sampling site or the collection location of the microorganisms for the purpose of assessing conventional patentability requirements. (See also Box 19.)

Given the concerns about illegal access, PDRs related to GRs and TK may focus primarily on the legal status of the GRs and TK – i.e., whether they have been acquired legally subject to prior informed consent and mutually agreed terms, if that is required by the provider country. Documented proof regarding the legal status of such materials or knowledge requested from patent applicants, for example in the form of a copy of a certificate of compliance issued by a provider country, cannot be considered as "material" to the patentability requirements; if it were, it would presumably be disclosed under the conventional duty of disclosure. Thus, it has no relationship whatever with conventional patent disclosure requirements. It is an additional and completely separate requirement.

In this regard, PDRs related to GRs and TK add a new "layer" to the conventional disclosure requirement by imposing an additional duty to disclose more technical or legal information or evidence. They may build on the basic obligation to disclose "information material to patentability" within the description of the invention and how to work it or they may be added as an entirely separate part of the formality requirements.

On the other hand, new PDRs related to GRs and TK may enhance compliance with standard requirements for patent protection, in particular the requirement of novelty. A proper scope of disclosure of information related to GRs and TK may help to ensure that relevant prior art is considered in the examination of the patent application, so reducing the risk that patents are erroneously awarded for inventions that lack novelty.

In most legal systems where some form of GRs and/or TK-related PDRs have been adopted, the patent applicant is expected to exercise due diligence with regard to the acquisition, possession and transfer of information regarding the country of origin and/or the legal provenance of GRs and TK utilized in the claimed invention (e.g., information about the legal status of GRs and TK). According to existing examples of PDRs, in the absence of this information, the direct source (i.e., the direct provider) of GRs and/or TK may be required to be disclosed. For example, universities and other *ex-situ* repositories in public research institutions often play a crucial role as intermediaries in the transfer to the private sector and other research partners of information, knowledge and intermediate research products, including biological materials (e.g., advanced breeding lines, isolated microorganisms, etc.).[16] In some examples of PDRs, if such a direct source is unknown then the applicant may be required merely to make a written declaration to that effect.[17]

In accordance with the sufficiency of disclosure requirement, regardless of PDRs, the disclosure of origin/source of GRs and TK is required if the lack thereof would not allow a person skilled in the art to carry out the invention (enablement). Conversely, if the lack of the disclosure of origin/source of GRs and TK does not affect the enablement, this means that a person skilled in the art and a properly trained examiner are able to "carry out" the invention without the disclosure of GRs and TK.

To sum up, the distinctive feature of additional PDRs related to GRs and TK is their primary focus on information or documentation that may concern the legal status of GRs and TK and the circumstances under which the GRs or TK have been acquired by the applicant. Since such information is not usually required for the substantive examination of patentability, in most cases it is not considered requisite to satisfy the sufficiency of disclosure requirement. Finally, it is worth stressing that there are also many cases where patents are properly granted for inventions relating to GRs or TK that have either been legitimately acquired following the grant of prior informed consent and the establishment of mutually agreed terms with the providing country (and/or the relevant communities) or sourced from countries which do not regulate ABS. In these cases, it would be a matter of legitimate appropriation of the claimed invention as it relates to the GRs or TK.

What is the relationship between new PDRs and ABS obligations?

A core issue to be considered when introducing PDRs is how to frame an appropriate interface, if any, between ABS schemes and the patent system. How might disclosure requirements be designed to promote mutual supportiveness, synergies and complementarity between the implementation of ABS mechanisms and obligations, on the one hand, and the innovation incentives of the patent system, on the other?

No single patent disclosure scenario can capture all existing concerns about GRs and TK relevant to patented inventions, nor can any one proposed solution easily fit diverse countries. Countries vary in terms of their biodiversity endowment, research and biotechnology capacity, level of public and private R&D spending and biocultural sensitivities as well as their national IP examination capacities.[18] While there is clearly no one-size-fits-all approach, a growing number of countries have been demanding some degree of harmonization through a new legally binding international IP instrument.

In principle, PDRs could be used as a tool to help monitor the utilization of GRs and TK, and thereby also help promote – at least in some cases – compliance with ABS obligations.[19]

Box 4: The Bonn Guidelines on ABS

> In 2002, the Contracting Parties to the CBD adopted voluntary guidelines, called the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, in order to support the implementation of ABS measures at the legislative, administrative and policy levels. The Bonn Guidelines are a non-binding instrument that provides an illustration of possible approaches to national ABS regulatory systems. They also provide some guidance on the possible interactions between the IP system and the CBD. In particular, they suggest measures to support compliance with ABS requirements, including "measures to encourage disclosure of the country of origin of [GRs] and of the origin of [TK], innovations and practices of indigenous and local communities in applications for [IP] rights", measures to prevent use of GRs obtained without prior informed consent, and measures discouraging unfair trade practices.

WIPO Technical Study, p.12.

What are the main critiques and opposing views?

Opponents of PDRs are concerned that they may add a layer of uncertainty to the patent system, and have raised additional criticisms as follows:

- The patent system is not suited for, and should not serve to implement, exogenous objectives or goals (such as ABS objectives) because this would compromise its integrity.
- It would be burdensome, expensive and time-consuming[20] for patent applicants and patent offices to implement new PDRs.
- Patent offices would not be equipped to judge whether information regarding the disclosure of origin or source of a GR or TK was correct and accurate, and whether any national ABS requirements had been fulfilled.
- If an examiner had to carry out substantive examination of a patent disclosure requirement, patent validity would no longer be a function of novelty, inventive step and industrial application.
- Since a disclosure requirement may involve an external entity deciding whether an inventor had the right to conduct research (and there have been experiences of significant delays in obtaining prior informed consent (PIC) and mutually agreed terms (MAT)), the need for PIC and MAT before filing a patent application confronts patent applicants with a risk and increased legal uncertainty.
- PDRs would put the general public interest of freedom to do research at stake.
- PDRs could reduce innovation incentives generated by the patent system, with inventors turning increasingly to secrecy to protect their innovation.

Some countries have therefore argued in international fora that only national mechanisms independent of patent law should be used to promote compliance with ABS obligations.[21] Those who share such a view generally emphasize the problem of erroneously granted patents and the role of conventional PDRs in addressing this. As an alternative solution to new PDRs related to GRs and TK, they highlight the importance of mechanisms such as searchable databases to make relevant information easily accessible to patent examiners, guidelines to improve the quality and efficiency of patent examination, due diligence measures and voluntary codes of conduct.

3. Objectives

Why have several countries introduced new patent disclosure requirements related to genetic resources and traditional knowledge?

PDRs are implemented in diverse ways, reflecting different policy motivations, political trade-offs, local priorities and needs, and legal and institutional systems. As a generalization, key motivations include but are not limited to the following.

Preventing misappropriation

In some countries, such as India, Norway, Peru and Vanuatu among others, new PDRs serve the public policy goal of preventing the misappropriation of GRs and TK that have been obtained without the authorization (e.g., in the form of prior informed consent) of the country providing such resources and/or the indigenous peoples and local communities (IPLCs) holding such knowledge.

Box 5: The definition of biopiracy in Peru

> The *Act on the Protection of Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples 2004, Law No. 28216 (third supplementary and final provision)* states that:
>
> "Biopiracy means unauthorized and non-remunerated access to and use of biological resources or collective knowledge of indigenous peoples by others, without the relevant authorization and in contravention of the principles established in the [CBD] and the rules in force on the matter. Such appropriation may occur by means of physical control, through ownership rights to products which incorporate such elements that were illicitly obtained or in some cases through invocation of such elements."

Legal uncertainty may arise from a lack of user-country measures, among other things.[1] In this regard, new PDRs may allow countries to monitor the use of GRs and TK within their patent systems and assist user countries in overcoming uncertainties related to the enforcement of ABS contracts and obligations. Many megadiverse countries[2] therefore regard PDRs as a crucial measure to encourage patent applicants to comply with requirements for prior informed consent and mutually agreed terms.[3] Such new PDRs – especially when mandatory – may lead to changes in the attitudes and behaviors of inventors. Thus, they may reinforce the effects of an ABS system and reduce the free-riding incentives to freely obtain a benefit from someone else's genetic source or traditional knowledge without proper compensation or authorization. Ultimately, this should help to prevent misappropriation.

Box 6: Spotlight
Fair and equitable benefit sharing concerning *Arogyapaacha*-based drugs

> In South India, the medicinal knowledge of the Kani tribe led to the development of "Jeevani", an anti-stress and anti-fatigue drug based on the medicinal plant *Arogyapaacha*. Indian scientists at the Tropical Botanical Garden and Research Institute (TBGRI) in Kerala, India, used tribal TK and know-how to develop the drug and isolated 12 active compounds from *Arogyapaacha*, which was used as a GR for research and development (R&D). The Institute initially applied for a variety of patents for the process of making drugs in 1994.[4] In 2008, an updated patent application was filed for the product Jeevani.[5]
>
> In the meantime, the Indian patent law had been amended[6] to include provisions on mandatory disclosure of source and geographical origin of the biological material and associated TK used in the invention in patent applications. Thus, the later-filed patent application for Jeevani refers to traditional use of *Arogyapaacha*,[7] stating: "The tribal inhabitants (Kani tribe) of this area call this plant Arogyapacha meaning 'evergreen health' and they use the seeds of this plant as a rejuvenator and antifatigue agent."
>
> The technology was licensed to Arya Vaidya Pharmacy Ltd., an Indian manufacturer pursuing the commercialization of Ayurvedic herbal formulations. A trust fund was established to share the benefits arising from the commercialization of the drug. The benefit-sharing agreement between TBGRI and the Kani people has been acclaimed as a model for similar agreements around the world. It is acknowledged as pioneering example of the effective use of IP in concert with benefit-sharing agreements with an indigenous community that held this knowledge.[8]

Enhancing efficiency, legal certainty and transparency

The essence of the patent system is transparency and disclosure.[9] The very operation of the patent system involves making publicly available a great deal of legal, administrative and technological information in an accessible format. Some

patent applications do, as a matter of practice, disclose information concerning GRs and TK. A new PDR could hold promise as a transparency measure. This could improve the examination of patent applications and the determinations of prior art and inventorship (or co-inventorship), thereby potentially increasing legal certainty about the status of granted patents.[10] This could enhance the overall efficiency of the patent system. But if transparency is something to be promoted, legislators and policymakers need to be clear on what exactly is to be made transparent, what the transparency is supposed to achieve and what should be the legal consequences if private actors fail to be transparent.

Box 7: Enhancing transparency of the patent system in Belgium

Law of April 28, 2005 modifying the Law of March 28, 1984 on Patents, in particular the Patentability of Biotechnological Inventions

Belgium amended its patent law of March 28, 1984 (BPL) in order to implement *Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions*. In particular, Article 15, § 1, 6 BPL provides "that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention." This is a formal requirement that aims to contribute to transparency with regard to the geographical origin of the genetic resource on which the invention is directly based. The standard form for national patent applications provides for tick boxes that oblige the applicant to declare (Yes or No) whether use has been made of GRs in the sense specified in Article 15, § 1, 6 BPL. The applicant is thus invited to provide information on the geographical source of the GR. If this information is not available, he or she may declare that the source is not known. This measure provides for a mere formality that does not put any burden on the patent office, i.e., the office does not have to undertake any further research regarding the geographical source of the material as declared by the applicant. Such information is made available to the public by means of inclusion of the application form in the public part of the patent file.

Source: WIPO/GRTKF/IC/16/INF/15, Annex, p.2.

Furthermore, the transparency and efficiency of the patent system can be enhanced by, *inter alia*, increasing the online availability and searchability of patent information on the disclosure of GRs and associated TK. As a supporting measure, the establishment of more comprehensive databases of GRs or similar mechanisms to prevent the granting of erroneous patents might also be considered; this is discussed further below in section 18, p.54.

Complementarity/mutual supportiveness with international agreements

The implementation of new PDRs at the national level could strengthen the mutual supportiveness and complementarity between IP and ABS regimes under the CBD and its Nagoya Protocol.[11] Laws on ABS have different objectives and scope of application from the laws underpinning the patent system, and are administered by different institutions. PDRs, if properly implemented, could promote coherence between these laws and ultimately enhance cooperation between their respective institutions.

Box 8: Interaction between GRs, TK and IP

There has been very extensive discussion of the possible linkages between GRs, TK and the patent system, both as a means of "improving benefit sharing by creating a positive link between[…] patent legislation and[…] legislation governing access to [GRs]" and as a means of policing restrictions on the use of GRs and TK. The objectives for clarifying and strengthening these linkages have variously been defined as transparency and monitoring, and as enforcing compliance with legal obligations governing access.

WIPO Technical Study, pp.30-32

Timely and effective communication about PDRs between patent offices and ABS authorities may also generate positive synergies and foster mutual supportiveness between these systems.

Box 9: Policy coherence between the ABS authority and the patent office in Panama

Executive Decree No. 25 of April 29, 2009 regulating Article 71 of the General Law on the Environment (Law No. 41 of July 1, 1998).

The *General Law on the Environment* establishes that the National Environmental Authority (*Autoridad Nacional del Ambiente*) as the competent authority that regulates and controls access to and use of GRs (with the exception of human GRs), including with respect to relevant IP issues. According to Article 72 of the Law, the right to use natural resources does not grant its users the right also to use the GRs contained therein. This Article is considered to be the legal base of ABS regulation.

Executive Decree No. 25 further establishes the conditions and procedures for accessing GRs and TK from Panama, including PIC and MAT requirements that are intended to promote benefit sharing. The Decree requires access contracts to include an obligation for the applicant to declare the origin and provenance of GRs in all the publications or summaries that incorporate the genetic or biological resources collected (Article 19, paragraph e). Likewise, a "certificate of origin and provenance for the genetic and/or biological resource or material that is used in the development of the invention should be presented in all patent applications that are submitted to the General Office of Intellectual Property and/or any other patent office of WIPO member countries" (Article 19, paragraph g).

Reportedly, the National Environmental Authority and the Ministry of Commerce and Industry, through the Directorate of Industrial Property, are working together in order to ensure compliance with ABS regulations under the Nagoya Protocol.[12] Periodic patent searches of databases held by the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and WIPO are regularly conducted. While searching these databases is a complex exercise, it has been suggested that a search strategy could be significantly improved based on the information included in research reports or publications that are submitted to the competent ABS authority under Article 19, paragraph (f) of the Executive Decree.[13] Moreover, the Panamanian patent regulations are under review to determine whether to include the communication of the source or origin of a genetic or biological resource as a requirement for patent applications.[14] However, reportedly there has been no case of misappropriation or erroneous patent grant detected in Panama since 1998.

Evidence of legal access to and use of a GR/TK may simply include information about the circumstances or geographic location in which the GR/TK was obtained in the interest of transparency, or – if there is a requirement to provide evidence of prior informed consent (e.g., from specific GR/TK holders) – then this will need to be obtained and presented before a patent application is filed or a patent is validly granted.[15]

Policies and legislation enacted to fulfil the policy objectives described in the above section may result in a regulatory system that explicitly chooses to achieve overlapping and mutually supportive policy goals. These goals should guide the specific design of policy options on new PDRs and their implementation at the national level.

4. Complementary and competing interests and objectives

What other interests and objectives may need to be balanced when shaping an appropriate disclosure obligation?

While efficient and dynamic interactions between ABS and IP systems through a new PDR may help governments serve the public interest in the (defensive) protection of GRs and TK[1] and preventing their misappropriation, governments may also need to monitor the effects of new PDRs on innovation.

Preventing the erroneous grant of patents has become a vital part of the debate over PDRs.[2] Those not seeking to develop new PDRs, and particularly those opposing them, including industry stakeholders,[3] have argued that mandatory new PDRs would hinder the legal certainty and predictability of the patent system, cause additional delays in the processing of patent applications and impede innovation.[4] Furthermore, patent term extensions (patent term adjustments or patent term restoration) have been proposed to compensate patent owners for (unreasonable)[5] delays incurred in the patent prosecution.

Box 10: Spotlight
Patent term extensions

> Under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patents expire 20 years after the initial filing date. Measures related to patent term extension go beyond what countries are already obliged to follow under TRIPS. However, such measures appear in U.S. law[6] and the laws of some other countries that have free trade agreements with the U.S., for example Chile,[7] Singapore[8] and the Republic of Korea.[9]

A number of mechanisms already exist or may be considered in the patent system – and can be further improved – to address patent quality and efficiency, and prevent and correct undesired effects of erroneously granted patents (i.e., patents that do not fulfil the requirements of novelty and inventiveness). Databases, guidelines and the adjustment of search tools and patent classification systems are some of the additional measures proposed to help patent examiners find relevant prior art, avoid granting erroneous patents and simplify and streamline administrative systems for the benefit of all users of the system and the public as a whole.

To sum up, there is a risk – particularly at a time of rapid scientific and technological advances and innovation – that new PDRs may become an obstacle to achieving the very economic and social well-being for which they are intended. PDRs may potentially slow down innovation and discourage investment. The interpretation and implementation of ambiguous ABS rules and regulations by biodiversity authorities and patent offices, and the perverse effects of regulations that are outdated or poorly designed to achieve their intended policy goals, may present serious challenges, particularly for local R&D and innovation. It has been said that overly strict ABS regimes could affect scientists in developing countries most severely, because they have few or no resources to establish adequate due diligence measures and obtain the required permits. Consequently, higher transaction costs could increase the expense of performing research and slow the pace of scientific and technological innovation particularly in those countries.[10]

In light of these policy considerations, a key challenge is to establish a coherent legal and policy framework for any new PDRs to ensure their balanced and synergetic implementation in the context of national innovation systems. The potential of new PDRs for ABS in general and local innovation in particular can only be realized if countries succeed in providing an innovation governance structure that is balanced, flexible and takes into account differences between access to GRs for pure or upstream research and for the development of commercial products.[11]

Box 11: Balancing ABS and innovation governance in Brazil

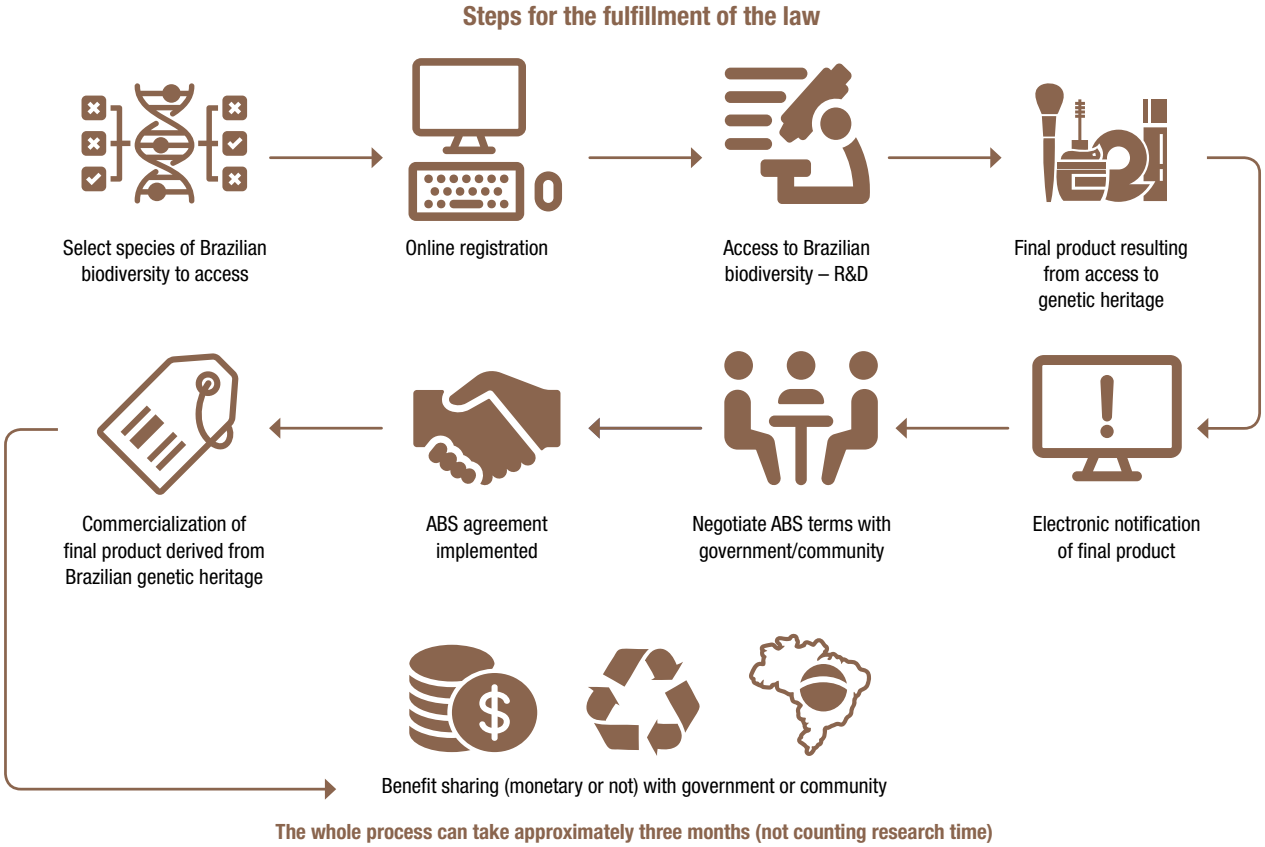
Brazil is widely acknowledged as one of the richest countries in the world in terms of its biodiversity and associated TK.[12] Biotechnology is one of the new generic technologies related to GRs underlying industrial growth in Brazil.[13]

Until very recently, granting IP rights for a process or product obtained from samples of "genetic heritage [GH] components" was linked to compliance with Provisional Act 2.186-16/2001.[14] The Brazilian disclosure system was fiercely criticized by stakeholders (industry, the scientific community and indigenous people) for being too complex, hard to navigate and burdensome.[15] The Act created barriers to R&D on GRs and TK, and posed additional challenges to the country's still-immature innovation system by creating excessive control over non-commercial research and increasing transaction costs.[16] As Pinto (2016) explains, the application of a PDR under Provisional Act 2.186-16/2001 had several unintended consequences, rendering benefit-sharing measures ineffective and suppressing R&D and patent-filing activity. In 14 years, only 136 ABS contracts were approved, with no synergy with the Brazilian innovation system.

The Provisional Act has now been repealed by Law Nº 13.123 of May 20, 2015, which provides a new framework for access to GRs and TK and the fair and equitable sharing of benefits for preserving and sustaining Brazilian biodiversity.[17] Decree Nº 8.772 of May 11, 2016 further implements specific aspects that concern, *inter alia*, a requirement to provide information on relevant research activities that involve genetic heritage components or associated TK through an electronic registry.

Pinto (2016) notes that the new *Biodiversity Law* (Nº 13.123 of May 20, 2015) emphasizes incentives rather than penalties It requires only that "the granting of intellectual property rights… on the finished product or on reproductive material obtained from access to GRs or associated TK, is conditioned to registration or authorization under the terms of the Law." While authorization is required only in cases of national security, fines may apply for failure to register the use of domestic GRs. ABS requirements apply only to the sale of a final product, and prior informed consent is mandatory in case of an identified TK holder. Part of the benefits will fund a National Benefit-Sharing Program. Under the old Provisional Act 2.816-16/2001, the mere application procedure for an ABS contract could take two years or more. Now, under the new law, scientific R&D merely requires an online registration which can be completed in a few minutes. Aside from the time necessary to undertake research, the estimated time from online registration to the request for a patent is approximately three months.[18]

It is therefore suggested that the combination of biological and cultural diversity in Brazil could lead to a competitive advantage for domestic R&D, if appropriate innovation policies are put in place to promote ethno-pharmacology and foster biological and cultural diversity via the flow of benefits back to TK holders.[19]



Source: Daniel R. Pinto, "Disclosure requirements and access and benefit sharing – an overview of recent developments in Brazilian biodiversity legislation", presentation delivered at the WIPO Seminar on IP and Genetic Resources (May 26-27, 2016), based on research by Manuela da Silva (FIOCRUZ, 2016), adapted from Nascimento e Mourão Advogados.

5. Legal nature

What is the difference between voluntary and compulsory PDRs?

Many countries, including both developed and developing countries, have adopted some form of PDRs relating to GRs and TK in their national laws.[1] They may impose various levels of obligations for the patent applicants. When considering the nature of the obligation to disclose, countries should decide whether a new PDR should be voluntary or mandatory for the patent applicant. In doing so, they may consider what the respective advantages and disadvantages of these options would be. For example, a voluntary PDR can be introduced as part of the patent procedure without any consequences for patent prosecution or patent validity. A compulsory PDR may take the form of a mere formality in the patent procedure – generally, with potential consequences for the pre-grant phase only – or it can be considered as a patentability criterion with potential implications for patent validity.

When made compulsory, these requirements may also be either substantive or formal in nature. The difference between formal and substantive PDRs hinges on whether their fulfilment is provided for as part of the procedure, the content or the form of an application, rather than during the substantive examination of the claimed invention. For example, a formality requirement may refer to the need to submit certain types of documents or a required physical format, whereas a substantive requirement may refer to the nature of the invention or to the underlying standards of patentability (e.g., novelty, inventive step, industrial application and sufficiency of disclosure). Drawing the dividing line between formal and substantive requirements is not always an easy task, since this difference can be nuanced in practice.[2]

A standalone PDR related to GRs and TK (i.e., separate from general requirements related to sufficiency of disclosure or enablement) may take several different forms, as follows.

A voluntary PDR. If an encouragement is included in the preamble of patent legislation, it may constitute an exhortation to disclose details of GRs or TK in patent specifications when relevant to the claimed invention and/or ABS compliance. For example:

> **European Union:** *Directive 98/44/EC on the Legal Protection of Biotechnological Inventions of July 6, 1998*. In its Preamble, the Directive encourages applicants to mention the geographical origin of biological material in the patent application:
>
> "(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.
>
> "(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

A voluntary PDR may also be introduced as a formal part of the patent application process, i.e., in the operative provisions. In this case too, non-fulfilment – namely, the absence of information on the origin or source of the material – will have no bearing on the further processing of the patent application or the validity of granted rights. Thus, a voluntary PDR does not constitute a *de facto* or *de jure* patentability criterion.[3] For example:

> **Germany:** Section 34(a) of the *Patent Act as published on December 16, 1980*[4] *(as last amended by Article 1 of the Act of October 19, 2013)*[5] provides:
>
> "Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents."

A mandatory requirement in relation to formalities. In some jurisdictions, a PDR must be complied with in order to obtain or preserve entitlement to a patent, akin to the obligation to provide details of priority documents (or copies and translations of priority documents) in order to sustain a priority date. In others, failure to comply with procedural requirements may, in some cases, have consequences including fines and other sanctions. A demonstrated bad-faith intention to provide a willingly false or deceptive disclosure may be subject to administrative or criminal sanctions. For example:

> **Viet Nam:** *Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property.*
>
> Under "additional provisions applicable to applications for registration of inventions concerning gene source or [TK]", Article 23.11 provides:

"[A]n application for registration of an invention concerning gene source or [TK] must also contain documents explaining the origin of the gene source and/or [TK] accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or [TK]. If the inventor or the applicant cannot identify the origin of the gene source and/or [TK], he/she shall so declare and bear responsibility for the truthfulness of his/her declaration."

Switzerland: Article 49(a) of the *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* states:

"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 [TK] of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource."

Article 81(a) of the Federal Act further states:

"Any person who willfully provides false information under Article 49(a) is liable to a fine of up to 100,000 francs. The court may order the publication of the judgment."

Norway: Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:

"If an invention concerns or uses biological material or [TK], the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of [TK] shall be subject to prior consent, the application shall state whether such consent has been obtained. […] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

A mandatory requirement of substantive nature, in the sense that the assessment of a patent (by an examiner or by a court) requires a determination as to whether the requirement has been met before deciding whether a patent should be granted (or an existing patent should be upheld). In some megadiverse countries such as South Africa, India and in the Andean Community, PDRs related to GRs and TK are considered as having consequences for patentability. They aim to promote compliance with the access and benefit-sharing requirements of the CBD, and assist in tracking the commercial use of GRs and associated TK in order to promote fair and equitable benefit sharing. For example:

Andean Community: Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states:

"The application for a patent shall be filed with the competent national office and shall contain the following: […] (h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from [GRs] or products derived therefrom of which any of the member countries is the country of origin; (i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the [TK] of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force."[6]

South Africa: Section 30 of the *Patents Amendment Act (Act No. 20 of 2005)* provides:

"(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use.

"(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, [GR], or of the [TK] or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use."

> **India:** Article 10(4)(d)(ii) of the *Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005,* provides:
>
> "If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b),[7] and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely: […] (d) disclose the source and geographical origin of the biological material in the specification, when used in an invention."

The substantive examination of a mandatory disclosure requirement may raise a question of private international law, for example when the legitimacy of the access to, and use of, GRs/TK is based on a permit or contract under the law of another country. Assuming there is a sufficiently close link between the GR/TK and a claimed invention, a patent office may be required to interpret and assess the validity and scope of contractual obligations under the relevant foreign law. Doing so would determine whether the nature of the invention and the act of filing of a patent application for that invention in the patent office's own jurisdiction was consistent with the contractual obligations under the law of the source country.[8]

6. Formal and substantive requirements

What role might the patent office play in checking the fulfillment of new formal or substantive PDRs?

Patent applications contain a combination of technical, legal and administrative information. Typically, patent applicants are required to provide information relating to subject matter, patentability and prior art, plus administrative or bibliographic information relevant to their application.

Typical **formality requirements** include the need to disclose information such as the names of inventor(s) and their addresses, to submit certain documents such as priority documents (i.e., copies and translations of foreign patent applications that form the basis of a claim to priority), and to submit the application in a prescribed physical format. In some jurisdictions, failure to satisfy certain formality requirements, for example failure to declare the true inventor or to include a co-inventor, failure to disclose known prior art, or failure to establish an entitlement derived from the inventor, may have severe consequences for the patent application.[1] Failure to comply with other formality requirements, such as payment of maintenance fees or good-faith errors in naming inventors, can normally be remedied once the failure is identified.[2]

Substantive requirements generally relate to the actual nature of the invention, including considerations for assessing compliance with the standards set for patentability. Not all "substantive" requirements have to do with the qualities of the invention *as such*; some deal with such issues as inventorship, entitlement to apply for or be granted a patent, and other interests in a patent right.

The distinction between substantive and formal requirements is often considered in terms of the consequences of non-compliance. Failure to comply with substantive requirements such as novelty is a ground for the dismissal of a patent application or invalidation of a granted patent (e.g., during litigation), whereas failure to comply in formal terms may not necessarily have irreparable consequences. Post-grant challenge to a patent is generally not possible for non-compliance with formalities unless the failure to comply was fraudulent, and non-fraudulent non-compliance with formalities does not normally constitute a ground for overturning a granted patent. However, failure to meet certain formal requirements may nonetheless lead to the refusal of a patent application if it is not rectified in time.[3] In regard to the patent office's role, if a PDR related to GRs and TK is considered as a mere formality or procedural requirement, then it will be subject only to a formality check – i.e., whether a disclosure (or a substitute declaration) has been made by the applicant in the required form – regardless of any examination of its substantive content. The burden on the patent office in such a case may well be minimal. It may include a duty to collect or receive relevant information or declarations and to transmit them to the appropriate competent authorities for the substantive checks, if any (e.g., national ABS focal points).

If the fulfilment of a PDR is considered a substantive eligibility requirement, its examination may well then entail an assessment of the information contained therein. A patent examiner may need to check whether the claim or evidence of prior informed consent (PIC) is valid, either *prima facie* or to a stronger standard, for example whether the PIC that has been disclosed by the applicant is actually sufficient consent for the filing of a certain patent application for a certain derivative invention in a particular jurisdiction. The patent office will then be assigned significant new functions, quite possibly requiring additional human, technical and financial resources.[4]

7. Placement

Where should new disclosure requirements be introduced?

The vast majority of countries that have introduced some sort of disclosure requirements related to GRs and/or TK have done so in their patent law or through other measures within their IP system.[1] However, some countries have opted to provide for disclosure-like requirements – either in general or more specific terms – in their biodiversity/ABS legislation.

Is it possible to introduce new disclosure requirements in legislation other than patent and/or IP law?

New disclosure-like requirements can be introduced in legislation other than patent and/or IP law. A review of national legislation reveals important variation and flexibilities as to which legislation may be used to implement them. In a growing number of cases, such disclosure-like requirements are provided for in biodiversity and/or ABS laws.

Box 12: Disclosure requirements in biodiversity laws
Brazilian ABS Law

Law No. 13.123 of May 20, 2015 on Access and Benefits Sharing of GRs and associated TK has created an electronic registration system for companies interested in exploiting genetic heritage or associated TK.[2] In particular, Article 12 states that "the access registration must be performed prior to the request of any [IP] rights" (e.g., a patent filing). Article 47 further provides that "the granting of [IP] rights by the competent body, regarding a final product or reproductive material obtained as a result of the access to [GRs] or associated [TK] is subject to registration or authorization in accordance with this Law."

Costa Rican Law on Biodiversity
Article 80 of the Biodiversity Law of 1998 provides that the Technical Office (TO) of the National Biodiversity Commission (CONAGEBIO) within the Ministry of Environment, Energy and Telecommunications (MEET) will act as a mandatory consultative body for all application procedures involving the protection of IP rights related to biodiversity. Its decisions are binding on the IP office. In particular, Article 80 states that "justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation".

In some of these cases, the IP/patent office contributes to collecting or receiving information regarding the utilization of GRs and/or associated TK which is then used by national ABS focal points and competent authorities to monitor and support compliance with any PIC and MAT requirements. Some countries have already implemented such measures in their biodiversity/ABS laws.

Box 13: Biodiversity Law of France[3]

Art. L. 412-18. II 2° provides that when a patent application arises from the utilization of GRs and associated TK, the applicant shall, on his or her own initiative, transmit relevant information to the National Industrial Property Institute (INPI). INPI then makes the information available to the competent administrative authorities (i.e., those responsible for the application of the *Regulation of the European Parliament and of the Council 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 of April 14, 2014)* without examining it. (See also Box 24.)

As shown in the above examples, it may be particularly important to:

- provide for a transparent interface between IP and ABS systems;
- clearly define the respective *implementing functions* of patent/IP offices and national ABS competent authorities with regard to an applicable disclosure requirement; and
- establish effective communication between them, while respecting their distinct instructional mandates and competences.

The provision of disclosure requirements in ABS legislation instead of patent legislation may reflect different motivations regarding their objectives as well as different implications regarding key operational features (e.g., triggers) and applicable compliance measures.[4]

PDRs that are formally embedded in national ABS legislation generally build on the national biodiversity framework with the goal of fostering mutual supportiveness. They may help to build solid bridges between ABS and patent regimes. They usually include measures directly related to monitoring and enforcing compliance with ABS requirements, such as the submission of evidence concerning prior informed consent and the establishment of mutually agreed terms. However, the implementation of this kind of disclosure requirement is not placed exclusively in the hands of biodiversity authorities. The patent/IP office may support the identification of

potential cases of non-compliance by transmitting relevant information to ABS competent authorities, to the country providing prior informed consent and/or to the ABS Clearing House of the Nagoya Protocol, as appropriate.

On the other hand, PDRs that are incorporated directly into patent law have the potential to generate information that may enable patent examiners to reach a more accurate, informed and fair decision about patent applications. Hence, the frequent use of specific "triggers" that refer to the invention being "*based on*" or "*directly based on*" a particular GR or associated TK.

Box 14: Vanuatu's framework for PDRs

> *Article 47 of the Patents Act No.2 of 2003* provides: "If it appears to the [patent] Registrar that an application is for the grant of a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge, the Registrar must refer the application to the National Council of Chiefs." The Registrar must not grant patents for such inventions unless: "(a) the custom owners of the indigenous knowledge have given their [prior informed consent] to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent." If an agreement on prior informed consent and mutually agreed terms "has not been entered into within 12 months after the patent application has been lodged: (a) the Registrar may grant the patent; (b) the owner may exploit the patent; and (c) the Registrar is to determine the amount payable to the custom owners or the National Council of Chiefs by the owner of the patent, being payment of an equitable share of the benefits from exploiting the patent."

In ABS legislation, the "trigger" for a disclosure obligation is frequently connected to the "utilization of" GRs and associated TK (in line with the terminology used in the Nagoya Protocol). Accordingly, activities that trigger benefit-sharing and/or ABS compliance-related monitoring obligations will also trigger a patent/IP-related disclosure obligation.[5]

Another important difference between PDRs in ABS legislation and in patent law rests on the consequences of non-compliance and the remedies available to address it. ABS legislation may provide for various penalties, sanctions and fines, including the seizure of GR samples, revocation or cancellation of the permission to access a GR, revocation of a bioprospecting agreement, a ban on future bioprospecting and even imprisonment. These remedies and sanctions normally operate outside the remit of the patent system. In some instances, non-compliance with a disclosure requirement in ABS legislation may have consequences not only for patent examination but also for patent granting (see the Costa Rican example in Box 12). However, post-grant remedies for non-disclosure such as the revocation of granted patents, should that be decided upon as a matter of policy, are normally excluded if the disclosure requirement is only provided as part of ABS legislation.

8. Subject matter

What is the subject matter covered by these new PDRs?

The subject matter of a new disclosure obligation raises three key policy issues:

i. whether disclosure obligations should apply only to patent rights (and patent applications) or also to other IP rights;
ii. whether the subject matter of disclosure should encompass only GRs and biological resources or also include TK; and
iii. whether the subject matter should encompass "derivatives", raising the issue of the definition of this term.

Patent rights versus other IP rights

Disclosure requirements have been incorporated into IP legislation in many countries. In several of them, these requirements apply specifically to patent law. For example:

> **Sweden:** Article 5a of *Regulation (2004:162) Amending the Patents Decree* states:
>
> "If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated."

In some countries, the scope of the requirements is not limited to patent law and applies to other IP rights, including plant variety protection and utility models. For example:

> **Costa Rica:** Article 80 of *Biodiversity Law No. 7788, 1998* establishes that:
>
> "Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent."

Disclosure requirements introduced in biodiversity/ABS legislation often apply to all relevant IP rights. For example:

> **Ethiopia:** Article 17 of the *Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006* states:
>
> "A person who shall be given an access permit shall have the following obligations: […] (12) where he seeks to acquire [IP] right over the [GRs] accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; (13) not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute […]."
>
> **Brazil:** Article 47 of *Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge)* provides:
>
> "The grant of [IP] rights by the competent body for the final product or for the reproductive material obtained through access to [GRs] or associated [TK] shall be subject to the registration or authorization provided for in this Law."

Some countries also provide for some sort of disclosure requirements specifically in their plant variety protection (PVP) legislation. For example:

> **Malaysia:** Section 12 of the *Protection of New Plant Varieties Act 2004* provides:
>
> "An application for the registration of a new plant variety and a grant of a breeder's right shall be made to the Board in the prescribed manner and shall:
> "e) contain information relating to the source of the genetic material or the immediate parental lines of the plant variety;
> "f) be accompanied with the prior written consent of the authority representing the local community or the indigenous people in cases where the plant variety is developed from traditional varieties;
> "g) be supported by documents relating to the compliance of any law regulating access to genetic or biological resources; and
> "h) be supported by documents relating to the compliance of any law regulating activities involving genetically modified organisms in cases where the development of the plant variety involves genetic modification."

Box 15: Disclosure requirements in the Plant Variety Act of Norway

> *Section 4 of Act No. 32 of March 12, 1993, relating to Plant Breeder's Rights (consolidated version of 2015)*
>
> The Plant Breeder's Act Section 4 [includes] an obligation [...] to disclose the origin of biological material and [TK] used in the breeding of the new variety. This means that information about [the] country of origin etc. shall be given for the plant material and possible [TK]. The penal provisions are the same as in the Patents Act Section 8 b, namely the General Civil Penal Code Section 166. A violation of the obligation to disclose does not influence the processing of the application or the validity of a protected plant variety.

Source: WIPO/GRTKF/IC/23/INF/10.

However, a requirement to disclose the geographical origin of a new plant variety under UPOV-type legislation can also be interpreted in a completely different manner (that is, unrelated to the origin of the background GRs/TK). For example, in the European Union and its Member States, this requirement is interpreted as the place where the variety has been developed by the breeder rather than the country of origin of the initial breeding materials used during the breeding process.

> **European Union and its Member States:** Article 50.1 of the *Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community plant variety rights* states*:*
>
> "The application for a Community plant variety right must contain at least the following: […] (g) the geographic origin of the variety […]"

GRs, biological resources and/or TK

The review of national legislation on PDRs shows that various concepts are used to define the subject matter of disclosure. Diverse terms could be used, for instance GRs, TK, associated TK, TK associated with GRs, indigenous knowledge and processes or products derived from, or developed with, biological resources and/or TK.

GRs are defined in the CBD 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".[1] The latter expression is commonly understood to require the presence of DNA (deoxyribonucleic acid) or RNA (ribonucleic acid) in the material,[2] so may exclude many gene products at the sub-organism level, non-DNA molecules as well as proteins, which do not contain "functional units of heredity".[3] On the other hand, the term TK may refer to knowledge resulting from intellectual activity in a traditional context and include know-how, practices, skills and innovations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with GRs.[4]

> **African Regional Intellectual Property Organization (ARIPO):** Section 2.1 of the *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the ARIPO* provides:
>
> "'Traditional knowledge' shall refer to any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources."

Box 16: WIPO Intergovernmental Committee on IP and GRs, TK and Folklore (the IGC)

The Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (as at the close of IGC 30 on June 3, 2016) provides for the following draft options for a definition of:

"[Traditional Knowledge Associated with Genetic Resources

"Option 1

"'Traditional knowledge associated with genetic resources' means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, [that subsist in] [that are associated with] genetic resources.]

"Option 2

"'Traditional knowledge associated with genetic resources' means substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by [rightful holders, including] indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]] [and where, but for the traditional knowledge, the invention would not have been made].]"

The CBD Bonn Guidelines envisage that countries could consider, among others, the adoption of "measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of [TK], innovations and practices of indigenous and local communities in applications for [IP] rights."[5] In this context, countries have adopted different approaches to the definition of the subject matter of new PDRs.

Box 17: The subject matter of disclosure

Reported or published national or regional measures apply several related concepts such as:

- "an invention is based on biological material of plant or animal origin or if it uses such material obtained or developed through an access activity"(*EU Biotechnology Directive, 1998*)
- "products or processes whose protection is being requested [were] obtained or developed on the basis of the knowledge originating in any one of the Member Countries" (*Andean Community Decision No.391, 2002*)
- "innovations involving elements of biodiversity"(*Biodiversity Law No. 7788, Costa Rica, 2008*)
- "biological material [...] when used in an invention" and "biological material used for the invention" (*Patents (Amendment) Act, India, 2005, India*).

WIPO Technical Study, p.35.

For the disclosure of GRs and TK, some countries have chosen to elaborate the wording that describes the subject matter by drawing on CBD Articles 8(j) and 15.

Andean Community: Article 26 of *Decision No. 486* (2000) *Establishing the Common Industrial Property Regime* states:

"[W]here applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin;

"[W]here applicable, a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force."

Philippines: Rule 12 Section 3(c) of the *Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010)* provides:

"The disclosure requirement under this section shall apply when the subject matter contained in a national or international IPR [intellectual property rights] application is directly based on any biodiversity, [GRs] or materials, [TK], and indigenous knowledge, systems and practices to which the research and development institutes and/or institutions (RDIs) have had access prior to the filing of the IPR application. The subject matter contained in the IPR application must depend on the specific properties of, or must be consciously derived from, such biodiversity and [GR] or materials, [TK], and indigenous knowledge, systems and practice."

Accordingly, some legal systems further extend the scope of disclosure to "biodiversity" (in general terms) and to "biological resources", which is a broader concept than the narrow definition of GRs. Under the CBD, biological resources "include GRs, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity".[6]

Denmark: Part I, Chapter 2 (5) of *Act 41 (31/5/2000) amending the Patent Act (consolidated Patent Act 926, September 2, 2000)* states:

"If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known."

Egypt: Article 13 of *Law No. 82 of 2002 on the Protection of Intellectual Property Rights* provides:

"Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner."

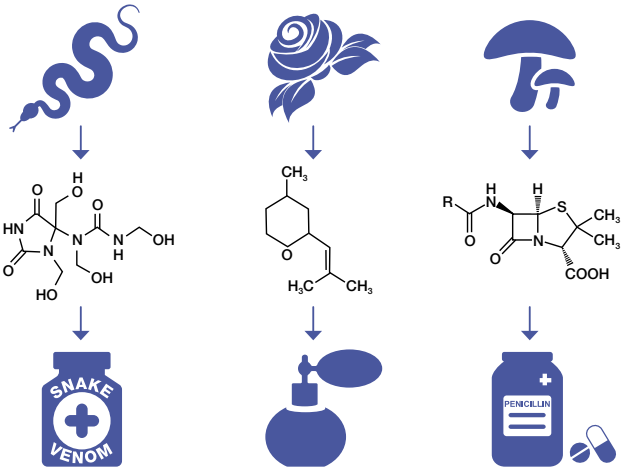
Derivatives

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". The definition comprises three key elements, namely:

- a naturally occurring biochemical compound
- which results from the genetic expression or metabolism of biological or genetic resources
- whether or not it contains functional units of heredity.[7]

Figure 1: Examples of genetic resources and their derivatives

Genetic resource (contained in)	Derivative
Snake	(Active ingredient of) Venom
Rose	(Chemical responsible for the) Scent
Fungus	(Antibiotic compound) Penicillin



Other relevant definitions in the Nagoya Protocol include the definitions of "utilization of genetic resources" and "biotechnology". The *Explanatory Guide* of the International Union for Conservation of Nature (IUCN) highlights that "the term derivative is not used […] in the operative text of the Protocol. However, it is linked to the term utilization, which is used directly (verbatim) or indirectly (adjusted depending on the context in which it appears) in many provisions of the Protocol."[8]

Box 18: The Nagoya Protocol on ABS

> As defined in Article 2(c) of the Nagoya Protocol, "'**Utilization of genetic resources**' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention".
>
> Article 2(d) then states: "'**Biotechnology**' as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".
>
> On the Nagoya Protocol, see also Box 31 below.

In this context, it has been suggested that the "utilization of derivatives" may also be covered by aforementioned definitions.[9] From one perspective, the definition of "derivative" expands the range of biochemicals that would be covered by ABS provisions beyond those that are GRs in a strict sense. If so, that such naturally occurring biochemicals may or may not contain "functional units of heredity" becomes essentially irrelevant for the purpose of ABS regulation – for example, the subject matter could be covered by access measures even if it does not contain DNA or RNA. In other words, the extraction of chemicals from a GR for the development of drugs could be included, and benefit sharing would be supported by the Nagoya Protocol.[10]

However, there is no universal consensus on the situation of "isolated derivatives" that have not been accessed simultaneously with the genetic resources.[11] Moreover, the current definition of "derivatives" may exclude, for instance, synthetic analogue chemicals that are merely *inspired by* a particular naturally occurring metabolite or gene segment.[12]

Indeed, the inclusion of a specific definition of the term "derivative" in the law is likely to limit the possible range of derivatives that would be covered by a patent disclosure requirement.

> **Andean Community:** Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime 2000* provides:
>
> "[W]here applicable, a copy of the access contract [should be provided] where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin."

A reference to GRs alone could instead exclude the application of a PDR where the subject matter or claimed invention neither includes utilization of nor is directly based on material containing DNA/RNA (for example, an invention based on a naturally occurring protein would not be covered *per se* – i.e., when no use was made of the GR from which it was initially derived).

> **Germany:** Section 34(a) of *Patent Act (as amended by the Law of July 31, 2009)* states:
>
> "Should an invention be based on biological material of plant or animal origin or if such material is used therefor, the patent application is to include information on the geographical origin of such material, if known."

However, contracts such as material transfer agreements (MTAs) which are used for the acquisition of biological and research materials may be required as part of the initial access procedure in the providing country. In such cases, a disclosure requirement or other reporting requirements could be introduced as a contractual obligation under the initial access agreement, rather than through specific provisions under patent law in the user country. However, the recognition, interpretation and application of contractual obligations across different jurisdictions raise private international law issues whose resolution might not always guarantee uniform outcomes in different user countries.[13] Nonetheless, ABS contracts may mandate the disclosure of origin or source, including for derivative products, as a contractual obligation – e.g., whenever a patent application is filed in foreign jurisdictions, regardless of whether the laws of such countries provide for the disclosure of derivatives or not.[14]

Box 19: Contract law: "derived product" under material transfer agreements

> An MTA will commonly establish a contractual relationship between provider and user, and this will often govern subsequent use of material derived from the genetic resource as received (including ownership, licensing or other aspects of patent rights on products derived from the genetic resource). This leads to a wide range of approaches to characterizing the link between GR or TK and a patented invention, including in terms of a "derivative product".

WIPO Technical Study, p.39.

9. Content

What might be the possible content of disclosure?

A disclosure obligation may require applicants to indicate one or more of the following categories of information (under various circumstances):

- the country of origin of GRs, if any,[1] and/or TK;
- the (direct) source of the GRs and/or TK;[2]
- the legal status of GRs and/or TK (i.e., their legal provenance), in particular compliance with ABS requirements including prior informed consent and evidence that mutually agreed terms have been established; or
- a mere due diligence declaration that the applicant has complied with all applicable legal requirements concerning access to and use of GRs and/or TK.

Information material to patentability

Some countries have expressly limited the content of their disclosure obligations exclusively to submission of information about TK or GRs that is relevant for the assessment of prior art.

> **Romania:** Article 16 of *Implementing Regulations of the Patent Law No. 64/1991* provides that the description of the invention shall include:
>
> "[…] presentation of the prior art considered by the applicant to be useful for understanding, performing the documentary search and examining the claimed invention, with the indication of the documents which substantiate it; at least one solution considered to be the closest to the claimed invention shall be presented; where the prior art also contains traditional knowledge, this and its source, if known, shall explicitly be indicated in the description."

Information not material to patentability

In addition to the type of information referred to in the above section, many countries that do provide for compulsory new PDRs in their legislation may also require information that (from a patent law perspective) would not be considered material to the patentability requirements. In this context, the concept of "source" has been broadly defined to include, for instance, the actual source of the GR/TK, the country of origin (e.g., to clarify under which jurisdiction the source material was obtained) or a more specific location.

> **Philippines:** Rule 12 of *Implementing Rules and Regulations of the Republic Act No. 10055 (Joint Administrative Order No. 02-2010)* requires written disclosure of:
>
> "The primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the subject matter contained in the IPR application; or the secondary source, if no information about the primary source is available."

In some legal systems, in addition to disclosure of origin and/or source, applicants may be required to disclose important elements of the legal context in which GRs and/or TK were accessed. This may entail showing that GRs and/or TK used in the invention were obtained and used in compliance with applicable laws in the country of origin or with the terms of any specific agreement recording prior informed consent or providing evidence that benefit sharing had been agreed to through the conclusion of mutually agreed terms.

> **Egypt:** Article 3.3 of *Council of Ministers Resolution No. 1366 of 2003 issuing Implementing Regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights Books One, Two and Four* provides:
>
> "[…] Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, [the patent application] shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt."

Specific contracts, known as material transfer agreements (MTAs), are also frequently considered as a substantial part of the access procedure. Such contracts can therefore be used to provide evidence in order to fulfil a patent disclosure obligation. MTAs can either be a mandatory element of the applicable access procedure or their use may simply be a common practice of the provider institutions. MTAs establish a contractual relationship between the provider of GRs/TK and the prospective user of such resources or knowledge. They often govern the subsequent use of materials derived from the GRs that were initially received (including ownership, licensing or other aspects of patent rights on products derived from the genetic resource).

National laws may accept a simple MTA signed with the direct provider entity or institution as proof of compliance with an applicable PDR. However, some countries may require enhanced disclosure that also includes information about the country of origin and the source as well as the provision of an internationally recognized certificate of compliance or an equivalent proof of legal provenance or acquisition of the relevant GRs/TK. (For more details, see also section 17, pp.50-51, below on issues related to the Nagoya Protocol.)

Andean Community: Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states that a patent application shall contain:

"[a] copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries; […] if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested [were] obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations."

South Africa: Section 30 of the *Patent Law (as amended in 2005)* provides:

"Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use."

10. Geographical scope

What is the geographical scope of disclosure?

National laws on PDRs may follow one of three broad approaches to the geographical scope of disclosure. The requirement can be applied:

i. nationally (i.e., only in respect of GRs and/or TK which are considered to be subject to the national jurisdiction of the country that provides for the PDR);
ii. on the basis of the principle of reciprocity (e.g., a club approach); or
iii. universally (i.e., independently of where the GR and/or TK were initially sourced from).

National scope

Several countries apply PDRs only to GRs and TK that originate within their own territory. The impact of such PDRs may be rather limited, since a patent applicant who files an application for an invention that is based on a GR or TK originating from a third country will not be subject to the requirement.

> **Ethiopia:** Article 17 of the *Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006* states:
>
> "A person who shall be given an access permit shall have the following obligations: […] (12) where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; (13) not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute; […]"
>
> **Costa Rica:** Article 80 of *Law No. 7788 on Biodiversity (as last amended by Law No. 8686 of November 21, 2008)* requires patent applications to be accompanied by a certificate of origin and prior consent, but this only applies if the resources or knowledge are from Costa Rica:
>
> "Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior consent."

Scope based on reciprocity or club approach

Some countries apply PDRs not only to their own GRs or TK, but also to GRs or TK that originate from within the territory of other countries that provide for the same kind of PDRs (absolute reciprocity) or for minimum standards of compliance with ABS legislation that are equivalent to those applied domestically (a club approach). This approach usually reflects a previous arrangement such as a regional or international framework establishing some form of reciprocity among participating countries.

Box 20: PDRs based on absolute reciprocity between the countries of the Andean Community

> Article 26(h) of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states:
>
> "Applications for patents shall be filed with the competent national office and shall contain: [...] a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries."

In countries that are parties to the Nagoya Protocol, the introduction of new PDRs as a checkpoint mechanism is only optional (see further section 17, pp.50-51, below). However, if such requirements are introduced then their scope of application should at least encompass, without discrimination, GRs originating from any other parties to the Nagoya Protocol. Thus, designation of a country's patent/IP office as a compliance checkpoint under Article 17 of the Nagoya Protocol is an example of a situation where the geographical scope of such PDR would be defined based on reciprocity and non-discrimination between the contracting parties.

Universal scope

Most legal systems that include PDRs already provide for universal disclosure of any GRs and TK used in the claimed invention, irrespective of the legal standards that are applied in the country of origin or provenance of the GRs or TK. Nonetheless, the applicability of specific ABS requirements in the jurisdiction of the country of origin or provenance may mean that the applicant is then required to present supplementary evidence to show that those requirements have actually been met.

People's Republic of China: Article 26(5) of *Patent Law Amendment, December 27, 2008, which entered into force in October 2009* states:

"[…] for an invention-creation, the completion of which depends on genetic resources, the applicant shall indicate the direct source and original source of said genetic resources in the application documents; the applicant shall state reasons if the original source of said genetic resources cannot be indicated."

Samoa: Article 7 of the *Samoa IP Act (2011, No.9)* requires patent applications to include:

"[…] a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere."

Norway: Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* adopts a very detailed rule:

"If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material, the application shall also state the country of origin. The country of origin means the country from which the material was collected from its natural environment. If the national law in the country of origin requires that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that."

The ongoing negotiations at the WIPO IGC have been considering the introduction of internationally agreed norms for the harmonization of new PDRs which could potentially cover GRs and TK from all participating countries while also clarifying the legal nature of such requirements.

11. Exclusions

What exclusions from the material scope of application of a new PDR might be envisaged?

The CBD defines "genetic material" as any material of plant, animal, microbial or other origin containing functional units of heredity (see section 8 above). The definition of GRs then refers to genetic material of actual or potential value. However, human genetic resources are excluded from the scope of application of the CBD.[1] This exclusion has been carried over into various national legal systems in respect of PDRs.

> **Andean Community:** *Decision 486, Establishing the Common Industrial Property Regime*, makes direct reference to Decision 391[2] implementing the CBD, whereby human genetic resources are expressly excluded from its purview. In particular, Article 4 of *Decision No. 391 Establishing the Common Regime on Access to Genetic Resources (1996)* states:
>
> "The following are excluded from the scope of this Decision:
> "(a) Human genetic resources and their by-products."
>
> **Costa Rica:** Article 4 of Costa Rica's Biodiversity Law (BL) of May 27, 1998 provides:
>
> "This law will not apply to access to biochemical or genetic material of human origin, which will continue to be regulated by the General Health Law, No. 5395, of the 30th of October 1973, and by the connected laws."

Nevertheless, from a scientific and technical standpoint, various human genetic materials, including samples taken from indigenous persons,[3] may be used in or be at the origin of a patented invention.[4] This issue has therefore also been addressed from a patent disclosure perspective by some national or regional laws:

> **Norway:** Section 8(c) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:
>
> "If an invention concerns or uses biological material from the human body, the patent application shall include information on whether the person from whom the material has been derived has given his/her consent to the use of the biological material, in accordance with the law of 21st February 2003 no. 12 about bio banks."

European Union: *Directive 98/44/EC on the Legal Protection of Biotechnological Inventions of July 6, 1998*. In its Preamble, the Directive distinguishes between biological material of human origin and biological material of plant or animal origin, and encourages applicants to obtain free prior informed consent from the person who provided the material:

"(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law."

Besides the explicit exclusions concerning human GRs that can be found in some national laws, international discussions have also focused on whether there should be other exceptions and limitations to a new PDR and, if so, which ones. Examples of subject matter that has been proposed for exclusion include commodities or GRs when they are used as commodities, TK in the public domain[5] and GRs from areas beyond national jurisdiction.[6] The issue whether the application of a new PDR should be time bound, for example so as to exclude all GRs accessed or acquired before the entry into force of the CBD and/or the Nagoya Protocol, has been considered too.[7] Furthermore, it has been suggested that an alternative approach would be to introduce public interest-related exceptions in more general terms, without the need to list such exceptions in great detail in relevant legal instruments.[8]

12. Triggers

What relationship or link between the subject matter of disclosure and the claimed invention will trigger the application of a new PDR?

In practice, the application of a new PDR depends on a "trigger" or link between the claimed invention and relevant GRs or TK – that is, the relationship with the subject matter of disclosure. In essence, the function of the trigger is to identify markers of "proximity" creating a boundary within which benefit-sharing requirements (and any related compliance-monitoring obligations) will apply. In what circumstances should a patent examiner or other receiving office demand additional disclosure related to GRs or TK from the applicant?

Box 21: Qualitative methods to identify appropriate markers for triggering a new PDR

> The trigger or link may relate to various issues, for example:
> - whether the GR/TK is incidental or fundamental to the development of the invention;
> - whether the GR/TK is necessary to assess, understand, replicate, or carry out the invention, or the GR/TK is in effect only a vehicle for a separate innovative concept;
> - whether the GR/TK contributes to one earlier step in a chain of innovations that over time culminated in the invention, or is a direct input to the claimed inventive step;
> - whether particular qualities of the GR/TKs are essential to the invention;
> - whether a GR is used in a particular embodiment or one example in a description of the invention, but is not indispensable to arrive at or replicate the invention as claimed.

The Technical Study (2004), p.2

In view of the above considerations, the trigger may be defined narrowly so as to exclude some of the more remote linkages between the claimed invention and underlying GRs/TK or it may be defined in broad terms to encompass the greatest range of situations.

Three main broad **categories of triggers** may be identified in national laws. The new disclosure requirement may apply to any IP and/or patent right (or application and/or claimed invention, as appropriate and subject to national law) that:

i. includes the utilization of GRs/TK; or
ii. is derived from GRs/TK; or
iii. is based on GRs/TK or "directly" based on them.

The invention includes the utilization of GRs/TK

As explained earlier, the concept of "utilization of genetic resources" derives from the Nagoya Protocol. It is defined as "conduct[ing] research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology [...]".[1]

Box 22: Background on definitions in the context of the Nagoya Protocol

> To fully understand the definition of "utilization of GRs", it is important to take a close look at these references included in Article 2(c) of the Nagoya Protocol:
> - research and development;
> - biochemical composition of genetic resources; and
> - application of biotechnology.
>
> The terms "research and development" are not defined in the Nagoya Protocol. Based on Article 31(1) of the Vienna Convention on the Law of Treaties,[2] the ordinary meaning of these terms in the context of the Nagoya Protocol is applicable. The Oxford Dictionaries definition of research is "the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions".[3] In particular, for the Nagoya Protocol "research" means the investigation and study of the genetic and/or biochemical composition of genetic resources in order to establish facts and reach conclusions. "Development" includes the creation of innovations and practical applications (e.g., applied research), including through the application of "biotechnology".
>
> The expression "[...] utilization of [GRs] as well as subsequent applications and commercialization" is used to trigger fair and equitable benefit-sharing obligations under Article 5 of the Nagoya Protocol. In addition, patent/IP offices may be designated as possible checkpoints under Nagoya Protocol Article 17. These "[...] checkpoints would collect or receive, as appropriate, relevant information related to [...] the utilization of genetic resources, as appropriate."

The use of the term "utilization of" GRs as the trigger for a new PDR obligation is consistent with the terminology used in the Nagoya Protocol. It may cover a broad range of upstream R&D activities on the genetic and/or biochemical composition of GRs which may or may not eventually result in the filing of a patent/IP application.[4] Any of the activities that would trigger benefit-sharing and/or compliance-related monitoring obligations under the Nagoya Protocol will then also trigger a disclosure obligation when an IP/patent application is filed.[5]

> **People's Republic of China (PRC):** Article 26 of the *Patent Law of the PRC (as amended by the Decision of December 27, 2008, regarding the Revision of the Patent Law of the PRC)* provides:
>
> "With regard to an invention-creation accomplished by relying on [GRs], the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources."
>
> Relevant implementing rules also explain that the expression "the invention-creation accomplished by relying on GRs" refers to "[…] those invention-creation of which the accomplishment uses the genetic function of [GRs]".
>
> **India:** Section 10 of the *Patents (Amendments) Act 2002* states:
>
> "Every complete specification shall […] disclose the source and geographical origin of the biological material in the specification, when used in an invention."
>
> **Norway:** Section 8b of *Patent Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:
>
> "If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained."

The invention is derived from GRs/TK

The use of the trigger "derived from" GRs/TK could possibly be the broadest of the three trigger categories. In the absence of a specific definition, the term could be interpreted to encompass different things, ranging from direct physical derivation from a GR – that is, when the genetic material is physically incorporated into the final product, such as in the case of "essentially derived varieties" under UPOV 1991[6] – to any synthetic biology product that is created using gene sequence data simply obtained from an online repository or database (such as a DNA library), and anything in between these two.

> **Andean Community:** Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states:
>
> "Applications for patents shall be filed with the competent national office and shall contain: […] (h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from [GRs] or byproducts originating in one of the Member Countries; (i) if applicable, a copy of the document that certifies the license or authorization to use the [TK] of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations […]."

If the subject matter of a disclosure obligation encompasses TK, the notion of "consciousness" may acquire particular significance where the invention was "consciously derived from TK".

> **Philippines:** Rule 12 Section 3 (c) of the *Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010)* provides:
>
> "[…] The subject matter contained in the IPR application must depend on the specific properties of, or must be consciously derived from, such biodiversity and [GR] or materials, [TK], and indigenous knowledge, systems and practice."

In such cases, the above notion would exclude any strict liability for lack of disclosure of TK that may be unknown to the applicant and for any independent discovery. It would also shift the burden of proof – that there is, in actual fact, a conscious act of derivation – from the applicant to the patent/IP office or any other competent authorities. However, the notion of consciousness may also be relevant when the subject matter of disclosure encompasses exclusively a gene-based invention (that is, independently of any TK lead). This is due to the fact that "[…] there are significant genetic similarities or 'homologies' across species, genera and classes of organism."[7] On the face of it, a consciousness requirement may well exclude a "proximity" marker for patent disclosure for the most broadly drafted, all-encompassing

claims in relation to DNA and genes (e.g., those claims with a reach well beyond the specific genetic resource that might have been at the origin of the claimed invention).

The invention is based on GRs/TK or "directly" based on such resources/knowledge

Review of national laws reveals that the concepts of "directly based on" or simply "based on" GRs/TK are widely used as a trigger.

> **Samoa:** Article 7 of the *Samoa IP Act* states:
>
> "3) An application must contain the following:
>
> "[…] (g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere;
>
> "[…]
>
> "10) […] if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge."
>
> **Viet Nam:** Article 23.11 of *Circular 01/2007/TT-BKHCN of February 14, 2007, Guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property* provides:
>
> "Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge
>
> "Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional knowledge."
>
> **Switzerland:** Article 49 of the *Amendment of Patent Law of June 2, 2007, RO 2008 2551* provides:
>
> "For inventions based on [GRs] or [TK] the patent application must contain information concerning the source:
> "(a) of the [GRs] to which the inventor or the applicant had access, when the invention is based directly on that resource;
> "(b) of [TK] of indigenous or local communities related to the [GRs] to which the inventor or applicant had access, when the invention is based directly on that knowledge."

The notion that the invention must be "directly based on" GRs/TK appears to be possibly the narrowest trigger. While there is currently no definition of the above expression in international law, some countries that support the use of such a trigger have indicated their preference for interpreting "directly based on" to mean that the invention must make immediate use of the GR; in other words, the invention must depend on the specific properties of the GR to which the inventor must have had physical access – the inventor must have been in possession of the genetic material or must at least have had contact with it sufficient to identify the properties of the GR that are relevant to the invention.[8]

This raises the question whether physical access to the subject matter is necessary to trigger the disclosure requirement or whether access to non-tangible subject matter (e.g., through a gene sequence data repository) might also suffice. The narrow interpretation of this trigger would potentially exclude the application of a disclosure requirement for subject matter and/or inventions that are simply based on (or obtained by accessing) a non-tangible source of bio-information.

13. Remedies and sanctions

What kinds of remedies and sanctions are available to address issues of non-compliance with any new PDRs?

A wide range of remedies and sanctions for non-compliance are provided under national laws. In some countries, non-compliance with a PDR may have no immediate consequences for the examination and granting of a patent application or its enforcement once the patent is granted, but remedies and sanctions may be imposed under civil, administrative and criminal laws. In other countries, by contrast, non-compliance may have major implications either during the patent application process or in determining the status of a granted patent (e.g., when enforcement is sought by the patent holder).

Box 23: Consequences of failure to comply

> [...] failure to meet these [PDRs] can lead to significant sanctions, ranging from penalties for false, misleading or fraudulent statements, to refusal, invalidation or transfer of the patent right.

WIPO Technical Study, p.50.

The available remedies and sanctions can be divided into two broad categories:

- those that operate *within* the immediate purview of the patent system and have implications for the prosecution or validity of patents; and
- those that do not have such implications, such as civil, administrative or criminal remedies and sanctions.

However, some countries may simply decide not to provide any PDR-related remedies or sanctions at all; in other words, no measures will be directly triggered if a PDR is not met. Even then, other measures to promote compliance with ABS requirements can be made available. Detailed analysis of such other measures is beyond the purview of this study, but an example is those provided under EU Regulation No. 511/2014.

European Union: *Regulation 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* provides:

"Article 9. Checks on user compliance

"9. […] where, following the checks referred to in […] this Article, shortcomings have been detected, the competent authority shall issue a notice of remedial action or measures to be taken by the user. Depending on the nature of the shortcomings, Member States may also take immediate interim measures.

"[…]

"Article 11. Penalties

"1. Member States shall lay down the rules on penalties applicable to infringements of Articles 4 [on obligations of users] and 7 [on monitoring user compliance] and shall take all the measures necessary to ensure that they are applied.

"2. The penalties provided for shall be effective, proportionate and dissuasive. […]"

Remedies and sanctions

Pre-grant remedies

Stay of proceedings

A failure to meet disclosure or documentation requirements within a specified time frame during the patent application phase may result in the halting of the application processing procedure. The normal procedure is that if an office checks the formal and/or substantive requirements, and non-compliance with them is found, the office invites the applicant to rectify the defect within a certain time period. During that period the procedure is put on hold.

For instance, if the applicant is invited to provide evidence of prior informed consent and mutually agreed terms or the source of a genetic resource to comply with a formality requirement, the procedure will resume once they submit the evidence in compliance with the patent office requirements. But if they do not provide it, the application is deemed to be withdrawn or rejected.

Italy: Article 170-*bis*, paragraph 7, of *Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Legislative Decree No. 131 of August 13, 2010)* provides:

"If the Italian Patent and Trademark Office ascertains the lack of the conditions for patenting a biotechnological invention or the failure to file the declarations under paragraphs 2, 3 and 4, it shall proceed in accordance with Article 173, paragraph 7 [see below], and in the event [that] it determines the absence of the conditions for patenting […], it shall reject the application."

Article 173, paragraph 7 provides:

"Before rejecting in full or in part an application or a related request, […] the Italian Patent and Trademark Office assigns the applicant a term of two months to submit observations. Once that term has expired, if no observations have been submitted or if the Office does not believe that it can accept those submitted, the application or request is rejected in full or in part."

Switzerland: Article 59a of *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* states:

"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.

"The Institute shall reject the patent application if […] b. the deficiencies mentioned in Article 59 paragraph 2[2] have not been remedied."

Samoa: Article 7 of the *Samoa IP Act (2011, No. 9)* provides:

"[…] if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge.

"If an applicant fails to provide evidence […], the Registrar may cease to deal further with the application."

For the effective functioning of the patent system, it is important to allow an opportunity to remedy defects in patent applications, particularly for unintentional or non-willful violations of disclosure obligations depending on the good faith and diligence of the applicant. Thus, the patent office may subsequently lift the stay and resume proceedings based on the disclosure or submission. This may be regarded as an "amendment" of the patent application that is prompted by the receiving office.

Andean Community: Article 39 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:

"If it emerges from the examination as to form that the application does not meet the conditions specified in Articles 26 and 27, the competent national office shall inform the applicant accordingly, so that he may meet those conditions within a period of two months following the date of notification. That period may be extended once by an equal amount at a request of a party without any loss of priority.

"If, on the expiry of the period specified, the applicant has not met the conditions mentioned, the application shall be considered abandoned and its priority shall be lost. The competent national office shall nevertheless respect the confidentiality of the application."

Amendments of a patent application may be also spontaneously introduced by the applicant. Usually, the applicant is allowed to rectify any defect that leads to non-compliance with the requirements under the applicable law within a certain period of time. However, if the effect of an amendment introduces new substantive technical matter about the invention, not disclosed by the applicant on the filing date, such an amendment is not allowed.

People's Republic of China (PRC): Article 5 of *Patent Law Amendment, December 27, 2008; entered into force October 2009* states:

"Patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations."

Egypt: Article 14 of *Law No. 82 of 2002 on the Protection of Intellectual Property Rights* provides:

"The Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article 13 [on description of invention and disclosure requirements]. If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application. The applicant may, within 30 days

and in accordance with the conditions stipulated in the Regulations, appeal such request by the Patent Office before the Committee [empowered to examine appeals against decisions by the Patent Office]."

Pre-grant opposition

Many national and regional patent systems provide opposition mechanisms which aim to improve the quality of patents by giving third parties the opportunity to oppose the grant of a patent within a certain period of time. Under a pre-grant opposition procedure, third parties may (depending on the precise national or regional law) raise the issue of non-compliance with PDRs or ABS requirements against the grant of a patent after the patent application has been published, but before a patent is granted.

Patent examiners have limited time and resources, and may not always have access to the best search tools to identify prior art. Therefore, pre-grant opposition may improve regulatory efficiency and accuracy by bringing prior art in general, as well as specific information on GRs and TK, to the attention of patent examiners.[3]

India: Article 25 of *Patent (Amendment) Act 2005* provides for pre-grant opposition:

"(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground […] (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; […] the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed."

Andean Community: Article 42 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:

"Within a period of 60 days following the publication date, any person having a legitimate interest may file one reasoned opposition contesting the patentability of the invention."

Third parties' observations

It is also possible in some jurisdictions for third parties to provide evidence concerning published patent applications that are not part of any formal pre-grant opposition process *per se*. For example, in relation to the potential grant of an allegedly erroneous patent, the EPO admits third-party observations concerning published applications which may eventually lead to the amendment (e.g., narrower claims as compared with the first filing) or withdrawal of a patent application.

Post-grant remedies

Even if a failure to meet disclosure requirements does not have immediate consequences during examination, it may have major implications for the patent later on (i.e., when it is enforced). Some view post-grant remedies as providing a necessary incentive to comply with new PDRs.

Non-compliance with new PDRs as a ground for revocation: annulment

If disclosure is inadequate or omits important information, failure to discharge the disclosure obligation may in some cases lead to the rejection or the subsequent invalidation of patent claims that are directly related to such disclosure or would need to be supported by the information that was not disclosed.

Andean Community: Article 75 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:

"The competent national authority shall decree the absolute invalidity of a patent at any time, either *ex officio* or at the request of any person, where:

"[…]

"(g) a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin;

"(h) a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the member countries is the country of origin."

South Africa: Section 61 of the *Patents Amendment Act 2005 (Act No. 20 of 2005)* states:

"Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely […] that the prescribed declaration lodged in respect of the application for

the patent or the statement lodged in terms of section 30(3A) [concerning the disclosure requirement] contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made."

Precondition to enforcement

When information about the source material used in the invention has been fraudulently withheld from the patent authorities or the material used to develop the invention has been obtained illicitly or inequitably, the misrepresentation or false statement may lead to the grant of a patent. In this scenario, the legal validity of the patent may not always be called into question. However, such misrepresentation or false statement could be raised as a defense in an infringement case, effectively making the patent right unenforceable under specific circumstances while not invalidating the patent itself. In practice, the availability of such a remedy would depend on a court's decision.

Viet Nam: Article 23.11 of *Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property* provides:

"If the inventor or the applicant cannot identify the origin of the gene source and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration."

PDRs and compensatory liability

In some cases disclosure requirements may not affect the substantive requirements relating to patentability of the invention or the entitlement of the applicant to receive or enforce a patent. However, they may be linked to distinct legal mechanisms, including in foreign jurisdictions; they may be aimed at monitoring or enforcing regulations or specific contracts; and they may eventually provide for compulsory benefit sharing through a compensatory liability rule, as is the case in Vanuatu.

Vanuatu: Article 47 of *Patents Act No. 2 of 2003* provides:

"The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless:

"(2)(a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and

"(2)(b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.

"(4) […] If an agreement mentioned in subsection (2) […] has not been entered into within 12 months after the patent application has been lodged:
"(a) the Registrar may grant the patent; and
"(b) the owner may exploit the patent; and
"(c) the Registrar is to determine the amount payable to the custom owners or the National Council of Chiefs by the owner of the patent, being payment of an equitable share of the benefits from exploiting the patent."

Civil, administrative and criminal remedies and sanctions

Sanctions outside the patent system vary among countries depending on their national legal traditions and practices. A failure to comply with PDRs may incur serious civil, administrative and criminal remedies such as penalties for provision of false information on public documents, particularly when information is withheld with fraudulent intent.

Switzerland: Article 81(a) of the *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* provides a fine for wrongful provision of false information but not patent invalidation:

"Any person who willfully provides false information under Article 49(a) [on disclosure of source] is liable to a fine of up to 100,000 francs. The court may order the publication of the judgment."

Norway: Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:

"Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

Depending on how they are designed and implemented, such civil law measures (e.g., claims for compensation) or administrative and criminal penalties (e.g., fines for refusal to submit information to the authorities or for submitting wrong information) may have limited effect as a deterrent.

For example, based on a cost-benefit analysis, a company may consciously prefer to run the risk of paying a fine at a later stage rather than comply with a disclosure requirement and meet the underlying ABS requirements in the country of origin, unless the fine is substantially higher that the estimated upfront transaction costs associated with the negotiation and conclusion of an ABS agreement.

Other relevant factors: good faith versus strict liability

Disclosure obligations may require patent applicants to prosecute their applications with candor, good faith and honesty (i.e., duty to disclose known prior art material to a patent claim).

In regard to PDRs, the intent of the applicant – in other words, whether a failure to provide relevant information was in good faith or fraudulent – may also become a significant factor. It may also be important to clarify where the burden of proof lies, that is, to determine whether the applicant is positively obliged to prove that access to GRs and associated TK meet a certain standard or whether legitimacy of access is assumed in the absence of evidence to the contrary.

If a strict liability rule applies then an applicant who fails to comply with a disclosure requirement will be subject to specific remedies or sanctions even if they were acting in good faith. But in other cases, such as in respect of granted patents, the courts generally possess adequate authority and capacity to require testimony and the production of documents that may be needed to determine good faith or fraudulent intention. If the patent holder proves that they have acted in good faith or that the failure to comply was due to a cause outside their control and which could not be reasonably foreseen, the court may decide that, absent any fraudulent behavior, they should not face sanctions for that non-compliance.

> **South Africa:** Section 61 of the *Patents Amendment Act 2005 (Act No. 20 of 2005)* provides:
>
> "Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely […] (g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made."

No remedies or sanctions directly linked to the enforcement of a PDR

In some countries, there may be no remedies or sanctions directly linked to the enforcement of a PDR as such, other than standard patent invalidation proceedings where it is determined that proper disclosure of information would have led to a refusal to grant the patent either on the grounds of lack of novelty and inventive step due to the existence of prior art or on grounds of "*ordre public* and morality" exceptions.[4]

Box 24: Biodiversity Law of France[5]

> "In France, users shall make available the information prescribed in Article 4 of EU Regulation on ABS[6] in the following occasions:
> "a) when they have received public research funding that involves the use of GRs or associated TK; or
> "b) at the time of commercialization of a product or process developed on the basis of GRs or associated TK.
>
> "[…] when a patent application arises from the utilization of GRs and associated TK, the applicant shall, on his or her own initiative, transmit the above information to the National Industrial Property Institute (INPI). In this case, the INPI makes this information available to the competent administrative authority that is responsible for the application of the EU Regulation on ABS without examining it."[7]

14. Evidence

What evidence might be submitted in the context of new PDR-related compliance mechanisms and procedures?

The petitioner in patent opposition proceedings has the burden of proof to establish the basis of their claim by a preponderance of the evidence. Such evidence usually relates to the particulars specified in the statement of grounds. It may comprise printed publications and other documents on prior art references which have been made available to the public by means of written or oral description or use, information about the claims of the opposed application or, in relevant cases, information regarding prior informed consent or mutually agreed terms.

Pre-grant opposition allows ABS authorities, indigenous peoples and local communities (IPLCs) and other relevant stakeholders to oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process (see also section 13, p.41). This may help the collection and evaluation of information on prior art, facilitate access to non-patent literature and improve patent quality and the accuracy of patent claims. The patent applicant should be given the opportunity to correct mistakes in the description or other relevant application documents by clarifying points that are unclear, changing claim dependencies, or providing a certificate of legal provenance or compliance with ABS requirements, as appropriate. If the applicant does amend the claims, the challenger may reply with new evidence in response.

In post-grant patent invalidation cases, the petitioner will need to establish, by a preponderance of the evidence, facts demonstrating the patent's invalidity (see also section 13, pp.41-42). Such evidence must be sufficiently clear, convincing and well established to rebut the usual presumption of patent validity once a patent has been granted. Existing prior art (patents, published patent applications and non-patent literature), and non-documentary evidence such as public use or TK practices which were documented before the filing date, can be submitted as evidence.

However, in recognition of the peculiar nature of TK concerning the conservation and sustainable use of biodiversity, opposition procedures may not be based purely on documentary evidence; an opportunity to make recourse to oral trials might also be considered. By a way of illustration, opposition proceedings may be initiated against a European patent within nine months after its grant. During the opposition procedure, any of the parties, including the EPO examiners, can request oral proceedings. These provide an opportunity to discuss matters raised in proceedings and settle outstanding questions.[1]

15. Standing

Who might have a right to take legal action for non-compliance with a new PDR?

In the context of PDR-related compliance procedures, "*locus standi*" (or "standing") can be described as the right of a person, entity or identified group (such as in class actions) to:

- initiate legal action to address an alleged situation of non-compliance with a PDR or to vindicate rights that would suffer prejudice from the alleged misconduct; and/or
- be heard and provide evidence of alleged misconduct by the patent applicant in the context of such procedures.

In addition, in the case of new PDRs, the actual IP/patent authority may be acting as if it had standing, in the interest of the State, when it demands disclosure of origin or evidence of legal provenance from the applicant. In case of non-disclosure or wrongful disclosure of the required information, a petitioner opposing a patent may be required to prove that they have legal standing in the narrow sense, that is, to show a concrete stake in the patent at issue (such as being an infringer, a licensee, or a potential licensee). The immediate interest of ABS authorities, TK holders and any interested party in challenging the patent application and/or the granted patent may also be recognized.

Patent opposition procedures may be open to any natural or legal person, and not limited only to interested parties such as potential competitors or researchers in a field relating to the claimed invention. Some patent laws provide substantive grounds in which "any person" is able to oppose a proposed patent and its validity.

> **India:** Article 25 of the *Patent (Amendment) Act 2005* provides for pre-grant opposition:
>
> "Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground […] (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; [and] (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."

> **Andean Community:** Article 42 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:
>
> "Within a period of 60 days following the publication date, any person having a legitimate interest may file one reasoned opposition contesting the patentability of the invention."

> **South Africa:** Section 61(1) of the *Patents Amendment Act 2005 (Act No. 20 of 2005)* provides:
>
> "Any person may at any time apply in the prescribed manner for the revocation of a patent […]"

In countries in which IP offices rely on decisions made by biodiversity-related authorities in order to certify that ABS conditions have been fulfilled, those authorities may have specific standing to oppose the granting of patents.

> **Costa Rica:** Article 80 of the *Biodiversity Law of 1998* provides:
>
> "Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation."

> **Andean Community:** Article 75 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* provides:
>
> "The competent national authority shall decree the absolute invalidity of a patent at any time, either *ex officio* or at the request of any person, where [specified conditions are not met]."

TK holders and indigenous peoples and local communities may also have standing to initiate opposition proceedings against a patent application or a granted patent.

Box 25: African geranium (the pelargonium patent)

Dr Willmar Schwabe GmbH & Co KG (Schwabe), a German company, obtained a patent for a method of producing extracts of South African pelargonium plants at the European Patent Office (EPO) in 2007. Pelargonium plants are commonly known as "African geranium" and are used by indigenous communities throughout south-eastern South Africa to treat inflammatory diseases and infections. The patent was opposed by the African Centre for Biosafety (ACB) from South Africa, acting on behalf of a rural community in Alice, in the Eastern Cape, in collaboration with a Swiss non-governmental organization known as the Berne Declaration (now renamed Public Eye).[1] The EPO revoked the patent for lack of inventive step. TK relating to the therapeutic characteristics of pelargonium was historically known to a number of communities in south-eastern Southern Africa, crossing tribal and national boundaries. ACB did not claim exclusive ownership or rights as knowledge holders; however, they asserted that the TK concerned was known among a number of communities. This was deemed a sufficient ground to support their legal standing as indigenous knowledge holders.[2]

If there is no explicit ground for opposition under national law, the validity of a patent may not easily be challenged by TK holders and indigenous communities once it has been granted. Complex foreign legal rules (such as legal standing for opposition, the burden of proof and a strong presumption of patent validity) and the high costs of taking legal action – possibly in a foreign jurisdiction – may also prevent them from taking further action. In sum, the construction of legal standing rights determines who may have access to the remedies available to redress the harm caused by an alleged misappropriation of GRs and/or TK (as defined under national law) or an erroneously granted patent.

16. Capacity

What legal, institutional and policy capacities might be needed to implement a new PDR?

The implementation of a new PDR requires, on one hand, a plan to be drawn up in accordance with the nature of the obligation to disclose described in section 5, and, on the other, instruments and resources to carry out that plan. The instruments and resources required to implement PDRs can be grouped into four categories:

i. institutional framework
ii. examination capacity
iii. information technologies
iv. human and financial resources.

Institutional framework

The introduction of a new PDR will usually place new procedural and/or documentation obligations on the applicant, such as the obligation to provide the patent authorities with a certificate of origin, an access contract or license, or other documentation supporting the assertion that prior informed consent has been obtained and that subsequent research and development were legitimately undertaken (e.g., in accordance with established mutually agreed terms). Depending on the kind of obligation placed upon the applicant (see section 6 above on formal and substantive requirements) and the consequences of failure to comply (see section 13 above on remedies and sanctions), implementing a PDR may entail the development of significant tracking and verification mechanisms.

In addition, compliance with a requirement to meet a substantive standard may need to be substantively assessed by the granting office, potentially requiring a consultative framework for structured dialogue between competent agencies.

Box 26: Indian Institutional Framework

The National Biodiversity Authority (NBA) is the national competent authority for the decisions related to ABS including prior informed consent and prior approval for applying for IP based in GRs and TK obtained from India. All IP applications in regard to biological resources require the express permission of the NBA before the patent application is filed. NBA approval ensures that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their byproducts, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

Some have stated that PDRs may only operate well if provider countries have effective and efficient ABS regimes in place at the national level. In such cases, the practical application of a PDR may depend on the effectiveness of separate regulatory and compliance-tracking mechanisms, such as an internationally recognized certificate of compliance, including in a foreign jurisdiction. Furthermore, a lack of legal and institutional linkages and coordination with ABS authorities may limit the efficient and effective implementation of any new PDRs.

Box 27: Regional Strategy for Andean Countries

Decision 391 of 1996 established, *inter alia*, a tracking system for IP applications in Andean Countries. Decision 486 (establishing the Common Industrial Property Regime of 2000) further developed certain compliance provisions anticipated in provisional stipulations of Decision 391. In particular, according to Article 26 of Decision 486, applications to patent inventions including GRs and/or TK originating in countries of the Andean region should present the corresponding access contract or the respective license or authorization of use of GRs and/or TK. Furthermore, with Decision 523 of 2002, the Andean Countries also approved a "Regional Biodiversity Strategy for the Tropical Andean Countries." Among other biodiversity-related priorities and measures, the Strategy aims to consolidate the relevant administrative mechanisms, build scientific capacity, establish a financial support, and create an information system.[1]

The impact of a new PDR on the capacity needs and the mode of operation of patent offices could be minimal. For instance, this would be the case if a new PDR was framed as a simple transparency obligation of a procedural nature, namely, a requirement to furnish copies of any documents considered in good faith to be relevant to the claimed invention. Such a procedural or formality requirement could be implemented without the need to undertake substantive checks of the content of such documents.

Box 28: German Law on new PDRs

German law requires disclosure of place of origin of biological material relating to plants or animals that are the subject matter of a patent application (Section 34a of the German Patent Act). However, this requirement is without prejudice to the examination of patent applications and the validity of rights arising from patents. The patent applicant is required only to complement an application with information on the geographical origin of a biological resource as requested by the Law. This requirement is a mere formality that does not add any burden on the work of the patent office.

Some patent or IP offices rely on decisions made by biodiversity-related authorities in order to certify the fulfillment of ABS conditions under a disclosure requirement and to allow the granting of patents.

> **Costa Rica:** Article 80 of *Biodiversity Law of 1998* provides that:
>
> The Technical Office (TO) of CONAGEBIO […] acts as the mandatory consultative body for all application procedures involving the protection of IP rights related to biodiversity and its decisions are binding for the IP office. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.[2]

In fact, a properly designed institutional framework for exchanges and consultation between the patent office and biodiversity agencies may translate into increased support, coordination and collaboration in the application of PDRs.

Examination capacity

Many developing countries' patent offices do not have the full capacity to undertake a substantive examination of patent applications. Thus, these developing countries often opt for a simple patent registration with only formality examination of patent applications, utilization of substantive examination reports for the corresponding foreign patent application (containing the same invention) prepared by other patent offices, or join a system of regional or international co-operation, such as OAPI[3] and ARIPO[4] in Africa and EAPO[5] in Eastern Europe and Central Asia, where substantive patent examinations are conducted through a centralized mechanism.

The lack of adequate technical capacity and expertise in patent offices to effectively conduct a thorough examination of patent applications may raise critical questions about their potential ability to examine compliance with additional PDRs beyond a mere formality check. In countries with depository or registration systems, the patent office does not check patent applications to ensure that patentability criteria are met prior to the granting of patents. The validity of a granted patent, however, can be challenged before a competent court, and if the patentability criteria have not been met, the patent will be revoked.

Box 29: South African depository system

South Africa has a depository system for granting patents. The Registrar examines the patent application in the prescribed manner and if the application complies with the formality requirements of the Patent Act, a patent is granted. A key shortcoming of the depository system is that some granted patents may fail to meet the patentability criteria. Compliance with the patentability criteria is only assessed by a court if the patents are challenged in litigation. On the one hand, the lack of a substantive examination system places a burden on the public to prove that a patented invention should not have been patented in the first place.[6] On the other, the registration system leads to cost saving, since establishing and maintaining a fully operational substantive patent examination unit in a patent office requires substantial human and financial resources.

Information technologies

Information technology systems are an important component of an efficient IP administration. Efficient IT systems are crucial not only for processing applications but also for the collection of important statistical and managerial information. Information technologies may aim to facilitate transmission of disclosed information for recording, evaluation and public notice purposes without generating undue administrative burdens and costs. Many countries still do not have patent status data in digital form and national online registries. This raises concerns that the legitimate right owners, including

indigenous peoples and local communities, might not necessarily be informed about relevant patent/IP applications and might therefore be unable to initiate opposition and/or revocation proceedings even when such remedies might potentially be available.

Box 30: Information technologies in South Africa

The National Recordal System (NRS) was launched in South Africa by the Department of Science and Technology to document and digitize its rich source of the country's GRs and TK. The System provides a variety of services including GR and TK hubs to government department and agencies and international patent offices.[7] It aims to mobilize, align and empower communities and related stakeholders countrywide and enable the discovery, cataloguing, capturing, validation and utilization of the national indigenous heritage in an appropriate framework.[8]

Human and financial resources

The efficient implementation of a PDR demands not only an appropriate institutional framework that supports a country's priorities and a coordinated mechanism of improved management of intellectual property but also an adequate number of properly trained staff. Developing countries, in particular, face shortages of professional staff in their national IP administrations. The availability of technical and legal expertise in IP related to GRs and TK tends to be in short supply. Strengthening capacity-building to facilitate national and regional consultations, providing legislative and policy guidance, organizing study visits, undertaking research and offering support for awareness raising and training could all help to advance a sustainable system.[9]

Apart from the development of extensive legal and scientific expertise, implementation of PDRs involves a range of both one-time and recurrent costs. Countries, particularly developing ones, may find it difficult to maintain a balance between revenues and expenditures and generate sufficient revenues from IP fees to cover administrative costs. Likewise, it may not always be realistic to expect to recover the full costs of implementing PDRs through the fees charged to the users of the system.

17. Relationship with other instruments

Under the Nagoya Protocol, is there an obligation to provide for PDRs in order to monitor users' compliance with domestic ABS requirements?

The simple answer to the above question is no. It is possible to do so, but there is no legal obligation under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010. The Nagoya Protocol implements and further specifies the ABS obligations of the CBD and also establishes additional obligations related to users' compliance with domestic legislation or regulatory requirements on ABS (for GRs and associated TK) in countries other than the provider country.[1] It does so by creating, among other things, a globally harmonized certification mechanism for users' compliance through an ABS Clearing-House,[2] and by institutionalizing the so-called internationally recognized certificate of compliance.

What are the main implications of establishing the patent/IP office as a designated checkpoint under the Nagoya Protocol?

The Nagoya Protocol requires all contracting parties to establish one or more checkpoints. These may include, among others, IP and/or patent offices. In particular: "checkpoints 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 [GRs]. […] Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing [prior informed consent] and to the [ABS] Clearing-House, as appropriate."[9] These provisions aim to promote increased transparency about the utilization of GRs in user countries as part of their compliance measures.

Under Article 13 of the Nagoya Protocol, each Party is also required to designate a national focal point on ABS and one or more competent national authorities (CNAs), which are responsible for, among other things, granting access to GRs. Parties may designate a single entity to fulfil the functions of both focal point and CNA. However, the CNA is usually separate from a country's checkpoint or checkpoints.

While historically patent/IP offices have been seen as an almost "natural" checkpoint by developing countries,[10] the Nagoya Protocol includes neither an indicative list of checkpoints[11] nor any reference to new PDRs. Instead, it provides that checkpoints must be effective and should have functions relevant to the utilization of genetic resources or the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization. An IP/patent office may therefore be designated as a checkpoint to assist the CNA in discharging its duties. As with any other designated checkpoint, the patent/IP office will then support the identification of potential cases of non-compliance by collecting or receiving, and subsequently transmitting, relevant information to the CNA, to the country providing prior informed consent and to the ABS Clearing-House of the Nagoya Protocol.

In sum, the Nagoya Protocol leaves it up to each contracting party to decide whether it may wish to use PDRs as a mechanism to monitor the utilization of GRs (and associated TK) within its jurisdiction.[12] Thus, contracting parties may freely choose to provide for voluntary PDRs, mandatory PDRs or no PDRs at all. A country that does decide to provide for a new PDR is free to use such mechanism as a checkpoint in order to monitor users' compliance in accordance with the Nagoya Protocol – but equally could instead choose to establish other relevant checkpoints, as appropriate, to fit its national circumstances.

What is the possible relationship between a new PDR and ABS obligations under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)?

The Nagoya Protocol requires the development and implementation of ABS regulatory frameworks at the national level. However, legislative, administrative or policy measures taken in this regard need to be consistent with and mutually supportive of other international ABS instruments such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[13] In particular, the latter establishes a Multilateral System (MLS) of ABS for the most important food crops and forages, which are listed in its Annex I. The MLS includes all Annex I plant genetic resources for food and agriculture (PGRFA) which are under the management and control of contracting parties and in the public domain. In particular, it provides for their facilitated access in accordance with standard conditions of ABS under the Standard Material Transfer Agreement (SMTA),[14] and implements benefit sharing through the mechanisms of information exchange, access to and transfer of technology, capacity building and the sharing of the benefits arising from commercialization. Proposals have been made that if PDRs are applicable to PGRFA transferred under the terms and conditions of the Multilateral System, the PDRs may require the source of the PGRFA to be indicated as the Multilateral System of the ITPGRFA.

Box 31: The Nagoya Protocol, 2010

The Nagoya Protocol proposes an international framework to ensure that the benefits arising from the use of genetic resources (i.e., "the conduct of research and development on the genetic and/or biochemical composition of genetic resources") and associated traditional knowledge are shared with the countries that may legitimately provide such resources (i.e., countries of origin or other countries that have legally acquired genetic resources).[3] Such sharing of benefits shall be based on prior informed consent and mutually agreed terms. With a view to linking the three objectives of the Convention, the Protocol encourages parties to use the income generated by this mechanism to fund activities aimed at the conservation and sustainable use of biodiversity.[4] The Nagoya Protocol reaffirms that genetic resources are subject to national sovereignty[5] and offers the opportunity to recognize the rights of indigenous and local communities over their genetic resources[6] and associated traditional knowledge.[7] The Nagoya Protocol thus responds not only to the concerns of the countries of origin of genetic resources, but also to those of the user countries, in that it aims to establish a clear and transparent framework for access to genetic resources.[8] The main content of the Protocol comprises four interrelated pillars: access to genetic resources, benefit sharing, traditional knowledge and compliance.

Source: Claudio Chiarolla, "Genetic resources" in Elisa Morgera and Kati Kulovesi (eds.) Research Handbook on International Law and Natural Resources (Edward Elgar, 2016).

Box 32: Nagoya Protocol Article 17 – Monitoring the Utilization of GRs

"1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of [GRs]. Such measures shall include […] the designation of one or more checkpoints […].

"2. A permit or its equivalent […] made available to the ABS Clearing-House, shall constitute an internationally recognized certificate of compliance.

"3. An internationally recognized certificate of compliance shall serve as evidence that the [GR] which it covers has been accessed in accordance with [PIC] and that [MATs] have been established, as required by the domestic [ABS] legislation or regulatory requirements of the Party providing [PIC].

"4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

a. Issuing authority;
b. Date of issuance;
c. The provider;
d. Unique identifier of the certificate;
e. The person or entity to whom prior informed consent was granted;
f. Subject-matter or genetic resources covered by the certificate;
g. Confirmation that [MATs] were established;
h. Confirmation that [PIC] was obtained; and
i. (i) Commercial and/or non-commercial use."

In addition to the 64 crops and forages that are listed in Annex I, non-Annex I plant genetic resources for food and agriculture may also be voluntarily exchanged under the SMTA, and this is a standard institutional practice for materials held by the *ex situ* collections of the Consultative Group on International Agricultural Research (CGIAR). However, the conditions of facilitated access under the SMTA apply only if the purpose of such access is the utilization and conservation of such resources for research, breeding and training for food and agriculture; they do not apply for chemical, pharmaceutical and/or other non-food/feed industrial uses.

According to the ITPGRFA, when certain conditions are met, those who commercialize a product developed from a PGRFA obtained from the Multilateral System must pay "an equitable share of the benefits arising from the commercialization of that product" into a benefit-sharing fund.[15] The SMTA also prevents the recipients of such resources from claiming IP rights over those resources in the form in which they received them.

While neither the ITPGRFA nor the SMTA impose a patent disclosure obligation *as such* on the recipients of plant genetic resources for food and agriculture, a contractual annual reporting obligation that covers, among other things, patent-related restrictions on access to such resources has been established.

Box 33: The SMTA reporting obligations

SMTA Annex 2, Article 3 (c) states:

> "The Recipient shall submit to the Governing Body, within sixty (60) days after each calendar year ending December 31st, an annual report setting forth [...] information that allows for the identification of any restrictions that have given rise to the benefit-sharing payment."

In addition to the above reporting obligations, countries are free to choose whether or not to subject any PGRFA-related inventions to a specific disclosure requirement under patent law.

18. Other measures

Are there alternative and/or complementary measures or mechanisms that can be used to promote PDR-related objectives?

Due diligence approach

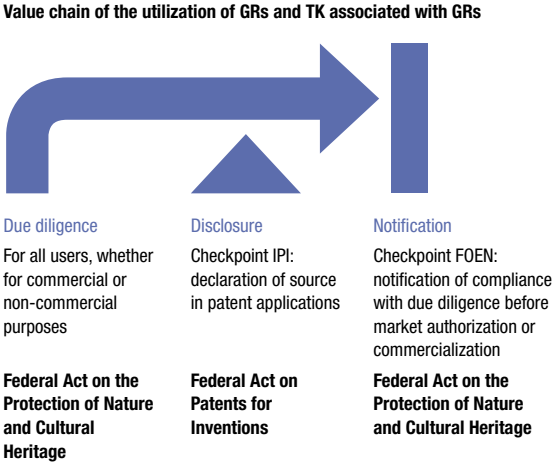
In the field of IP, due diligence refers to extensive research into and examination of the ownership, status and control of IP assets, the strength and economic value of those assets (for instance, in the context of an acquisition), and the potential liability for infringement when undertaking R&D.

Regarding the implementation of compliance-related ABS obligations, the due diligence approach was established in 2014 as the cornerstone of the EU Regulation on user compliance with ABS. The Regulation provides a broad scope for due diligence, which apply to all users of genetic resources falling within the scope of the Regulation – independent of their size or the intended use (i.e., commercial or non-commercial) – including individuals, researchers, small and medium-sized enterprises (SMEs) and multinational companies. Users must exercise due diligence to ascertain that any GRs and associated TK they utilize comply with applicable ABS rules in the provider country.

> **European Union:** *Regulation No. 511/2014 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, 16 April 2014* adopts a "due diligence" approach consisting of three elements: information gathering, risk assessment and risk mitigation:
>
> "Article 4 – Obligations of users
>
> "Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.
>
> "Users shall keep the information relevant to access and benefit-sharing for 20 years after the end of the period of utilization."

In the EU context,[1] a mere declaration that due diligence was duly undertaken (instead of actual disclosure of the source or prior informed consent and mutually agreed terms) is sufficient to fulfill user-related obligations at the compliance checkpoints established under the Regulation. In Switzerland, by contrast, due diligence obligations complement the required declaration of source in patent applications.

Figure 2: The relationship between declaration of source under the Swiss Federal Act on Patents for Inventions and the due diligence and notification requirements of the Swiss Federal Act on the Protection of Nature and Cultural Heritage (NCHA)



The Swiss Federal Institute of Intellectual Property (IPI) is a checkpoint to enhance transparency within the patent system, while the Federal Office for the Environment (FOEN) is the centralized checkpoint for implementation of the Nagoya Protocol. The due diligence requirement means 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 traditional knowledge associated with genetic resources.

Source: WIPO/GRTKF/IC/31/8, Annex, p.103.

Disclosure of the source as a contractual obligation

The legal basis for an obligation to disclose information about the source of GRs or TK could be provided by the contract or agreement establishing the terms of access, in line with Nagoya Protocol Article 17.1(b). In such cases, a disclosure-like requirement and other reporting requirements could be enforced as contractual obligations.[2] Thus, specific clauses in an ABS agreement can be utilized to support monitoring and tracking the use and commercialization of GRs and TK. For example, contracts may include a requirement to expressly disclose the existence of a benefit-sharing agreement and to indicate the source of biological materials or TK in a related patent application. A possible shortfall of contractual disclosure obligations is that they may not be relied on against third parties.[3]

Databases and information systems

The development of information tools and databases in the field of GRs and associated TK can be a valuable mechanism to address the problem of erroneously granted patents. Databases can increase the likelihood that relevant information about GRs and TK is available to patent-granting authorities for the substantive examination of patent applications, and that this information can be located and accessed during the patenting process. Databases may compile and reference a wide range of information and reference materials, including, for example, GRs, associated TK, derivatives, known uses of GRs and relevant scientific articles. Their status may be formal or informal and they may be held and compiled by States, research institutions or indigenous peoples and local communities.

Box 34: Traditional Knowledge Digital Library (TKDL), India

The TKDL is an easily accessible non-patent literature database on India's traditional knowledge as well as knowledge on plant use by practitioners of classical medical knowledge systems commonly known by and/or provided to the population of India, neighboring countries, and to the South Asian diaspora.[4] It contributes to overcoming language barriers and to bridging the gap in information about TK in major patent offices.

The TKDL contains 34 million pages of formatted information on 2,260,000 medical formulations selected from various classical texts of Indian systems of medicine, namely, Ayurveda, Unani, Yoga and Siddha.[5] It is modeled on the WIPO International Patent Classification (IPC) and designed to assist patent examiners of major IP/patent offices, including the US Patent and Trademark Office, the European Patent Office and the Japanese Patent Office, in their prior art searches. Access to the TKDL requires individual IP/Patent offices to sign a TKDL (Non-disclosure) Access Agreement. The IP/patent office may not disclose information about TKDL content to third parties unless such specific information is necessary for the purposes of the patent grant procedure.

According to the Government of India, the TKDL has been useful in challenging the grant of erroneous patents.[6] Reportedly, 1,400 pre-grant patent oppositions have been filed using the TKDL, and 222 patents have been revoked.[7] However, independent sources have been more skeptical as to how far the TKDL may really have helped in challenging erroneous patents.[8]

Key issues that need to be considered with respect to the development of such databases include, in particular:

- responsibility for compiling and maintaining the database;
- the cost of establishing, operating and updating the database;
- the structure and content of the database;
- the form in which that content would be expressed;
- its interoperability with other databases both nationally and internationally;
- the category of persons or institutions authorized to access the content of the database;
- the type and level of protection afforded to the information included in the database;
- management of rights pertaining to the database; and
- that safeguards have been put in place in order to ensure that the inclusion of TK-related information in the database is subject to free prior informed consent from the relevant knowledge holders/custodians.

Some concerns have been raised as to whether databases are appropriate mechanisms for the protection of GRs and TK.[9] For instance, some countries and indigenous representatives have questioned whether they might further facilitate the dissemination of information contained in the database, thereby potentially contributing to its misappropriation. Without proper security measures in place, the use of databases may also raise security issues regarding who can access the content and the information that is made publicly available.

Subject matter eligibility

Patent examination starts by determining whether a claim is eligible for patenting and falls into one or more categories listed under patent-eligible subject matter. The term subject matter eligibility denotes limitations on the categories of subject matter that may be considered for patent protection. This inquiry is different from and always precedes the question whether the subject matter meets the patentability criteria of novelty, industrial application and inventive step.

Article 27.1 of the TRIPS Agreement establishes minimal criteria for patentability, but leaves countries flexibility to define the threshold level for patent-eligible inventions. WTO Members have full discretion to determine what should be deemed an invention and may take advantage of TRIPS-enumerated exclusions on diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms; and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Box 35: The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

"Article 27 – Patentable Subject Matter

"Subject to the provisions of paragraphs 2 and 3 [on exclusions from patentability], patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

Box 36: Indian Patent Act, 1970

Article 3 (c) states:

"[...] The following are not inventions within the meaning of this Act: [...] the discovery of any living thing or non-living substance occurring in nature."

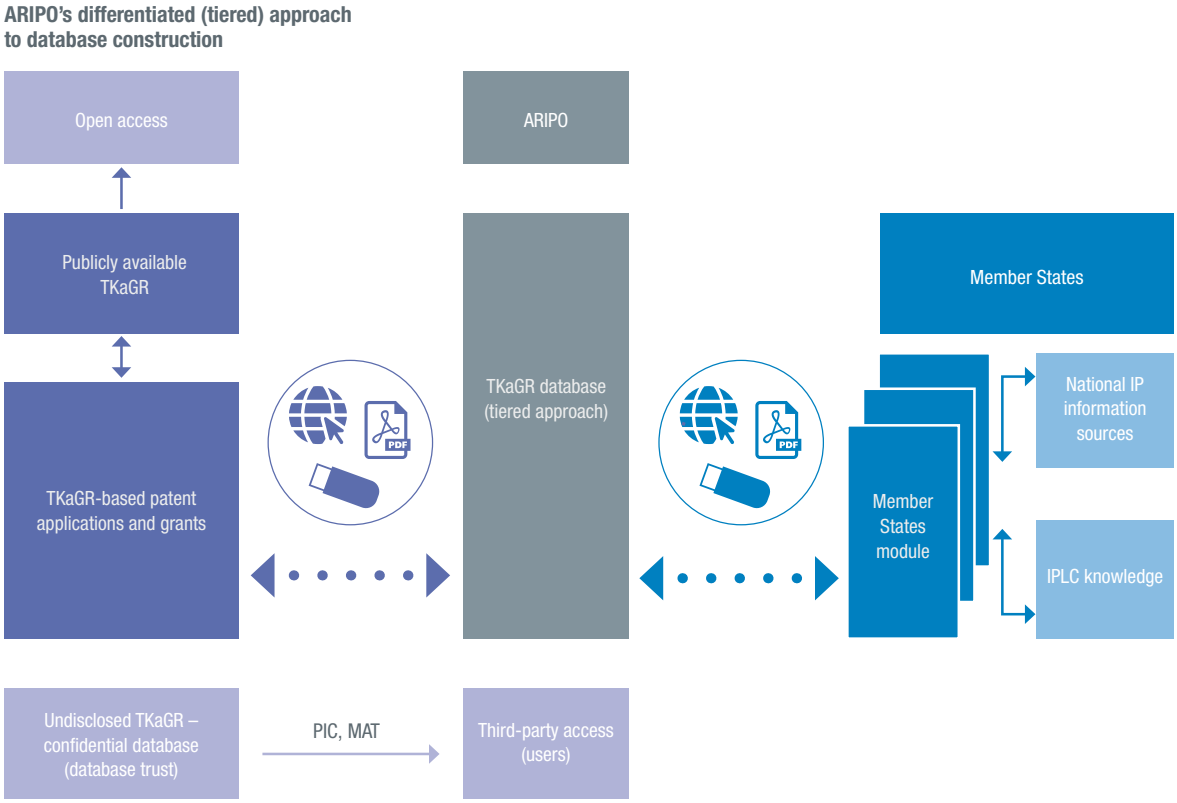
Thus, the extraction and isolation of biological materials is generally considered to be the mere discovery of a naturally occurring substance, and is not patent-eligible subject matter in India.

Some countries exclude the mere extraction or isolation of a naturally existing substance from patent-eligible subject matter. Genetic resources and (their derivatives) as found in nature or isolated therefrom may not be considered as patent-eligible subject matter and can be excluded from patent protection.

For countries rich in biodiversity, especially if they have little capacity to examine complex biotechnology patents, the provision of exclusions from patent subject matter eligibility could provide a TRIPS-compliant alternative for addressing misappropriation concerns nationally.[10]

Figure 3: African Regional Intellectual Property Organization (ARIPO) TK database

ARIPO is considering whether to develop a TK database through national authorities. A "tiered approach" has been proposed to address some concerns such as confidentiality and public domain issues.[11]



Source: Emmanuel Sackey (ARIPO), presentation delivered at the WIPO Seminar on IP and GRs on May 27, 2016, Roundtable 4: Databases and Other Defensive Measures relating to GRs and Associated TK, www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_16/wipo_iptk_ge_16_presentation_15sackey.pdf

19. Patent disclosure requirements – a checklist for policymakers

Deciding whether to create new patent disclosure requirements related to genetic resources and traditional knowledge, and, if so, how to implement them, is not straightforward. It depends on a broad range of factors, including policy goals and objectives, competing interests, legal nature of the requirements, institutional framework and capacities, among others.

As this study has explained, there are many options to consider – different forms of law in which a new PDR might be included, important differences in terms of the possible scope and content of obligations, the consequences of breaching those obligations, the mechanisms and institutions that might enforce them, and so on. Each of these options may entail different opportunities, risks and costs that will vary depending on the national context in which a disclosure requirement is implemented.

By identifying the key options in a systematic way, drawing on the experience of implementing PDRs in various countries, this study aims to enable policymakers to reach informed decisions and facilitate understanding, implementation and training on these issues at the national and regional levels, as appropriate. It is each country's prerogative to make its own decisions and address the challenges presented by the possible creation and implementation of new PDRs, if it wishes to do so, while providing a careful balance of the various interests at stake.

The following checklist may provide useful information to policymakers.

1

Assess the need, if any, for new patent disclosure requirements (PDRs) related to genetic resources and traditional knowledge. What objectives would they meet?

Consider the potential risks and opportunities of implementing different PDR options in the context of national innovation systems.

Consider any alternative or complementary tools and measures (such as other monitoring mechanisms to promote compliance with domestic legislative, administrative or policy measures on access and benefit sharing (ABS), and the creation of traditional knowledge databases).

Pay attention to the changing and diverse research and development landscape to better determine where and how connections between IP and ABS systems may occur, and drive policy changes accordingly.

2

Identify key stakeholders from different government agencies, organizations, indigenous peoples and local communities (IPLCs), the research sector and industry that deal with IP, ABS, research and development, bioprospecting, bio-trade and biodiversity issues.

Create a fair and transparent engagement process for all stakeholders to bring credible expertise, and integrate and balance various domestic priorities.

Decide which of the available patent disclosure options and flexibilities may be appropriate for your national circumstances, if any.

3

Assess the required implementation capacities and costs.

Consider how to initiate and sustain legal and institutional linkages and coordination among ABS authorities and IP/patent offices, as appropiate.

4

Develop a plan to implement any new PDR in a mutually supportive manner together with policies and practices that provide a balanced and flexible innovation governance structure, taking into account differences between uses of GRs and TK for pure or upstream non-commercial research and the development of commercial products.

Develop a plan to implement any new PDR in a mutually supportive manner together with policies and practices that provide a balanced and flexible innovation governance structure, taking into account differences between uses of GRs and TK for pure or upstream non-commercial research and the development of commercial products.

5

Implement a well-structured and efficient information technology (IT) system for processing applications and the collection of important statistical and managerial information related to new PDRs.

6

Consider whether to provide opportunities for natural or legal persons (ABS authorities, IPLCs and other relevant stakeholders) to oppose a patent application by submitting information and analysis concerning the alleged violation of a PDR to patent examiners, under an adversarial administrative process (i.e., pre-grant opposition), or if any other remedies should be available once the patent has been granted (i.e., post-grant opposition).

7

Consider how to monitor progress and ensure compliance and continuous improvement of the system in light of its set objectives.

Review implementation of new PDRs on a regular basis to determine if they are effective or if they undermine other competing goals and benefits, and make modifications as necessary.

8

Invest in capacity building and training, raising awareness among stakeholders and facilitating consultations on IP, genetic resources and traditional knowledge, as appropriate.

9

Take advantage of WIPO's capacity-building activities and resources to strengthen national capacities, organize study visits and receive legislative and policy advice, as needed.

The Traditional Knowledge Division of the WIPO Secretariat can be contacted at: grtkf@wipo.int

Endnotes

1. Introduction

1. See, for instance, Stephanie Heyl (November 27, 2014) "Bioanalysis – techniques for the characterization of biological material", https://www.analytic-news.com/papers/pdf/bioproe2.pdf

2. While the primary focus of this study is on disclosure requirements within the patent system, in several countries relevant disclosure requirements may also apply to other IP rights (see section 8). In addition, such requirements may also be introduced via biodiversity legislation (see section 7). Therefore, at some points in this study references may be made in general terms to disclosure requirements in the context of the patent and/or IP system, as well as to the patent/IP office as the competent authority, as applicable, and subject to national legislation.

3. Semi-structured informal interviews were conducted with selected Member States as a preliminary step in the research process in order to develop a better understanding of their national experiences. They provided useful insights into the implementation of patent disclosure requirements in various national settings, the challenges faced, key lessons learned and best practices. Data was collected through interviews with patent/IP office representatives in eight countries on a non-attributable basis. This allowed the interviewees to share their knowledge and experiences. The interview data provided background information on country-specific issues including legal aspects of disclosure requirements and their implementation, and also provided insights into the interpretation of data contained in the current literature.

4. The Nagoya Protocol was adopted on October 29, 2010 and entered into force on October 12, 2014. For more information, see pp.50-51.

5. This study draws on the following resources:

- The WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge, which provides detailed technical explanations regarding specific disclosure requirements and their implementation;
- The Disclosure Requirements Table (see the Annex), which presents a compilation of extracts from national and regional legislative texts that provide for specific disclosure requirements related to genetic resources and/or associated traditional knowledge;
- The Draft Examination of Issues regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in IPR Applications, contained in the Annex to Document WO/GA/32/8;
- The WIPO Database of Traditional Knowledge, Traditional Cultural Expressions & Genetic Resources Laws, which provides access to laws, treaties and regulations on the protection of the above subjects (www.wipo.int/tk/en/databases/tklaws).

The immediate context for the 2004 WIPO Technical Study referred to above was a request of the Conference of the Parties (COP) to the UN Convention on Biological Diversity at its sixth meeting in The Hague from April 7 to 19, 2002 (Decision VI/24C). The preparation of the Technical Study was based on responses to a questionnaire circulated to the Member States of WIPO. The Technical Study was made available to the seventh meeting of the COP in Kuala Lumpur, Malaysia, from February 9 to 20, 2004, as document UNEP/CBD/COP/7/INF/17. The COP noted "with appreciation the Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge prepared by [WIPO]... and consider[ed] the contents of the Technical Study to be helpful in the consideration of intellectual property-related aspects of user measures" (Decision VII/19E).

The Twenty-Ninth Session of the IGC, which took place from February 15 to 19, 2016, endorsed the ongoing progress on updating and improving the WIPO Technical Study. See the Decisions of the Twenty-Ninth Session of the IGC under Agenda Item 7 (WIPO/GRTKF/IC/29/8), p.119.

2. Background and concept

1. Robert P. Merges and Richard R. Nelson, "On the complex economics of patent scope", 90 *Colum. L. Rev.* 839, 908 (1990).

2. Andrew Pollack, "Patenting life: a special report; 'Biological products raise genetic ownership issues'", *New York Times*, November 26, 1999.

3. Gordon Gerard Birch, *Ingredients Handbook – Sweeteners*. (Ingredients Handbook Series) Leatherhead Food Research Association, Leatherhead, United Kingdom, 2000.

4. U.S. patent 5326580, Hellekant BG, Ming D, "Brazzein sweetener", issued 1994-07-05.

5. "Pentadiplandra Brazzeana", World Heritage Encyclopedia, http://worldheritage.org/Find/Pentadiplandra%20brazzeana

6. John Madeley, "Hungry for trade: how the poor pay for free trade", *Political Science*, 2000, pp.101-103.

7. House of Commons, Select Committee on Environmental Audit Appendices to the Minutes of Evidence, November 1999, www.publications.parliament.uk/pa/cm199900/cmselect/cmenvaud/45/4502.htm#evidence

8. Pádraig Carmody, *The New Scramble for Africa*, Polity Press, Cambridge, United Kingdom, 2011, p.1970.

9. Scheherazade Daneshkhu, "Health drive whets drink industry's thirst for sugar alternative", *Financial Times*, April 5, 2015.

10. Elaine Watson, "Brazzein entrepreneur seeks partner to take next-generation natural sweetener to market", *Food Navigator*, February 2014, www.foodnavigator-usa.com/Suppliers2/Brazzein-entrepreneur-seeks-partner-to-take-next-generation-natural-sweetener-to-market

11. See Nagoya Protocol Articles 6.2 and 7, and Decision CBD/NP/MOP/DEC/2/7 of 10 December 2016 on the use of the term "indigenous peoples and local communities".

12. Novelty is a fundamental requirement in any examination as to substance and is an undisputed condition of patentability. It must be emphasized, however, that novelty is not something which can be proved or established; only its absence can be proved. An invention is new if it is not anticipated by the prior art. "Prior art" is, in general, all the knowledge that existed prior to the relevant filing or priority date of a patent application, whether it existed by way of written or oral disclosure. (*WIPO Intellectual Property Handbook*, 2008).

13. In relation to the requirement of inventive step (also referred to as "non-obviousness"), the question as to whether or not the invention "would have been obvious to a person having ordinary skill in the art" is perhaps the most difficult of the standards to determine in the examination as to substance. The inclusion of a requirement like this in patent legislation is based on the premise that protection should not be given to what is already known as part of the prior art, or to anything that the person with ordinary skill could deduce as an obvious consequence thereof. (*WIPO Intellectual Property Handbook*, 2008)

14. An invention, in order to be patentable, must be of a kind which can be applied for practical purposes, not be purely theoretical. If the invention is intended to be a product or part of a product, it should be possible to make that product. And if the invention is intended to be a process or part of a process, it should be possible to carry that process out or "use" it (the general term) in practice. (*WIPO Intellectual Property Handbook*, 2008).

15. On conventional disclosure under patent law, see *WIPO Technical Study*, p.2.

16. That being so, there is a clear need to raise awareness of, and promote respect for, applicable legal requirements, including customary laws, regarding the use of GRs and associated TK. This need is accentuated when R&D occurs in the context of transnational research projects or larger consortia, where researcher partners in other jurisdictions could also access research materials and results, and could take important decisions regarding the protection of the resulting IP. It is therefore important to consult national IP and other applicable laws in respect of disclosure of GRs and TK, benefit-sharing and prior informed consent from relevant TK/GR owners and holders. Universities should undertake sound due diligence in relation to the initial collection, use and possible transfer of GRs and associated TK. Due diligence also helps universities ensure future investment in the development of their IP assets. Although non-compliance with ABS-related due diligence may not necessarily impair fundamental research in the labs, it can certainly become an obstacle when universities attempt to commercialize their research assets (through licensing or otherwise). This is because compliance check-points under the Nagoya Protocol may target the final products, when they are placed on the market. It is therefore of great importance for universities to be able to show to commercial partners that they have actually undertaken upstream due diligence. See IP Policies for Universities and Research Institutions, www.wipo.int/policy/en/university_ip_policies

17. See, for instance, Article 49a(2) of the revised *Swiss Patent Act*. Introduit par le ch. I de la LF du 22 juin 2007, en vigueur depuis le 1er juil. 2008 (RO 2008 2551; FF 2006 1). « Si la source n'est connue ni de l'inventeur ni du requérant, ce dernier doit le confirmer par écrit. » https://www.ipi.ch/en/legal-info/legal-areas/intellectual-property-and-sustainable-development/disclosure-of-source.html

For countries which have adopted similar provisions, an additional PDR need not create an undue burden on the applicant.

18. See section 16 on capacity.

19. See the Disclosure Requirements Table annexed to this study.

20. See also section 4 on complementary and competing interests and objectives.

21. Queen Mary Intellectual Property Research Institute, *Report on Disclosure of Origin in Patent Applications*, European Commision, 2004 (hereinafter QMUL report), p.21, http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc_123533.pdf

3. Objectives

1. Shakeel Bhatti, Tomme Young, Santiago Carrizosa, and Patrick McGuire, *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts,* 2009, p.12.

2. "Megadiverse countries" is a term used to refer to the world's top biodiversity-rich countries. See www.biodiversitya-z.org/content/megadiverse-countries

3. See for example, WTO, "The TRIPS Agreement and Convention on Biological Diversity", IP/C/W/368/Rev.1, revised 8 February 2006, pp.28-31.

4. Indian patent law did not permit product patents at that point. India started to grant patents for pharmaceutical products in 2005. *The Patents (Amendment) Act, 2005 No. 15 of 2005*, http://www.wipo.int/wipolex/en/text.jsp?file_id=128116

5. 2319/DEL/2008, Application Awaiting Examination.

6. *The Patents (Amendment) Act, 2002,* ACT NO. 38 OF 2002 [25th June, 2002.], S 10(4)(d)(ii).

7. 2391/DEL/2008.

8. WIPO, "Using traditional knowledge to revive the body and a community", IP Advantage Case Study, http://www.wipo.int/ipadvantage/en/details.jsp?id=2599

9. The concept of laying open for public inspection is the source of the Latin verb "patere" from which the English word "patent" is derived.

10. See, for instance, WIPO Patent Register Portal, www.wipo.int/branddb/portal/portal.jsp

11. The Nagoya Protocol is a supplementary agreement to the CBD. It sets out the rules and mechanisms for ABS and provides a legal framework for the effective implementation of the fair and equitable sharing of benefits arising out of the utilization of GRs. See Box 31.

12. Jorge Cabrera Medaglia, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol,* 2014, CISDL Biodiversity & Biosafety Law Research Program, p.46, http://www.absfocalpoint.nl/upload_mm/5/f/4/008c-9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf

13. Several access permits have been issued under Decree 25. Jorge Cabrera Medaglia, *The Disclosure of Origin Requirement in Central America,* (ICTSD Programme on Natural Resources, International Trade and Sustainable Development, Issue Paper No.3.), International Centre for Trade and Sustainable Development, 2010, Geneva, Switzerland, p.12.

14. Medaglia, *supra* note 12, p.47.

15. However, there is usually a race to file patents since all patent offices now follow a first-to-file system. PIC and MAT requirements combined with PDRs could delay patent applications. Patent applicants would weigh the risk of incurring sanctions for the violation of a PDR requirement against the risk of losing the right to the patent altogether.

4. Complementary and competing interests and objectives

1. The "defensive" protection of GRs/TK reduces the chance that patents are granted that incorrectly and/or illegally claim inventions using GRs/TK.

2. See section 18, p.54 on databases and information systems.

3. Manisha Desai, Eli Lilly and Company, USA, "Roundtable 2: Policy Objectives relating to Intellectual Property and Genetic Resources", Seminar on Intellectual Property and Genetic Resources, May 26-27, 2016, WIPO/IPTK/GE/16/INF/1, http://www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_16/wipo_iptk_ge_16_presentation_7desai.pdf

4. See statements from Japan, the Republic of Korea and the United States of America, WIPO/GRTKF/IC/29/8, p. 11, 54, 94. For instance, it has been argued that "if an applicant is required to perform due diligence and provide information on source of origin of a GR to a patent office, that would take some time and it would also take some legal expense". Dominic Keating, Director of IP Attaché Program from the United States Patent and Trademark Office, "Roundtable 2: Policy Objectives relating to Intellectual Property and Genetic Resources", Seminar on Intellectual Property and Genetic Resources, May 26-27, 2016, WIPO/IPTK/GE/16. Keating also refers to a study which found that, in general, "delays in the patent examination process significantly reduce firm growth, job creation, and innovation, even when a firm's patent application is eventually approved". See Joan Farre-Mensa, Deepak Hegde and Alexander Ljungqvist, "The Bright Side of Patents," Harvard Business School Working Paper No. 16-071, December 2015. See also section 16 on capacity.

5. An "unreasonable delay" is usually defined as more than five years from the date of filing or three years after an examination request in U.S. free trade agreements.

6. See Term Extensions or Adjustments for Delays Within the USPTO Under 35 U.S.C. 154 [R-07.2015] https://www.uspto.gov/web/offices/pac/mpep/s2710.html

7. Section 53 *bis*1, *Law No. 19.039 on Industrial Property* (Consolidated Text of January 26, 2007, approved by Decree-Law No. 3).

8. Section 36A, *Singapore Patents Act* (Revised Edition 2005, as amended up to the Statutes (Miscellaneous Amendments) Act 2014).

9. Article 89, *Republic of Korea Patent Act* (Act No. 950 of December 31, 1961, as amended up to Act No. 6411 of February 3, 2001).

10. Edson Beas Rodrigues Jr., "Property rights, biocultural resources and two tragedies: some lessons from Brazil" in Tania Bubela and E. Richard Gold (eds.), *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests,* 2012, pp.149-150

11. For more information, see Nagoya Protocol Articles 8(a) and 6.3(iii), and ABS-Management Tool. Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities, Swiss State Secretariat for Economic Affairs (SECO), 2012, p. I-30, 31, www.sib.admin.ch/fileadmin/chm-dateien/ABS-Protokoll/ABS_MT/Updated_ABS_Management_Tool_May_2012.pdf

12. R. Barbieri, J. Gomes, A. Alercia and S. Padulosi, "Agricultural biodiversity in Southern Brazil: integrating efforts for conservation and use of neglected and underutilized species", *Sustainability* 2014, 6, pp.741-757.

13. See John Vogler and Alan M. Russell, *The International Politics of Biotechnology: Investigating Global Futures,* Manchester University Press, 2000, p.91.

14. *Brazilian Provisional Act 2.816-16/2001,* Art. 31.

15. See id. and The Biotechnology Industry Organization (BIO), *Proposal for Reform of Brazil's Bioprospecting and Genetic Resources Regulations* (18 November 2013), https://www.bio.org/sites/default/files/BIO%20Brazil%20Bioprospecting%20&%20Genetic%20Resources%20FINAL.pdf

16. Luiz Antonio Barreto de Castro, "The future of sustainable use biodiversity in Brazil", Bioentrepreneur – Trade Secrets, 24 March 2015.

17. According to the Minister of Science, Technology and Innovation, Mr. Aldo Rebelo, Brazil "had a protectionist legislation which was criminalizing research. It was holding back scientific research and development based on biodiversity, as well as private investment in research". Mr. Rebelo added that "the new legislation protects the environment, research, traditional knowledge, and innovation in industry, thus encouraging the creation of new jobs, income and tax revenues". "Brazilian President signs new biodiversity law", www.moellerip.com/brazilian-president-signs-new-biodiversity-law/

18. See Daniel R. Pinto, "Roundtable 3: Disclosure Requirements relating to GRs and Associated TK", Seminar on Intellectual Property and Genetic Resources, May 26-27, 2016, WIPO/IPTK/GE/16 and WIPO/GRTKF/IC/30/10 PROV. 2, pp.18-23.

19. Edson Beas Rodrigues Jr., *supra* note 10, pp.118-119.

5. Legal nature

1. See also section 7 on placement.

2. WIPO, Document SCP/5/6, para 34.

3. However, a knowingly false, fraudulent or deceptive disclosure might, in principle, be sanctioned outside the patent system.

4. *German Federal Law Gazette* of 1981, p.1.

5. *German Federal Law Gazette* of 2013, p.3830.

6. As regards the consequences of non-compliance with these provisions, see section 13 on remedies and sanctions.

7. Article 10(4) of the *Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005,* provides:

"Every complete specification shall (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection."

8. The Nagoya Protocol and its Internationally Recognized Certificate of Compliance may be one way to overcome this burden (see in particular, Article 17. 2, 3 and 4) and see Box 32.

6. Formative and substantive requirements

1. See also section 13 on remedies and sanctions.

2. For more information about formal or substantive requirements, see *WIPO Technical Study* (2004), pp.16, 32, 47-49.

3. *Ibid.*

4. See also section 16 on capacity.

7. Placement

1. See also section 8 on the subject matter of disclosure – patent rights versus other IP rights.

2. *Federal Law Nº 13.123/2015* New Legal Framework concerning Brazilian Biodiversity, www.mattosfilho.com.br/EscritorioMidia/memoamb190615en.pdf

3. *Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages:* https://www.legifrance.gouv.fr/eli/loi/2016/8/8/2016-1087/jo/texte

4. For more information, see section 13 on remedies and sanctions to address situations of non-compliance.

5. For more information, see section 12 on triggers.

8. Subject matter

1. See Article 2 of the CBD and the Nagoya Protocol, as well as the definitions in document WIPO/GRTKF/IC/34/4, Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (as at the close of IGC 30 on June 3, 2016).

2. Lyle Glowka et al. (eds.), *A Guide to the Convention on Biological Diversity,* Environmental Policy and Law Paper no. 30 (Gland; Cambridge: IUCN the World Conservation Union, 1994), p.21-22.

3. See pp.29-30 and Claudio Chiarolla, "Genetic resources" in Elisa Morgera and Kati Kulovesi (eds.) *Research Handbook on International Law and Natural Resources* (Edward Elgar, 2016).

4. WIPO Glossary, www.wipo.int/tk/en/resources/glossary.html#49

5. Article 16(D)(ii) of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (2002).

6. CBD Article 2.

7. The IUCN Explanatory Guide to the Nagoya Protocol (2012) explains that "[…] the biochemical components of genetic resources […] are the non-modified chemical components, other than DNA or RNA, formed by the organisms' metabolic processes that exist in samples of biological materials (that is, active biological components found in collected material) and that have yet to be modified and used in technological applications." Available at: https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf, p.67.

8. *Ibid.,* p.26.

9. *Ibid.* However, Parties that decide to require prior informed consent (PIC) for access to their genetic resources will need to regulate expressly research and development on both the genetic material and any naturally occurring biochemical compounds contained in material acquired under their domestic ABS framework.

10. *Ibid.,* p.65.

11. *Ibid.*, p.67.

12. Under the Nagoya Protocol, Penicillin, the original antibiotic, is a "derivative" of the fungal species Penicilium notatum in that it is formed by that particular organism. On the other hand, a wide range of products that might be considered as derived from a GR in a general sense would not qualify as "derivatives" in accordance with the legal definition provided in the Nagoya Protocol. A good example is "Captopril", the first of the ACE inhibitor class of drugs, whose discovery was inspired by the observed physiological effect of venom of the Brazilian viper Bothrops jararaca. Captopril is an orally active synthetic chemical and mimics the effect of the venom's active compound, but not its chemistry. In the context of patent disclosure, applying disclosure requirements not just to claimed inventions comprising unmodified biochemical compounds, but also to other substances resulting directly from their utilization would appear to go beyond what might be enabled by the provisions of the Nagoya Protocol. For example, an attempt to capture biochemical products as different as Captopril and the other members of the ACE inhibitor class of cardiovascular treatments derived from snake venom is likely to be controversial.

13. Claudio Chiarolla, "The role of private international law under the Nagoya Protocol", in E. Morgera, M. Buck and E. Tsioumani (eds.), *The Nagoya Protocol in Perspective: Implications for International Law and Implementation Challenges* (Brill/Martinus Nijhoff, 2013).

14. See further section 18, p.53 on other remedies – disclosure of the source as a contractual obligation and *WIPO Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements* (forthcoming in 2017).

9. Content

1. As regards, for example, marine genetic resources from areas beyond national jurisdiction, see: Claudio Chiarolla, "The work of WIPO and its possible relevance for global ocean governance", in *IMO-IMLI Comprehensive Study on Effective and Sustainable Global Ocean Governance* (forthcoming in 2017) and Claudio Chiarolla, "Intellectual property rights and benefit sharing: the emerging case of marine genetic resources in areas beyond national jurisdiction", *Queen Mary Journal of Intellectual Property* 3 (2014). See also section 11 on exclusions.

2. As regards the concept of direct source, see section 2, p.12.

11. Exclusions

1. See CBD COP 2 Decision II/11, paragraph 1(a), Access To Genetic Resources, available at: https://www.cbd.int/decision/cop/?id=7084

2. For more details, see Box 27.

3. See "Bioethics and patent law: the cases of Moore and the Hagahai People", in *WIPO Magazine* (September 2006), www.wipo.int/wipo_magazine/en/2006/05/article_0008.html

4. For a review of legal and policy developments pertaining to the issue of gene patents in this field see, "Myriad gene patent litigation", in *Genomics Law Report*, https://www.genomicslawreport.com/index.php/category/badges/myriad-gene-patent-litigation/

5. This may be considered as TK that is so widely dispersed and "unmoored" from any particular origin that no legitimate benefit claimants could be identified.

6. See, for example, WIPO/GRTKF/IC/34/4, Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources, Article 4, ALT 4.1.

7. *Ibid.*, (ALT) Article 4.1(f).

8. *Ibid.*, Article 4.

12. Triggers

1. See Figure 1 on derivatives.

2. See the *Vienna Convention on the Law of Treaties*, signed in Vienna on May 23, 1969, and which entered into force on January 27, 1980.

3 Definition of research in English, www.oxforddictionaries.com/us/definition/american_english/research

4. Apart from upstream R&D activities, there are also downstream activities of value that may be patented but fall outside patents on biochemical products *per se*. The "development" part of R&D includes the industrial production system and production methods which are often the subject of patents (e.g., recombinant DNA and metabolic engineering methods such as those used for engineering yeast cells to produce plant metabolites). These patented processes may in fact be extremely valuable. This begs the important question whether a trigger should limit the application of a new PDR to patents having product claims only or whether it might also be extended to "secondary patenting" including process patents.

5. However, the use of such a trigger in respect of the utilization of TK would have to be carefully tested, since what would constitute "utilization of TK" is not defined by the Nagoya Protocol.

6. For example, a new plant variety obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. See UPOV (August 31, 2009) "Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention", www.upov.int/edocs/mdocs/upov/en/c/43/upov_exn_edv_draft_3.pdf

7. Paul Oldham (2004), "Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology", UNEP/CBD/WG-ABS/3/INF/4, p. 5. Oldham also emphasizes that "the nature of genetic homologies between organisms signifies that [IP] claims in relation to the biological or genetic components of one organism may permit [IP] claims in relation to the biological or genetic components of other organisms [...]".

8. WTO, "The TRIPS Agreement and Convention on Biological Diversity", IP/C/W/368/Rev.1, revised 8 February 2006, p. 32.

13. Remedies and sanctions

1. Article 170-*bis*, paragraphs 2, 3 and 4, of *Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Legislative Decree No. 131 of August 13, 2010)* provide:

> "2. The observations from third parties and the observations which result from the examination of the application for new plant varieties are communicated to the interested party granting a term for response not longer than six months. In the event that an observation refers to the denomination, the new proposal is to be accompanied by a supplemental declaration also including the declaration indicated in letter e) of paragraph 1 of Article 165. The Office and the Ministry of Agricultural and Forestry Policies communicate to each other their comments and the observations transmitted to the applicant and the responses received.
>
> "3. When due to irregularities in the appointment of the attorney, as per Article 201, the failure to comply with the observations determines the rejection of the application and the related requests, the observations must be communicated to the applicant.
>
> "4. When the term has elapsed without receiving a response to the observations, the application or request is rejected by a decision to be notified to the owner of the application or the request, by a registered mail letter, return receipt requested. However, if the observation concerns the claim of a right of priority, failure to respond determines only the loss of that right."

2. Article 59, paragraph 2, of *Federal Act of June 25, 1954* states: "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."

3. Such evidence may include, for example, written materials about existing inventions that may preempt the requested patent (see further section 14 on evidence).

4. See Daniel F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan, 2010) p.119. See also section 18, pp.54-55 on subject matter eligibility.

5. *Loi n° 2016-1087 du 8 août 2016.* See also Box 13 above.

6. Article 4(3) of *EU Regulation 511/2014* states:

"[...] users shall seek, keep and transfer to subsequent users: (a) the internationally recognised certificate of compliance, as well as information on applicable benefit-sharing obligations; or (b) where no [such] certificate is available, information and relevant documents on: i) the date and place of access of [GRs] or of traditional knowledge associated with [GRs]; ii) the description of the [GRs] or of [associated TK]; iii) the source from which [GRs] or [associated TK] were directly obtained as well as subsequent users of [GRs] or [associated TK]; iv) the presence or absence of rights and obligations related to [ABS] including rights and obligations regarding subsequent applications and commercialization; v) access permits, where applicable; vi) [MATs], including benefit sharing agreements, where applicable."

7. Art. L. 412-18. II 2°, *Loi n° 2016-1087 du 8 août 2016,* unofficial translation based on Claudio Chiarolla, "Commentary on the ABS provisions of the draft Biodiversity Law of France" in B. Coolsaet et al. (eds), *Implementing The Nagoya Protocol – Comparing Access and Benefit-Sharing Regimes in Europe* (Brill/Martinus Nijhoff, 2015), pp.97-98.

14. Evidence

1. Article 116, Oral Proceedings, *The European Patent Convention,* Amended on October 27, 2005, entered into effect on December 13, 2007.

15. Standing

1. The Pelargonium Patent Challenges, available at: https://www.publiceye.ch/fileadmin/files/documents/Biodiversitaet/080505_Factsheet_Pelargoniumpatente_final_en.pdf

2. Pelargonium Patent Challenge against Dr. Willmar Schwabe, African Centre for Biodiversity, available at: http://acbio.org.za/pelargonium-patent-challenge-against-dr-willmar-schwabe/

16. Capacity

1. Regional Biodiversity Strategy for the Tropical Andean Countries, Decision 523, Andean Community, intranet.comunidadandina.org/Documentos/decisiones/DEC523.doc

2. See also Box 12.

3. See the African Intellectual Property Organization, www.wipo.int/edocs/mdocs/aspac/en/wipo_tm_tyo_12/wipo_tm_tyo_12_z_oapi.pdf

4. African Regional Patent Systems and the PCT: Brief Overview of the ARIPO Patent System, http://www.wipo.int/edocs/mdocs/pct/en/wipo_pct_nbo_09/wipo_pct_nbo_09_www_121074.pdf

5. See the Eurasian Patent Organization, with the Eurasian Patent Office (EAPO) acting as its executive body, www.eapo.org/en/

6. See Committee on Development and Intellectual Property (CDIP), Eighth Session Geneva, November 14-18, 2011, Study on Patents and the Public Domain, CDIP/8/INF/3 REV. 2.

7. Introduction IKSCD Project, www.ufh.ac.za/centres-and-institutes/emthonjeni/sites/default/files/INTRODUCTION%20IKSDC%20PROJECT.pdf

8. "The National Recordal System", presentation by Yonah Seleti, www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_2_15/wipo_iptk_ge_2_15_presentation_yonah_seleti.pdf

9. See *Inspiring Innovation and Sustaining Traditional Knowledge – WIPO's Capacity-building Program,* Traditional Knowledge Division WIPO, June 25, 2015, www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_2_15/wipo_iptk_ge_2_15_presentation_tk_side_event.pdf

17. Relationship with other instruments

1. See also section 3, pp.15-16 on objectives – complementarity and mutual supportiveness with international agreements.

2. Nagoya Protocol, Article 14, https://absch.cbd.int/

3. Nagoya Protocol, Article 5.1.

4. Nagoya Protocol, Article 9.

5. Nagoya Protocol, Article 6.1.

6. Nagoya Protocol, Article 6.2.

7. Nagoya Protocol, Article 7.

8. Nagoya Protocol, Article 6.3.

9. Nagoya Protocol, Article 17.

10. In fact, in the period that preceded the coming into effect of the Nagoya Protocol, patent/IP offices became the first "checkpoints" ever established – at least in some in some countries – to monitor compliance with ABS obligations under the CBD.

11. Ultimately, the Nagoya Protocol did not include any provisions on PDRs, since there was disagreement on whether an indicative list of checkpoints should be referenced in the text.

12. UNCTAD, *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property,* (United Nations Conference on Trade and Development, 2014), p.56.

13. C. Chiarolla, S. Louafi and M. Schloen, "Genetic resources for food and agriculture and farmers' rights: an analysis of the relationship between the Nagoya Protocol and related instruments", in *The Nagoya Protocol in Perspective* (2013).

14. Claudio Chiarolla, "Plant patenting, benefit sharing and the law applicable to the FAO Standard Material Transfer Agreement", JWIP (2008) Vol.11 (1), pp.1-28.

15. ITPGRFA Article 13.2(d)(ii).

18. Other measures

1. It has been highlighted that "due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation. […] As such it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts. […] If a user […] takes reasonable measures in the seeking, keeping, transferring and analyzing of information, the user will be compliant with the due diligence obligation under the EU ABS Regulation." Swedish Environmental Protection Agency (2016), "Guidance on the EU ABS Regulation implementing the Nagoya Protocol", https://www.naturvardsverket.se/upload/stod-i-miljoarbetet/vagledning/genetiskaresurser/scope-guidance-march2016.pdf

2. For example, see Box 9 above.

3. For example, in the case of insolvency of a first user of GRs/TK with whom mutually agreed terms were initially concluded, it would be impossible to enforce any obligations in those terms against a third-party creditor who has acquired the remaining assets (e.g., background and foreground IP, research tools and materials). See also *WIPO Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements* (forthcoming in 2017).

4. Historically, the origins of these "traditions" are to some extent mixed with roots in the Indian subcontinent, Persia, Muslim Arabia and Ancient Greece.

5. "Protecting India's traditional knowledge", *WIPO Magazine,* June 2011, www.wipo.int/wipo_magazine/en/2011/03/article_0002.html

6. Biswajit Dhar, "Relevance of databases for protecting traditional knowledge: evidence from India", Seminar on Intellectual Property and Genetic Resources, WIPO, Geneva, May 26-27, 2016.

7. *Ibid.*

8. David Pearce "India's claims to Traditional Knowledge washed up and spat out", July 21, 2015, http://ipkitten.blogspot.ch/2015/07/indias-claims-to-traditional-knowledge.html; David Pearce, "An analysis of TKDL at the EPO", July 25, 2015, http://tuftythecat.blogspot.ch/2015/07/an-analysis-of-tkdl-at-epo.html; and Darren Smyth, "No traditional knowledge for hair loss treatment: another alleged attempt to patent traditional knowledge does not bear scrutiny", August 3, 2015, http://ipkitten.blogspot.ch/2015/08/no-traditional-knowledge-for-hair-loss.html

9. *WIPO Toolkit on Traditional Knowledge Documentation* (forthcoming in 2017). An earlier version of the *Draft WIPO Toolkit* (2012) is available at: http://www.wipo.int/tk/en/resources/tkdocumentation.html. See also D.F. Robinson and C. Chiarolla, "The role of databases, contracts and codes of conduct", in D. Robinson, P. Roffe and A. Abdel-Latif (eds.), *Protecting Traditional Knowledge: The Intergovernmental Committee on Intellectual Property and Genetic Resources,* Traditional Knowledge and Folklore. Routledge/Earthscan Press (forthcoming).

10. At the time of writing, this option is addressed in IGC draft article 3.5, which states:

"[Genetic resources and [their derivatives] as found in nature or isolated therefrom shall/should not be considered as [inventions] [IP] and therefore no [IP] [patent] rights shall/should be granted.]]"

See WIPO/GRTKF/IC/34/4, Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (as at the close of IGC 30 on June 3, 2016). Further updates and revisions of the Consolidated Document will be published on WIPO's website as they become available. For regular updates, visit our website and sign up to our newsletter: www.wipo.int/tk

11. In general, a tiered approach to the scope of TK protection is an approach "[…] whereby different kinds or levels of rights or measures would be available to rights holders depending on the nature and characteristics of the subject matter, the level of control retained by the beneficiaries and its degree of diffusion. The tiered approach proposes differentiated protection along a spectrum from TK that is available to the general public to TK that is secret/not known outside the community and controlled by the beneficiaries." See Ian Goss (2016), WIPO/GRTKF/IC/32/REF/INFORMATION NOTE.

Annex: Disclosure requirements table

This table comprises a non-exhaustive selection of extracts from existing national and legislative texts which, in one way or another, provide for a specific disclosure requirement related to genetic resources and/or traditional knowledge. The extracts are taken directly from the legislative texts as contained in WIPO's global database of laws, WIPO Lex. The table contains no interpretation or commentary, and the extracts appear in the languages in which the laws appear in WIPO Lex. In order to facilitate reading and comprehension of the table, some relevant parts of extracts may appear in bold; this highlighting does not appear in the original legislative texts.

All information provided is for information purposes only, and is *not* a substitute for legal advice. The WIPO Secretariat makes every effort to ensure, but cannot guarantee, the accuracy of the data contained in this selection. In particular, WIPO assumes no responsibility for any discrepancy that may occur in the electronic manipulation of the said data. The WIPO Secretariat will continue to add to and update the table over time. Additional contributions to the table, and any corrections and comments, would be appreciated and may be sent to: grtkf@wipo.int.

The current version of the Disclosure Requirements Table was updated May 2017. Further updates will be made available on the WIPO website: www.wipo.int.

Country/region	Title	Subject matter
Andean Community	Decision No. 486 Establishing the Common Industrial Property Regime (2000) (www.wipo.int/wipolex/en/details.jsp?id=9451)	**Article 26** 1. genetic resources or products derived therefrom 2. traditional knowledge of the indigenous Afro-American or local communities of member countries

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 26. The application for a patent shall be filed with the competent national office and shall contain the following: […] (h) where applicable, a copy of the access contract **where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin**; (i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries **where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force**.	**Article 26.** The application for a patent shall be filed with the competent national office and shall contain the following: […] (h) where applicable, a copy of the **access contract** where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin; (i) where applicable, a copy of **the document accrediting the licensing or the authorization of the use of the traditional knowledge** of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force.	**Article 42.** Within a period of 60 days following the publication date, **any person having a legitimate interest may file one reasoned opposition contesting the patentability of the invention**. **Article 39.** If it emerges from the examination as to form that the application does not meet the conditions specified in Articles 26 and 27, **the competent national office shall inform the applicant accordingly, so that he may meet those conditions within a period of two months following the date of notification. That period may be extended once by an equal amount at a request of a party without any loss of priority.** If, on the expiry of the period specified, the applicant has not met the conditions mentioned, **the application shall be considered abandoned and its priority shall be lost**. The competent national office shall nevertheless respect the confidentiality of the application. **Article 75. The competent national authority shall decree the absolute invalidity of a patent at any time, either *ex officio* or at the request of any person**, where: […] (g) where applicable, a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin; (h) where applicable, a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the member countries is the country of origin.

Country/region	Title	Subject matter
Belgium	Loi du 28 avril 2005 modifiant la loi du 28 mars 1984 sur les brevets d'invention, en particulier la brevetabilité des inventions biotechnologiques (Law of April 28, 2005 modifying the Law of March 28, 1984 on Patents, in particular the Patentability of Biotechnological Inventions) (www.wipo.int/wipolex/en/details.jsp?id=6114)	Article 15 § 1er […] La matière biologique d'origine végétale ou animale
Brazil	Law No. 13.123 of May 20, 2015 Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge (http://www.wipo.int/wipolex/en/text.jsp?file_id=376795)	
China	Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China) (www.wipo.int/wipolex/en/details.jsp?id=5484)	**Article 26** **Genetic resources**
	Rules for the Implementation of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China) (www.wipo.int/wipolex/en/details.jsp?id=6504)	**Rule 26** The genetic resources referred to in the Patent Law mean **any material taken from human, animal, plant or microorganism containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creations of which the accomplishment uses the genetic function of genetic resources.**
Costa Rica	Law No. 7788 on Biodiversity (as last amended by Law No. 8686 of November 21, 2008) (www.wipo.int/wipolex/en/details.jsp?id=11314)	**ARTÍCULO 80.** Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren **elementos de la biodiversidad**. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo.

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 15 § 1er La demande de brevet doit contenir : (6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale **à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.**	**Article 15 § 1er** La demande de brevet doit contenir : (6) **une mention de l'origine géographique de la matière biologique d'origine végétale ou animale** à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.	
	Article 47 A **concessão de direito de propriedade intelectual** pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado fica condicionada ao cadastramento ou autorização, nos termos desta Lei.	**Article 47** A concessão de direito de propriedade intelectual pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado fica condicionada **ao cadastramento ou autorização, nos termos desta Lei.**	
	Article 26. With regard to **an invention-creation accomplished by relying on genetic resources**, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.	**Article 26**. With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, **indicate the direct and original source of the genetic resources**.	**Article 5.** Patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations. **Article 26**. If the applicant cannot indicate the original source, he shall state the reasons.
			Rule 53 […] an application for a patent for invention shall **be rejected** by the Patent Administration Department under the State Council after examination, […] where the application does not comply with the provisions of Article 26 […] of the Patent Law.
	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de **otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad**. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.	**ARTÍCULO 80.** Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre **aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo**. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.	**ARTÍCULO 80.** Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. **La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.**

Country/region	Title	Subject matter
Cuba	Decree-Law No. 290 of November 20, 2011 on Inventions and Industrial Designs and Models (www.wipo.int/wipolex/en/details.jsp?id=12026)	**ARTÍCULO 26.1.** material biológico
	Decree-Law No. 291 of November 20, 2011 on the Protection of Plant Varieties (www.wipo.int/wipolex/en/details.jsp?id=12027)	**ARTÍCULO 31.1.** Para solicitar un derecho de obtentor, el solicitante presenta ante la Oficina la correspondiente solicitud, integrada por los documentos siguientes: […] e) el documento que indique el país de origen y fuente del **material vegetal inicial y conocimientos y prácticas tradicionales asociados**, así como las referidas indicaciones sobre la variedad vegetal en cuestión; este requisito se extiende a los híbridos; […]
Denmark	Order No. 25 of January 18, 2013, on Patents and Supplementary Protection Certificates (www.wipo.int/edocs/lexdocs/laws/en/dk/dk191en.pdf)	**Part I Chapter 2** **3(5) biological material**

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	ARTÍCULO 26.1. Para obtener una patente, el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes: […] j) copia de la previa y expresa autorización para el acceso a material biológico, expedida por la autoridad competente de conformidad con la legislación vigente en la materia, **cuando la invención se refiere a dicho material, incluido el genético y sus partes o derivados del que Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país;** k) declaración que exprese que el material biológico al que se refiere la invención no ha sido obtenido en el territorio de la República de Cuba, **en cuyo caso debe indicarse el país de origen y fuente del material biológico y de los conocimientos tradicionales asociados a estos y el consentimiento fundamentado previo al acceso;** […]	**ARTÍCULO 26.1.** Para obtener una patente, el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes: […] j) **copia de la previa y expresa autorización para el acceso a material biológico, expedida por la autoridad competente de conformidad con la legislación vigente en la materia**, cuando la invención se refiere a dicho material, incluido el genético y sus partes o derivados del que Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país; k) **declaración que exprese que el material biológico al que se refiere la invención no ha sido obtenido en el territorio de la República de Cuba**, en cuyo caso debe indicarse el país de origen y fuente del material biológico y de los conocimientos tradicionales asociados a estos y el consentimiento fundamentado previo al acceso; […]	**ARTICULO 28.2** Los documentos a que se refieren los incisos f), j) y k), del apartado 26.1 del artículo 26, deben presentarse en el término de dieciséis meses, contado a partir de la fecha de presentación de la solicitud o, en su caso, de la fecha de prioridad que se reivindique.
	ARTÍCULO 31.1. **Para solicitar un derecho de obtentor**, el solicitante presenta ante la Oficina la correspondiente solicitud, integrada por los documentos siguientes: […] e) el documento que indique el país de origen y fuente del material vegetal inicial y conocimientos y prácticas tradicionales asociados, así como las referidas indicaciones sobre la variedad vegetal en cuestión; este requisito se extiende a los híbridos; f) **cuando la variedad vegetal se derive de un material vegetal inicial, del que el territorio de la República de Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país**, copia del documento en el que conste el expreso consentimiento para el acceso a dicho material o materiales iniciales, expedido por autoridad competente, de conformidad con la legislación vigente en la materia; y g) en caso contrario a lo previsto en el inciso anterior, una declaración en que se exprese que el material que es fuente de inicio de la variedad vegetal no ha sido obtenido en el territorio de la República de Cuba, y que se ha obtenido el consentimiento previo al acceso.	**ARTÍCULO 31.1.** Para solicitar un derecho de obtentor, el solicitante presenta ante la Oficina la correspondiente solicitud, integrada por los documentos siguientes: […] **e) el documento que indique el país de origen y fuente del material vegetal inicial y conocimientos y prácticas tradicionales asociados, así como las referidas indicaciones sobre la variedad vegetal en cuestión; este requisito se extiende a los híbridos;** f) cuando la variedad vegetal se derive de un material vegetal inicial, del que el territorio de la República de Cuba es país de origen o que está presente en especies domesticadas y cultivadas en el país, **copia del documento en el que conste el expreso consentimiento para el acceso a dicho material o materiales iniciales, expedido por autoridad competente, de conformidad con la legislación vigente en la materia**; y g) en caso contrario a lo previsto en el inciso anterior, **una declaración en que se exprese que el material que es fuente de inicio de la variedad vegetal no ha sido obtenido en el territorio de la República de Cuba, y que se ha obtenido el consentimiento previo al acceso**.	**ARTÍCULO 32.** Los documentos a que se refieren los incisos c) y e) Apartado 1 del artículo 31 del presente Decreto-Ley, que integran la solicitud, redactados en idioma español o con la correspondiente traducción y elaborados conforme se establezca en las demás normas complementarias, tienen que presentarse ante la Oficina dentro del término de tres meses, contado a partir de la fecha de presentación de la solicitud.
	Part I Chapter 2 **3(5) If an invention relates to or makes use of a biological material**, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. […]	**Part I Chapter 2** 3(5) […] If an invention relates to or makes use of a biological material, the patent application shall contain **information about the geographical origin of the material** if the applicant is aware thereof. **If the applicant is not aware of the geographical origin of the material, that shall appear from the application.** […]	**Part I Chapter 2** **3(5)** […] **Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.**

Country/region	Title	Subject matter
Ecuador	Reglamento Nacional al Régimen Común de Acceso a los Recursos Genéticos en aplicación a la Decisión No. 392 de la Comunidad Andina (Decreto Ejecutivo Nº 905 de 3 de octubre de 2011) (www.wipo.int/wipolex/en/text.jsp?file_id=268505)	**PRIMERA** un recurso genético o un producto derivado del mismo
Egypt	Law No. 82 of 2002 on the Protection of Intellectual Property Rights (www.wipo.int/wipolex/en/details.jsp?id=1301)	**Article 13** biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage
	Council of Ministers Resolution No. 1366 of 2003 issuing Implementing regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights Books One, Two and Four (www.wipo.int/wipolex/en/details.jsp?id=7299)	**Article 3** [. . .] plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	PRIMERA **Previo al otorgamiento de un derecho de propiedad intelectual**, el Instituto Ecuatoriano de Propiedad Intelectual solicitara la presentación del número del registro del contrato de acceso y copia del mismo, cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicila hayan sielo obtenidos a partir de un recurso genético o de un producto derivado del mismo, y que esté en consonancia con lo establecido en la Constitución y normative applicable.	**PRIMERA** Previo al otorgamiento de un derecho de propiedad intelectual, el Instituto Ecuatoriano de Propiedad Intelectual **solicitara la presentación del número del registro del contrato de acceso y copia del mismo**, cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicila hayan sielo obtenidos a partir de un recurso genético o de un producto derivado del mismo, y que esté en consonancia con lo establecido en la Constitución y normative applicable.	
	Article 13 […] **Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage**, the inventor should have acquired the sources in a legitimate manner. […]	**Article 13** […] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired **the sources** in a legitimate manner. […]	**Article 14** The Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article 13. **If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application.** The applicant may, within 30 days and in accordance with the conditions stipulated in the Regulations, appeal such request by the Patent Office before the Committee provided for in Article 36.
	Article 3 The patent application shall be accompanied by […] 3. **Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage**, it shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.	**Article 3** The patent application shall be accompanied by […] 3. Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, it shall be accompanied by **documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt**.	**Article 4** Documentation mentioned under items 3, 4, 5, 6 and 7 of Article 3 of these Regulations may be furnished within four months from the filing date of the application.

Country/region	Title	Subject matter
Ethiopia	Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 (http://www.wipo.int/wipolex/en/text.jsp?file_id=234308#LinkTarget_376)	**Article 17** genetic resources, community knowledge
European Union	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions (www.wipo.int/wipolex/en/details.jsp?id=1440)	**Paragraph 27 of the Preamble** biological material of plant or animal origin

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 17. Obligations of Access Permit Holder A person who shall be given an access permit shall have the following obligations: […] (12) where **he seeks to acquire intellectual property right over the genetic resources accessed** or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; (13) **not apply for a patent or any other intellectual property protection** over the community knowledge accessed without first obtaining explicit written consent from the Institute; (14) recognize the locality where the **genetic resource or community knowledge accessed from as origin in the application for commercial property protection** of the product developed there from; (15) share the benefit that may be obtained from the utilization of the genetic resource or community knowledge accessed to the state and the concerned local communities; […]	**Article 17. Obligations of Access Permit Holder** A person who shall be given an access permit shall have the following obligations: […] (12) where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, **negotiate new agreement with the Institute based on the relevant laws of Ethiopia**; (13) not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining **explicit written consent** from the Institute; (14) **recognize the locality where** the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; (15) **share the benefit that may be obtained from the utilization** of the genetic resource or community knowledge accessed to the state and the concerned local communities; […]	
	Paragraph 27 of the Preamble. Whereas **if an invention is based on biological material of plant or animal origin or if it uses such material**, the patent application should, where appropriate, include information on the geographical origin of such material, if known;	**Paragraph 27 of the Preamble.** Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, **where appropriate, include information on the geographical origin of such material, if known**;	**Paragraph 27 of the Preamble.** Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; **whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.**

Country/region	Title	Subject matter
France	LOI n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (1) (www.wipo.int/wipolex/en/details.jsp?id=16565)	**Art. L. 412-18.-II** ressources génétiques et de connaissances traditionnelles associées
	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 (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511)	

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Art. L. 412-18.-II Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014 précité, dans les cas suivants : […] 2° […] Lorsque [**l'utilisation de ressources génétiques et de connaissances traditionnelles** associées aux ressources génétiques] **conduit à une demande de brevet**, les informations mentionnées au premier alinéa du présent II sont adressées à l'Institut national de la propriété industrielle à la seule initiative du déclarant. L'Institut national de la propriété industrielle procède aux démarches normales de l'examen de la demande de brevet et à l'attribution d'une date de dépôt et transmet les informations sans examen à l'autorité compétente chargée de l'application des règles édictées par l'Union européenne visant à ce que chaque Etat membre contrôle que l'utilisateur sur son territoire de ressources génétiques et, le cas échéant, de connaissances traditionnelles associées à ces ressources y a eu accès dans le respect de toute disposition législative ou réglementaire alors applicable. […]	**Art. L. 412-18.-II** Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les **informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014** […] (See below **Article 4** of the *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*.)	**Article 39** […] Est puni d'un an d'**emprisonnement** et de **€ 150 000 d'amende** : 1° Le fait d'utiliser des ressources génétiques ou des connaissances traditionnelles associées, au sens de l'article L. 4123 L. 4124, sans disposer des documents mentionnés au 3 de l'article 4 du règlement (UE) n° 511/2014 du Parlement européen et du Conseil, du 16 avril 2014, précité lorsqu'ils sont obligatoires ; 2° Le fait de ne pas rechercher, conserver ou transmettre aux utilisateurs ultérieurs les informations pertinentes sur l'accès et le partage des avantages pour les ressources génétiques et les connaissances traditionnelles associées en application du même article 4. L'amende est portée à **un million d'euros** lorsque l'utilisation des ressources génétiques ou des connaissances traditionnelles mentionnée au 1° du présent I a donné lieu à une utilisation commerciale. II. Les personnes physiques ou morales coupables des infractions prévues au I du présent article encourent également, à titre de peine complémentaire, **l'interdiction, pendant une durée ne pouvant excéder cinq ans, de solliciter**, en application des articles L. 4128 et L. 4129, **une autorisation d'accès aux ressources génétiques** ou à certaines catégories d'entre elles **et aux connaissances traditionnelles** associées en vue de leur utilisation commerciale.
		Article 4 1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements. […] 3. For the purposes of paragraph 1, users shall seek, keep and transfer to subsequent users: **(a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or** **(b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:** **(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;** **(ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;** **(iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;** **(iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;** **(v) access permits, where applicable;** **(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.** […]	

Country/region	Title	Subject matter
Germany	Patent Act as published on 16 December, 1980 (Federal Law Gazette 1981 I p.1), as last amended by Article 2 of the Act of 4 April, 2016 (www.wipo.int/edocs/lexdocs/laws/en/de/de223en.pdf)	**Section 34a** biological material of plant or animal origin
India	The Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005) (www.wipo.int/wipolex/en/details.jsp?id=13104)	(**Article 10(4)(d)(ii)**) biological material

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Section 34a (1) Where an **invention is based** on biological material of plant or animal origin **or if it uses such material**, the application should include information on the geographical origin of such material, if known. […]	**Section 34a** (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include **information on the geographical origin of such material,** if known. […] (2) **If the application includes information on the geographical origin** pursuant to the first sentence of subsection (1), **the German Patent and Trade Mark Office shall notify this application to the Federal Agency for Nature Conservation** (*Bundesamt für Naturschutz*) as the competent authority within the meaning of section 6 (1) of the Act Implementing the Obligations Under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014 of 25 November 2015 (Federal Law Gazette I p.2092) **following publication of the information** pursuant to section 32 (5).	**Section 34a** (1) […] **This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.** […]
	Article 10(4)(d)(ii) If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— […] (D) disclose the source and geographical origin of the biological material in the specification, **when used in an invention**.	**Article 10(4)(d)(ii)** If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— […] (D) disclose **the source and geographical origin of the biological material** in the specification, when used in an invention.	**Article 25 Opposition to the patent.** (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of **opposition to the Controller against the grant of patent** on the ground […] (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; […] **but on no other ground, and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.** (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may **give notice of opposition to the Controller** in the prescribed manner on any of the following grounds, namely: […] (j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention; […]. **Article 64 Revocation of patents.** (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, **be revoked** on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say— […] (p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; […]

Country/region	Title	Subject matter
Indonesia	Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (www.wipo.int/wipolex/en/details.jsp?id=16392)	**Article 26** Genetic resources and/or traditional knowedge

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional knowledge.	**Article 26** (1) If an invention as being associated with and/or derived from a genetic resource and/or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional knowledge.	Article 35 (1) In a case where requirements and supporting documents of an application substantiated in article 25 has not been completed, the Minister sends a written reminder to the Applicant to fullfil the lack of requirement/s and supporting document/s in question within a maximum time of 3 (three) months starting from the sending date of the Minister's written reminder. (2) The maximum time of 3 (three) months determined in sub article (1) can be extended with the additional maximum time of 2 (two) months. (3) The length of the extension time determined in sub article (2) can be re-extended for another maximum time of 1 (one) month on payment of a fee. (4) To obtain the extension and re-extension of times regulated in sub articles (2) and (3), Applicant should submit a written request to the Minister describing the reasons for such request before the due completion mentioned in sub article (1) or (2). (5) In a case of emergency situation, Applicant may submit for a length of time extension other than those which have been determined in sub article 2 and 3 in the form of a written request accompanied by supporting evidence to the Minister. (6) The Minister may approve the request regulated in sub article (5) by granting a certain time extension not exceeding 6 (six) months starting from the end of the time determined in sub article (3).

Country/region	Title	Subject matter
Italy	Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Decree-Law No. 1 of January 24, 2012, converted into law with changes by Law No. 27 of March 24, 2012) (www.wipo.int/wipolex/en/details.jsp?id=13123) (Unofficial translation provided by LES-Italy, at: www.les-italy.org/pubblicazioni-les/book_code/english/en-t4_s1.html)	Article 170-*bis* biological material of animal or plant origin

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 170-*bis*. Requirements concerning biotechnological inventions [...] 2. The provenance of **biological material** of animal or plant origin, **which is the basis of the invention**, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated. […].	**Article 170-*bis*. Requirements concerning biotechnological inventions** […] 2. The **provenance** of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both **with reference to the country of origin**, in order to verify compliance with import and export legislation, **and in relation to the biological organism from which it was isolated**. […]	**Article 170-*bis*. Requirements concerning biotechnological inventions** […] 7. If the Italian Patent and Trademark Office ascertains the lack of the conditions for patenting a biotechnological invention or the failure to file the declarations under **paragraphs 2**, 3 and 4, it **shall proceed in accordance with Article 173, paragraph 7**, and in the event it determines the absence of the conditions for patenting as set forth by Articles 81-*quater*, 81-*quinquies* and Article 162, it **shall reject the application**. [*Article added by paragraph 1 of Article 87, Legislative Decree No. 131 of 13 August 2010.*] **Art. 170-*ter*. Sanctions** […] 2. Unless the action constitutes a crime, whoever, in the declaration required by Article 170-*bis*, paragraph 2, makes false statements concerning the provenance of biological material of animal or plant origin, shall be punished with **an administrative fine from 10.000,00 to 100.000,00 Euros**. […] 4. Within the minimum and maximum limits established by this article, the amount of the administrative fines shall be determined taking account the criteria set forth by Article 11 of Law No. 689 of 24 November 1981, the different potential for causing harm to the protected interest that each violation has in the abstract, the specific personal qualities and the property advantage that the violation can bring to the guilty party or the person or entity in whose interest he acts. […] **Article 173. Observations** 7. […] the Italian Patent and Trademark Office assigns the applicant a term of two months to submit observations. Once that term has expired, if no observations have been submitted or if the Office does not believe that it can accept those submitted, **the application or request is rejected in full or in part**.

Country/region	Title	Subject matter
Kyrgyzstan	Law of the Kyrgyz Republic on the Protection of Traditional Knowledge (www.wipo.int/wipolex/en/details.jsp?id=5571)	Traditional knowledge

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 8. Patenting of subject-matters created on the base of Traditional Knowledge **When patenting the subject-matters created on the base of Traditional Knowledge**, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public.	**Article 8. Patenting of subject-matters created on the base of Traditional Knowledge** When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain **reveal of origin of Traditional Knowledge which is used as prior art or prototype**. The applicant shall indicate the source of making Traditional Knowledge available to the public. **Article 9. Application for registration and granting the right to use Traditional Knowledge or for granting the right to use registered Traditional Knowledge** […] An application shall contain the following: 1) application for traditional knowledge registration and granting the right to use Traditional Knowledge or granting the right to use registered Traditional Knowledge stating the applicant as well as his location and place of residence; 2) specific and complete description of Traditional Knowledge, including: point of origin of Traditional Knowledge (borders of a geographic object); description of genetic resource, which is being used in connection with particular traditional knowledge; field of application and expected positive result of traditional knowledge used; information relevant to previously issued publications regarding a particular traditional knowledge. The following documents shall be attached to the application: 1) An official document granted by the competent authority confirming a practical applicability of Traditional Knowledge and positive result of use thereof in appropriate field of activity. 2) Conclusion of the competent body (bodies) confirming membership of the applicant in a local community and/or is located in geographic object for which Traditional Knowledge is pertained to. In case of filing the application for registration of Traditional Knowledge by State bodies, the said conclusion shall not be required. 3) For foreign applicant a document confirming his/her right for the claimed Traditional Knowledge in the country of origin.	

Country/region	Title	Subject matter
Norway	Patents Act (Act No. 9 of December 15, 1967) (consolidated version of 2016) (www.wipo.int/wipolex/en/details.jsp?id=15925)	**Chapter 2, Section 8b.** […] If an invention concerns or uses **biological material or traditional knowledge**, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). […] The duty to disclose information concerning biological material under the first and second paragraphs **applies even where the inventor has altered the structure of the received material**. The duty to disclose information **does not apply to biological material derived from the human body**.
Peru	Resolution approving the Complementary Provisions to Decision 486 of the Andean Community Commission establishing the Common Regime on Industrial Property (Legislative Decree No. 1075 of June 27, 2008) (www.wipo.int/wipolex/en/details.jsp?id=6541)	See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) (www.wipo.int/wipolex/en/details.jsp?id=9451)
	Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources (www.wipo.int/wipolex/en/details.jsp?id=3420)	Collective knowledge **Article 2(b)** "Collective knowledge" means the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. The intangible components referred to in Decision 391 of the Commission of the Cartagena Agreement include this type of collective knowledge. **Complementary Provisions** **Second.** Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, **except where the collective knowledge concerned is in the public domain**. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Chapter 2, Section 8b. If an **invention concerns or uses biological material or traditional knowledge,** the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). **If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent**, the application shall state whether such consent has been obtained. **If the providing country is not the same as the country of origin of the biological material or the traditional knowledge**, the application shall also state the country of origin. The country of origin means for biological material the country from which the material was collected from its natural environment and for traditional knowledge the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.	**Chapter 2, Section 8b.** […] the patent application shall include **information on the country from which the inventor collected or received the material or the knowledge (the providing country)**. If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, **the application shall state whether such consent has been obtained.** If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state **the country of origin**. If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that. […] When the biological material is acquired in accordance with Art. 12 No. 2 and 3 of the International Treaty on Plant Genetic Resources for Food and Agriculture of November, 3, 2001, **a copy of a standard material transfer agreement according to Art 12.4 of the Treaty** shall accompany the patent application instead of the information mentioned in paragraphs two and three.	**Chapter 2, Section 8b.** […] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. (Repealed by Act of 4 July 1991 No. 47.) The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.
	See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) (www.wipo.int/wipolex/en/details.jsp?id=9451)	See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) (www.wipo.int/wipolex/en/details.jsp?id=9451)	See Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) (www.wipo.int/wipolex/en/details.jsp?id=9451)
	Complementary Provisions **Second.** Submission of the license contract as a requirement for obtaining a patent. **Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge**, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.	**Complementary Provisions** **Second.** Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to **submit a copy of the license contract** as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.	**Complementary Provisions** **Second.** Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. **Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.**

Country/region	Title	Subject matter
Philippines	Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010) (www.wipo.int/wipolex/en/details.jsp?id=9629)	**Rule 12, Section 3 (c)** […] biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices.

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Rule 12, Section 3 – *Disclosures* Disclosure of potential IPRs and/or all biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices shall be governed by the following rules: […] (c) With respect to biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices, the following provisions shall govern: i. [The research and development institutes and/or institutions] RDI shall provide the [Government Funding Agencies] GFA with a written disclosure on the following: (1) any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices **utilized in or which formed as basis in the development of the subject matter** contained in the IPR application; (2) the primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices **utilized in or which formed as basis in [the development of] the subject matter** contained in the IPR application; or (3) the secondary source, if no information about the primary source is available. ii. The disclosure requirement under this section shall apply when the subject matter contained in a national or international IPR application is **directly based on any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices to which the RDI has had access to prior to the filing of the IPR application. The subject matter contained in the IPR application must depend on the specific properties of, or must be consciously derived from, such biodiversity and genetic resource or materials, traditional knowledge, and indigenous knowledge, systems and practices.** iii. Where the RDI, for reasons beyond its control, does not have the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, the RDI shall submit an affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof. The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule. […]	**Rule 12, Section 3 –** *Disclosures* Disclosure of potential IPRs and/or all biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices shall be governed by the following rules: […] (c) With respect to biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices, the following provisions shall govern: i. The RDI shall provide the GFA with a written disclosure on the following: **(1) any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the IPR application; (2) the primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in [the development of] the subject matter contained in the IPR application; or (3) the secondary source, if no information about the primary source is available.** […] iii. Where the RDI, for reasons beyond its control, does not have the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, **the RDI shall submit an affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof.** The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule. […] v. A national or international IPR application filed by the RDI before the appropriate IP office shall include **in the abstract and/or description of said application** the same disclosure on biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that such disclosure may not be required for the grant or issuance of certificate of IPR registration.	**Rule 12, Section 3 –** *Disclosures* […] iii. Where the RDI, for reasons beyond its control, does not have the necessary information to fulfill the disclosure requirement pertaining to any biodiversity, genetic resources or materials, traditional knowledge, and indigenous knowledge, systems and practices, such as, for instance, where a plant stored in a gene bank was collected decades ago and no information about its source exists, the RDI shall submit an affidavit from its researcher/s that the latter do not have the necessary information or that the source is unknown, and state the reasons thereof. **The GFA shall review the affidavit to determine if this will constitute compliance with the disclosure requirement under this rule.** […] v. A national or international IPR application filed by the RDI before the appropriate IP office shall include in the abstract and/or description of said application the same disclosure on biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that **such disclosure may not be required for the grant or issuance of certificate of IPR registration.**

Country/region	Title	Subject matter
Philippines (cont.)		
	Philippine Technology Transfer Act of 2009 (Republic Act No. 10055) (www.wipo.int/edocs/lexdocs/laws/en/ph/ph067en.pdf)	
Romania	Implementing Regulations of the Patent Law No. 64/1991 (www.wipo.int/wipolex/en/details.jsp?id=8457)	(Article 16(1)(c)) Traditional knowledge

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	v. A national or international IPR application filed by the RDI before the appropriate IP office shall include in the abstract and/or description of said application the same disclosure on biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the said application, notwithstanding that such disclosure may not be required for the grant or issuance of certificate of IPR registration.		
	Article III, Sec. 8(c) The following are the rights and responsibilities of the [research and development institutes and/or institutions] RDIs that **availed of research funds from [Government Funding Agencies] GFAs**: […] (c) **Notify** the GFA within a reasonable time of all IPR applications, licenses and assignments made. All applications for IP protection shall disclose any biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices as these terms are defined in Republic Act No. 8371 or the Indigenous Peoples Rights Act and Republic Act No. 9.147 or The Wildlife Act […]		
	Article 16 (1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: […] c) presentation of the prior art considered by the applicant to be useful for understanding, performing the documentary search and examining the claimed invention, with the indication of the documents which substantiate it; at least one solution considered to be the closest to the claimed invention shall be presented; **where the prior art also contains traditional knowledge**, this and its source, if known, shall explicitly be indicated in the description; […]	**Article 16** (1) The description of the invention according to Art. 14 paragraph (1) letter c) of the Law shall contain the following: […] c) presentation of the prior art considered by the applicant to be useful for understanding, performing the documentary search and examining the claimed invention, with the indication of the documents which substantiate it; at least one solution considered to be the closest to the claimed invention shall be presented; where the prior art also contains traditional knowledge, **this and its source, if known, shall explicitly be indicated in the description**; […]	

Country/region	Title	Subject matter
Samoa	Intellectual Property Act 2011 (www.wipo.int/wipolex/en/details.jsp?id=13492)	**Article 7** Biological material or knowledge available within any local or indigenous community
South Africa	Patents Amendment Act 2005 (Act No. 20 of 2005) (www.wipo.int/wipolex/en/details.jsp?id=5765)	(Section 2) Genetic resource Indigenous biological resource Traditional knowledge Genetic resource means (a) any indigenous genetic material; or (b) the genetic potential or characteristics of any indigenous species. Indigenous biological resource means an indigenous biological resource as defined in section 1 of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004). Traditional knowledge means the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource.
Sweden	Regulation (2004:162) Amending the Patents Decree (www.wipo.int/wipolex/en/details.jsp?id=3672)	(Article 5a) Biological material of plant or animal origin

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 7 – Application for a patent (also applies to PVP) (3) An application must contain the following: […] (g) a statement stating whether or **not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere**; (h) a statement disclosing the source and geographical origin of any biological material used for the invention […] (10) Subject to subsection (11), **if the application is based on or derived from biological material or knowledge available within any local or indigenous community** the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge.	**Article 7** – Application for a patent (also applies to PVP) (3) An application must contain the following: […] (g) **a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere;** (h) **a statement disclosing the source and geographical origin of any biological material used for the invention** […] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to **furnish evidence as to the applicant's title or authority to make use of such material or knowledge**.	**Article 7** **(12) If an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may, cease to deal further with the application.**
	Section 30 (3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, **before acceptance of the application**, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. (3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that **the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use**.	**Section 30** (3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar **a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.** **(3B)** The registrar shall call upon the applicant to **furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.**	**Section 61** **(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely** **[…]** **(g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made.**
	Article 5a **If an invention concerns biological material of plant or animal origin or if it uses such material**, the patent application shall include information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.	**Article 5a** If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include **information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated.** Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.	**Article 5a** If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated. **Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.**

Country/region	Title	Subject matter
Switzerland	Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012) (www.wipo.int/wipolex/en/details.jsp?id=11895)	**Article 49(a)** Genetic resource; traditional knowledge of indigenous or local community
Vanuatu	Patents Act No. 2 of 2003 (www.wipo.int/wipolex/en/details.jsp?id=107207)	Indigenous knowledge
Viet Nam	Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property (www.wipo.int/wipolex/en/details.jsp?id=5013)	**Article 23.11** Gene source and/or traditional knowledge

	Trigger of disclosure	Content of disclosure	Consequences of non-compliance
	Article 49(a) 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 **to which the inventor or the patent applicant had access, provided the invention is directly based on this resource.**	**Article 49(a)** 1. The patent application must contain **information on the source** […]. **2. If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing.**	**Article 59** **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.** **Article 59(a)** **3.** The Institute shall **reject the patent application** if: […] **b. the deficiencies mentioned in Article 59 paragraph 2 have not been remedied.** **Article 81(a)** 1. Any person who wilfully provides false information under Article 49a is liable to **a fine of up to 100,000 [Swiss] francs**. 2. The court may order the publication of the judgment.
	Article 47 (1) If it appears to the Registrar that an application is for the grant of a patent for an **invention that is based on, arose out of, or incorporates elements of, indigenous knowledge**, the Registrar must refer the application to the National Council of Chiefs.	**Article 47** (2) The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their **prior informed consent to the grant**; and (b) the applicant and the custom owners have entered into **an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.**	**Article 47** (2) The Registrar **must not grant a patent** for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent. […] **(4) If an agreement mentioned in subsection (2) or (3) has not been entered into within 12 months after the patent application has been lodged:** **(a) the Registrar may grant the patent; and** **(b) the owner may exploit the patent; and** **(c) the Registrar is to determine the amount payable to the custom owners or the National Council of Chiefs by the owner of the patent, being payment of an equitable share of the benefits from exploiting the patent.**
	Article 23.11 Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of **an invention concerning gene source or traditional knowledge** must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional knowledge. […]	**Article 23.11** Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must **also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant,** if the invention is directly based on that gene source and/or traditional knowledge. […]	**Article 23.11** […] If the inventor or **the applicant cannot identify the origin of the gene source and/or traditional knowledge**, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration

World Intellectual Property Organization
34, chemin des Colombettes
P.O. Box 18
CH-1211 Geneva 20
Switzerland

Tel: +41 22 338 91 11
Fax: +41 22 733 54 28

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